federal register

THURSDAY, MARCH 27, 1975

WASHINGTON, D.C.

Volume 40 ■ Number 60

Pages 13477–14049

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federal register
Area Code 202 Phone 523–5240

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rules and regulations

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM

SUBCHAPTER A—BOARD OF GOVERNORS

[Reg. Y]

PART 225—BANK HOLDING COMPANIES

Nonbanking Activities of Bank Holding Companies

As an incident to the amendment to 12 CFR 125.123 (FR document 75-6558 appearing at page 11710 of the issue for Thursday, March 13, 1975), paragraphs (a) through (g) are redesignated as (a), (b), (c), (d), and (e).[1]

By order of the Board of Governors, March 20, 1975.

[SEAL] THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc.75-7991 Filed 3-26-75;8:45 am]

PART 265—RULES REGARDING DELEGATION OF AUTHORITY

Review and Determination of Appeals Under the Freedom of Information Act

The purpose of this amendment is to reflect the delegation of authority to review and make determinations with respect to an appeal of denial of access to records of the Board requested pursuant to the Freedom of Information Act and provided for in § 261.4(e) of the Board's rules regarding availability of information. To accomplish this delegation § 265.1a(b) is added as set forth below.

Section 265.1(b) is added to read as follows:

§ 265.1 Specific functions delegated to Board Members.

* * * * *

(b) Any Board member designated by the Chairman is authorized:

(1) Under section (a)(6) of the Freedom of Information Act (5 U.S.C. 552) and Part 261 of this Chapter (Rules Regarding Availability of Information) to review and make a determination with respect to an appeal of denial of access to records of the Board made in accordance with the procedures prescribed by the Board.

(2) The provisions of section 553 of title 5, United States Code, relating to notice and public participation and to deferred effective dates, are not followed in connection with the adoption of § 265.1(b) because the rule involved therein is procedural in nature and accordingly does not constitute a substantive rule subject to the requirements of such section.

Effective date. This amendment is effective immediately.

By order of the Board of Governors, March 19, 1975.

[SEAL] THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc.75-7910 Filed 3-26-75;8:45 am]

[1] A copy of the entire interpretation is available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

Title 14—Aeronautics and Space

CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Airworthiness Docket No. 75-WE-17-AD; Amdt. 39-2144]

PART 39—AIRWORTHINESS DIRECTIVES

AiResearch Model TFE731-2 and -3 Series Engines

Pursuant to the authority delegated to me by the Administrator (31 FR 13697), an airworthiness directive was adopted on February 28, 1975, and distributed by airmail letter dated February 28, 1975, to all known United States operators or owners of aircraft incorporating AiResearch Model TFE731-2 and -3 series engines. The directive requires: an initial and recurring inspection of the transfer gearbox bearing support; replacements, if required; and provides for termination of these inspections when an improved bearing support is installed.

Since it was found that immediate corrective action was required, notice and public procedure thereon was impractical and contrary to the public interest and good cause existed for making the airworthiness directive effective immediately as to all known operators of AiResearch Model TFE731-2 and -3 series engines by individual airmail letter dated February 28, 1975.

The AD, as published herein, provides for the use of later FAA-approved revisions to the Service Bulletin referenced in paragraph (B).

These conditions still exist and the airworthiness directive is hereby published in the FEDERAL REGISTER as an Amendment to § 39.13 of Part 39 of the Federal Aviation Regulations to make it effective as to all persons.

AIRESEARCH MANUFACTURING COMPANY OF ARIZONA. Applies to AiResearch TFE731-2 and -3 series engines.

Compliance required as indicated.

To detect, prevent and correct wear of the transfer gearbox vertical bevel gear bearing support which can result in failure of the accessory drive and contamination of the engine lubrication system, accomplish the following:

(a) Within the next 25 hours time in service after receipt of this airmail letter, unless previously accomplished, and at intervals not to exceed 50 hours time in service thereafter, inspect the lower shoulder of transfer gearbox vertical bearing support for wear and replacements as required per AiResearch Service Bulletin TFE731-72-3019, dated February 27, 1975, or later FAA-approved revisions.

(b) The inspection required by paragraph (A), above, may be discontinued when the transfer gearbox bearing support, P/N 3070217-1, is replaced with an improved bearing support, P/N 3070217-3, per AiResearch Service Bulletin TFE731-72-3020, dated February 27, 1975, [or later FAA-approved revisions], or the transfer gearbox assembly, P/N 3070093-3, is replaced with a serviceable assembly which has been modified by incorporation of change No. 2, described in the above referenced Service Bulletin. Bearing supports, P/N 3070217-1, which are removed from service shall be rendered unserviceable.

(c) Equivalent procedures may be approved by the Chief, Aircraft Engineering Division, FAA Western Region, upon submission of adequate substantiating data.

(d) Aircraft may be flown to a base for performance of maintenance required by this AD per FAR's 21.197 and 21.199.

This amendment becomes effective April 3, 1975, for all persons except those to whom it was made effective by airmail letters dated February 28, 1975.

(Secs. 313(a), 601 and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 and 1423) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Los Angeles, California, on March 18, 1975.

ROBERT H. STANTON,
Director,
FAA Western Region.

[FR Doc.75-8041 Filed 3-26-75;8:45 am]

[Airspace Docket No. 74-NE-59]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE AND REPORTING POINTS

Alteration of Transition Area

On Page 4444 of the FEDERAL REGISTER dated January 30, 1975, (40 FR 4444), the Federal Aviation Administration published a notice of proposed rule making which would alter the Providence, Rhode Island, 700-foot Transition Area.

Interested parties were given thirty (30) days after publication in which to submit written data or views. No objections to the proposed regulations have been received.

In view of the foregoing, the proposed regulations are hereby adopted effective 0901 G.m.t., June 19, 1975 as set forth below.

(Sec. 307(a) of the Federal Aviation Act of 1958 (72 Stat. 749; (49 U.S.C. 1348)) and section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Burlington, Massachusetts, on March 13, 1975.

QUENTIN S. TAYLOR,
Director, New England Region.

The Federal Aviation Administration, having completed a review of the airspace requirements for the terminal area of Providence, Rhode Island, proposes the airspace action hereinafter set forth:

§ 71.181 [Amended]

1. Amend the description of the Providence, Rhode Island, Transition Area in § 71.181 of Part 71 of the Federal Aviation Regulations as follows:

After the words "within a 7-mile radius of the New Bedford, Massachusetts, Municipal Airport (Latitude 41°40'37" N., Longitude 70°57'34" W.), within 8 miles SE and 11 miles NW of the New Bedford ILS localizer SW course, extending from the localizer to 12 miles SW of the Om."

Add: "and within 3 miles each side of the 038° bearing from the New Bedford, Massachusetts, OM, extending from the 7-mile radius to 14.5 miles NE of the New Bedford, Massachusetts, OM, * * *"

[FR Doc.75-8044 Filed 3-26-75;8:45 am]

[Airspace Docket No. 74-NE-59]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE AND REPORTING POINTS

Transition Area; Correction

On Page 7627 of the FEDERAL REGISTER dated February 21, 1975 (40 FR 7627), the Federal Aviation Administration published an editorial correction to the description of the Providence, Rhode Island, Transition Area by deleting all reference to "NAS Quonset Point" and inserting in lieu thereof "Quonset Point, Rhode Island, Airport." The correct reference should have been "Quonset State Airport." Accordingly, the description of the Providence, Rhode Island, Airport is hereby amended by deleting all reference to "Quonset Point, Rhode Island, Airport" and inserting in lieu thereof the words "Quonset State Airport."

Since this amendment is editorial in nature and no substantive change in the regulation is effected, notice and public procedure thereon are unnecessary, and good cause exists for making this amendment effective in less than thirty (30) days.

In view of the foregoing, the description of the Providence, Rhode Island, Transition Area in § 71.181 of Part 71 of the Federal Aviation Regulations is hereby amended by deleting all reference to "Quonset Point, Rhode Island, Airport" and inserting in lieu thereof "Quonset State Airport."

(Sec. 307(a) of the Federal Aviation Act of 1958 [49 U.S.C. 1348(a)] and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Burlington, Massachusetts, on March 13, 1975.

QUENTIN S. TAYLOR,
Director, New England Region.

[FR Doc.75-8043 Filed 3-26-75;8:45 am]

[Airspace Docket No. 75-SO-7]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Redesignation and Alteration of Transition Areas

On February 5, 1975, a Notice of Proposed Rule Making was published in the FEDERAL REGISTER (40 FR 5373), stating that the Federal Aviation Administration was considering an amendment to Part 71 of the Federal Aviation Regulations that would redesignate and alter the Meridian, Miss. (Key Field) and (NAS Meridian), transition areas.

Interested persons were afforded an opportunity to participate in the rule making through the submission of comments. There were no comments received.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., June 19, 1975, as hereinafter set forth.

§ 71.181 [Amended]

In § 71.181 (40 FR 441), the Meridian, Miss. (Key Field) and (NAS Meridian) transition areas are amended to read:

MERIDIAN, MISS.

That airspace extending upward from 700 feet above the surface within an 11-mile radius of Key Field (Lat. 32°19'58" N., Long. 88°45'05" W.); within 3 miles each side of the ILS localizer south course, extending from the 11-mile radius area to 8.5 miles south of the RBN; within 3 miles each side of the 191° bearing from Meridian RBN, extending from the 11-mile radius area to 8.5 miles south of the RBN; within 5 miles each side of Meridian VORTAC 315° radial, extending from the 11-mile radius area to 11.5 miles northwest of the VORTAC; within a 10-mile radius of NAS Meridian (Lat. 32°33'27" N., Long. 88°33'33" W.); within 3.5 miles each side of the 021° bearing from NAS Meridian UHF RBN, extending from the 10-mile radius area to 11.5 miles north of the RBN, and the airspace east, bounded on the north by the arc of a 10-mile radius circle centered on NAS Meridian, on the east by the Kewanee VORTAC 005° and 179° radials, on the south by the Meridian VORTAC 110° radial, and on the west by the arc of an 11-mile radius circle centered on Key Field.

Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of Sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in East Point, Ga., on March 17, 1975.

PHILLIP M. SWATEK,
Director, Southern Region.

[FR Doc.75-7915 Filed 3-26-75;8:45 am]

[Airspace Docket No. 74-EA-96]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE AND REPORTING POINTS

Alteration of Control Zone and Transition Area

On page 2824 of the FEDERAL REGISTER for January 16, 1975, the Federal Aviation Administration published a proposed rule which would alter the Lancaster, Pa., Control Zone (40 FR 398) and Transition Area (40 FR 525).

Interested parties were given 30 days after publication in which to submit written data or views. No objections to the proposed regulations have been received.

In view of the foregoing, the proposed regulation is hereby adopted, effective 0901 G.m.t. June 19, 1975.

Sec. 307(a), Federal Aviation Act of 1958 (72 Stat. 749; (49 U.S.C. 1348); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c))).

Issued in Jamaica, N.Y., on March 7, 1975.

DUANE W. FREER,
Director, Eastern Region.

§ 71.171 [Amended]

1. Amend § 71.171 of Part 71 of the Federal Aviation Regulations by deleting the description of the Lancaster, Pa. Control Zone and by substituting the following in lieu thereof:

Within a 5-mile radius of the center, 40°07'16" N., 76°17'47" W. of Lancaster Airport, Lancaster, Pa.; within 3 miles each side of the Lancaster VORTAC 260° radial, extending from the VORTAC to 8.5 miles west; within 3 miles each side of the Lancaster VORTAC 128° radial, extending from the VORTAC to 8.5 miles southeast; within 2 miles each side of the Lancaster VORTAC 055° radial, extending from the VORTAC to 5 miles northeast. This control zone is effective from 0700 to 2300 hours, local time, daily.

§ 71.181 [Amended]

2. Amend § 71.181 of Part 71 of the Federal Aviation Regulations by deleting the description of the Lancaster, Pa. Transition Area and by substituting the following in lieu thereof:

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of the center 40°07'16" N., 76°17'47" W. of Lancaster Airport, Lancaster, Pa.; within 3 miles each side of the Lancaster VORTAC 260° radial, extending from the 7.5-mile radius area to 8.5 miles west of the VORTAC; within 9.5 miles northeast and 4.5 miles southwest of the Lancaster VORTAC 128° radial, extending from the VORTAC to 18.5 miles southeast of the VORTAC; within 3.5 miles each side of the Lancaster Airport ILS southwest localizer course, extending from the 7.5-mile radius area to 10.5 miles southwest of the OM; within 5 miles each side of the Lancaster VORTAC 055° radial, extending from the 7.5-mile radius area to 16.5 miles northeast of the VORTAC.

[FR Doc.75-7919 Filed 3-26-75;8:45 am]

[Docket No. 14454; Amdt. No. 961]

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

Recent Changes and Additions

This amendment to Part 97 of the Federal Aviation Regulations incorporates by reference therein changes and additions to the Standard Instrument Approach Procedures (SIAPs) that were recently adopted by the the Administrator to promote safety at the airports concerned.

The complete SIAPs for the changes and additions covered by this amendment are described in FAA Forms 3139, 8260-3, 8260-4, or 8260-5 and made a part of the public rule making dockets of the FAA in accordance with the procedures set forth in Amendment No. 97-696 (35 FR 5609).

SIAPs are available for examination at the Rules Docket and at the National Flight Data Center, Federal Aviation Administration, 800 Independence Avenue SW., Washington, D.C. 20591. Copies of SIAPs adopted in a particular region are also available for examination at the headquarters of that region. Individual copies of SIAPs may be purchased from the FAA Public Document Inspection Facility, HQ-405, 800 Independence Avenue SW., Washington, D.C. 20591 or from the applicable FAA regional office in accordance with the fee schedule prescribed in 49 CFR 7.85. This fee is payable in advance and may be paid by check, draft or postal money order payable to the Treasurer of the United States. A weekly transmittal of all SIAP changes and additions may be obtained by subscription at an annual rate of $150 per annum from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Additional copies mailed to the same address may be ordered for $30 each.

Since a situation exists that requires immediate adoption of this amendment, I find that further notice and public procedure hereon is impracticable and good cause exists for making it effective in less than 30 days.

In consideration of the foregoing, Part 97 of the Federal Aviation Regulations is amended as follows, effective on the dates specified:

§ 97.23 [Amended]

1. Section 97.23 is amended by originating, amending, or canceling the following VOR-VOR/DME SIAPs, effective May 8, 1975:

Albert Lea, Minn.—Albert Lea Municipal Arpt., VOR Rwy 16, Amdt. 3
Charleston, S.C.—Charleston AFB/Municipal Arpt., VOR Rwy 33, Amdt. 6.
Cheraw, S.C.—Cheraw Municipal Arpt., VOR-A, Amdt. 4
Dallas, Tex.—Dallas Love Field, VOR/DME Rwy 13R, Amdt. 1
Dallas, Tex.—Dallas Love Field, VOR Rwy 18, Amdt. 17
Dallas, Tex.—Dallas Love Field, VOR Rwy 36, Amdt. 9
Dayton, Ohio—Montgomery County Arpt., VOR-A, Amdt. 8
Dayton, Ohio—Montgomery County Arpt., VOR Rwy 20, Amdt. 4
Lawton, Okla.—Lawton Municipal Arpt., VOR Rwy 35, Amdt. 15
New Orleans, La.—Lakefront Arpt., VOR/DME Rwy 35, Orig.
Philadelphia, Pa.—Philadelphia Int'l. Arpt., VOR/DME-A, Orig.
Philadelphia, Pa.—Philadelphia Int'l. Arpt., VOR/DME, Rwy 27R, Amdt. 3, cancelled
Rock Springs, Wyo.—Rock Springs-Sweetwater County Arpt., VOR-B, Amdt. 1
Rock Springs, Wyo.—Rock Springs-Sweetwater County Arpt., VOR/DME Rwy 25, Amdt. 1
Springfield, Ohio—Springfield Municipal Arpt., VOR Rwy 5, Amdt. 2
Springfield, Ohio—Springfield Municipal Arpt., VOR Rwy 23, Amdt. 2
Starkville, Miss.—Oktibbeha Arpt., VOR-B, Amdt. 5

* * * effective April 24, 1975:

Aurora, Ill.—Aurora Municipal Arpt., VOR-A, Amdt. 5

* * * effective March 18, 1975:

Poughkeepsie, N.Y.—Dutchess County Arpt., VORTAC Rwy 24, Amdt. 1

§ 97.25 [Amended]

2. Section 97.25 is amended by originating, amending, or canceling the following SDF-LOC-LDA SIAPs, effective May 8, 1975:

Brownsville, Tex.—Brownsville Int'l. Arpt., LOC (BC) Rwy 31L, Amdt. 2
Charleston, S.C.—Charleston AFB/Muncipal Arpt., LOC (BC) Rwy 33, Amdt. 5
Dallas, Tex.—Dallas Love Field, LOC (BC) Rwy 13R, Amdt. 8
Dallas, Tex.—Dallas Love Field, LOC (BC) Rwy 31R, Amdt. 22
Des Moines, Iowa—Des Moines Municipal Arpt., LOC (BC) Rwy 12L, Amdt. 5
Fort Worth, Tex.—Meacham Field, LOC (BC) Rwy 34R, Amdt. 1
Philadelphia, Pa.—Philadelphia Int'l. Arpt., LOC Rwy 27R, Orig.
Redding, Calif.—Redding Municipal Arpt., LOC/DME (BC) Rwy 16, Amdt. 1
Valparaiso, Ind.—Porter County Municipal Arpt., LOC Rwy 27, Amdt. 2

* * * effective March 20, 1975:

Nashville, Tenn.—Nashville Metropolitan Arpt., LOC Rwy 31, Amdt. 1

§ 97.27 [Amended]

3. Section 97.27 is amended by originating, amending, or canceling the following NDB/ADF SIAPs, effective May 8, 1975:

Aiken, S.C.—Aiken Municipal Arpt., NDB-A, Amdt. 3
Blanding, Utah—Blanding Municipal Arpt., NDB Rwy 35, Amdt. 2
Corning, Iowa—Corning Municipal Arpt., NDB Rwy 17, Amdt. 1
Dallas, Tex.—Dallas Love Field, NDB Rwy 13L, Amdt. 8
Dallas, Tex.—Dallas Love Field, NDB Rwy 31R, Amdt. 11, cancelled
Dayton, Ohio—Montgomery County Arpt., NDB Rwy 9, Orig.
Fairview, Okla.—Fairview Municipal Arpt., NDB Rwy 17, Amdt. 1
Fort Worth, Tex.—Meacham Field, NDB Rwy 34R, Amdt. 1
French Lick, Ind.—French Lick Municipal Arpt., NDB Rwy 26, Amdt. 2
Kahului, Hawaii—Kahului Arpt., NDB Rwy 20, Orig.
Philadelphia, Pa.—Philadelphia Int'l Arpt., NDB Rwy 27L, Amdt. 1
Red Oak, Iowa—Red Oak Municipal Arpt., NDB Rwy 17, Amdt. 1
Rock Springs, Wyo.—Rock Springs-Sweetwater County Arpt., NDB-A, Amdt. 1
Springfield, Ohio—Springfield Municipal Arpt., NDB Rwy 23, Amdt. 9
Valparaiso, Ind.—Porter County Municipal Arpt., NDB Rwy 27, Amdt. 2

* * * effective April 24, 1975:

Angola, Ind.—Tri-State Arpt., NDB Rwy 5, Orig.

* * * effective March 19, 1975:

Mt. Vernon, Ill.—Mt. Vernon-Outland Arpt., NDB Rwy 23, Amdt. 2, cancelled

* * * effective March 18, 1975:

McRae, Ga.—Telfair-Wheeler Arpt., NDB Rwy 20, Amdt. 3

§ 97.29 [Amended]

4. Section 97.29 is amended by originating, amending, or canceling the following ILS SIAPs, effective May 8, 1975:

Dallas, Tex.—Dallas Love Field, ILS Rwy 13L, Amdt. 22
Dallas, Tex.—Dallas Love Field, ILS Rwy 31L, Amdt. 10
Lawton, Okla.—Lawton Municipal Arpt., ILS Rwy 35, Amdt. 1
Orlando, Fla.—McCoy AFB, ILS Rwy 36L, Amdt. 3
Philadelphia, Pa.—Philadelphia Int'l. Arpt., ILS Rwy 27R, Amdt. 2, cancelled
Rock Springs, Wyo.—Rock Springs-Sweetwater County Arpt., ILS Rwy 25, Amdt. 18

* * * effective April 3, 1975:

Buffalo, N.Y.—Greater Buffalo Int'l. Arpt., ILS Rwy 23, Amdt. 23

* * * effective March 12, 1975:

Washington, D.C.—Dulles Int'l. Arpt., ILS Rwy 19L, Amdt. 4
Washington, D.C.—Dulles Int'l. Arpt., ILS Rwy 19R, Amdt. 13

§ 97.31 [Amended]

5. Section 97.31 is amended by originating, amending, or canceling the following RADAR SIAPs, effective May 8, 1975:

Baton Rouge, La.—Ryan Arpt., RADAR-1, Amdt. 2
Charleston, S.C.—Charleston AFB/Municipal Arpt., RADAR-1, Amdt. 8
Columbia, S.C.—Columbia Metropolitan Arpt., RADAR-1, Amdt. 1
Dallas, Tex.—Dallas Love Field, RADAR-1, Amdt. 20

6. Section 97.33 is amended by originating, amending, or canceling the following RNAV SIAPs, effective May 8, 1975:

Columbia, Mo.—Columbia Regional Arpt., RNAV Rwy 20, Orig.
Hastings, Neb.—Hastings Muncipal Arpt., RNAV Rwy 14, Orig.

* * * effective April 24, 1975:

Aurora, Ill.—Aurora Municipal Arpt., RNAV Rwy 9, Amdt. 2

* * * effective March 12, 1975:

Washington, D.C.—Dulles Int'l. Arpt., RNAV Rwy 12, Amdt. 3
Washington, D.C.—Dulles Int'l. Arpt., RNAV Rwy 19R, Amdt. 2

(Secs. 307, 313, 601, 1110, Federal Aviation Act of 1958; (49 U.S.C. 1438, 1354, 1421, 1510), sec. 6(c) Department of Transportation Act, (49 U.S.C. 1655(c)) and (5 U.S.C. 552(a)(1)).)

Issued in Washington, D.C., on March 20, 1975.

JAMES M. VINES,
Chief,
Aircraft Programs Division.

NOTE.—Incorporation by reference provisions in §§ 97.10 and 97.20 approved by the Director of the Federal Register on May 12, 1969 (35 FR 5610).

[FR Doc.75-8042 Filed 3-26-75;8:45 am]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket C-2608]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

American Credit Bureau, Inc., et al.

Subpart—Coercing and intimidating: § 13.356[1] *Delinquent debtors.* Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements:* § 13.533-20 *Disclosures,* Subpart—Enforcing dealings or payments wrongfully: § 13.1045 *Enforcing dealings or payments wrongfully.* Subpart—Misrepresenting oneself and goods—Business status, advantages or connections: § 13.1390 *Concealed subsidiary, fictitious collection agency, etc.;* § 13.1440 *Identity;* § 13.1490 *Nature;* § 13.1500 *Official connections;* § 13.1520 *Personnel or staff.* Subpart—Securing information by subterfuge: § 13.2168 *Securing information by subterfuge.* Subpart—Threatening suits, not in good faith: § 13.2264 *Delinquent debt collection.*

(Sec. 6, 38 Stat. 721; (15 U.S.C. 46). Interprets or applies sec. 5, 38 Stat. 719, as amended; (15 U.S.C. 45))

In the Matter of American Credit Bureau, Inc., American Credit Bureau of Nevada, Inc., American Credit Bureau of Tucson, Inc., American Creditors Bureau of Dallas, Inc., American Creditors Bureau of Houston, Inc., American Creditors Bureau of Philadelphia, Inc., American Creditors Bureau of Colorado, Inc., American Collections, Inc., American Collections, Inc. of Georgia, Doctors' Business Bureau, Lusk Collection Agency, Affiliated Creditors Bureau, Inc., all Corporations, and Jemama Investment Company, Inc., a Corporation, Also Trading as American Creditors Bureau of San Diego, American Creditors Bureau of Los Angeles, and American Creditors Bureau of San Francisco, and Jerry Raker, Jerry Middleman and Jack J. Schwartz, Individually and as Officers of Said Corporations

Consent order requiring thirteen debt collection agencies, among other things to cease misrepresenting the nature of their business; misrepresenting that legal actions have been instituted against debtors; misrepresenting the remedies available to respondents or defenses available to debtors; harrassing debtors; and misrepresenting the position or function of respondents' agents or employees.

The Decision and Order, including further order requiring report of compliance therewith, is as follows:[2]

ORDER

It is ordered, That respondents American Credit Bureau, Inc., American Credit Bureau of Nevada, Inc., American Credit Bureau of Tucson, Inc., American Creditors Bureau of Dallas, Inc., American Creditors Bureau of Houston, Inc., American Creditors Bureau of Philadelphia, Inc., American Creditors Bureau of Colorado, Inc., American Collections, Inc., American Collections, Inc. of Georgia, Doctors' Business Bureau, Lusk Collection Agency, Affiliated Creditors Bureau, Inc., all corporations, and Jemama Investment Company, Inc., a corporation, also trading as American Creditors Bureau of San Diego, American Creditors Bureau of Los Angeles, and American Creditors Bureau of San Francisco, their successors and assigns, and Jerry Raker, Jerry Middleman and Jack J. Schwartz, individually and as officers of said corporations, and respondents' officers, agents, representatives and employees, directly or through any corporate or other device, in connection with the collection of, or attempt to collect, accounts in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing directly or by implication, contrary to fact through the use of the terms "credit," "credit bureau" or "creditor's bureau," or any other terms of similar meaning or import, that the corporate respondents are credit reporting agencies or maintain general files concerning the credit worthiness of members of the public unless respondents clearly and conspicuously disclose in all communications, both oral and written, to alleged debtors from whom respondents seek to collect past due accounts, the true nature of their business operation by using the phrase "collection agency" in close conjunction with the name under which they are doing business.

2. Representing, directly or by implication, orally or in writing, contrary to fact, that legal action has been, is being or will be taken against a debtor.

3. Representing, directly or by implication, orally or in writing, contrary to fact or law, that failure by any debtor to pay amounts requested will result in garnishment of wages or attachment of property of the debtor; or misrepresenting, in any way, the remedies available to the respondents or to creditors or the defenses available to debtors in the jurisdiction in which collection is sought.

4. Representing, directly or by implication, orally or in writing, that failure by debtors serving in the U.S. Armed Forces to pay amounts requested will result in disciplinary action or unfavorable information in military personnel files unless such representations are expressly permitted by official directives or policy statements of the Department of Defense or the Department of Army, Navy or Air Force; or misrepresenting, in any manner, the consequences of refusal by debtors serving in the U.S. Armed Forces to pay amounts requested.

5. Representing, directly or by implication, orally or in writing, that failure by debtors to pay the amounts requested will result in criminal action by law enforcement authorities.

6. Placing telephone calls to any alleged debtor at his place of employment or appearing in person at any alleged debtor's place of employment; *Provided, however,* That nothing herein shall prohibit any contact with the debtor at his place of employment before such debtor has requested, orally or in writing, that no telephone calls or personal visits be made to him at his place of employment, where respondents have been totally unable, after having exercised available lawful means, to a reasonable extent, to contact an alleged debtor by telephone or in person at his residence or elsewhere.

7. Representing, directly or by implication, orally or in writing, that any of respondents' employees are government officials, law enforcement officers or agents of businesses other than debt collection; or misrepresenting to any debtor, in any manner, the position or function of any of respondents' agents or employees.

8. Placing of any telephone call to any debtor between the hours, in the time zone of the debtor, of 9 p.m. and 8 a.m. on weekdays, including Saturdays, and between the hours of 9 p.m. and 11 a.m. on Sundays, without first receiving permission from such debtor to call during those hours.

It is further ordered, That respondents, their successors and assigns, with respect to communications to persons other than the alleged debtor, cease and desist from:

a. Communicating or threatening to communicate, or implying the fact or existence of any debt to a debtor's employer prior to any judgment, unless specifically called for by or necessary to a procedure prescribed by statutes.

b. Communicating with or threatening to communicate, or implying the fact or existence of any debt to any other third parties, including former employers, other than one who might be reasonably expected to be liable therefor, except with the written permission of the debtor.

c. Reporting a debt or an alleged debt to a credit bureau unless respondents also promptly report to said credit bureau the subsequent payment of said debt or alleged debt, or the resolution of any dispute concerning said debt, or alleged debt, or any change of status favorable to the debtor.

d. Using any language or symbol, other than the identification of respondents as a collection agency, on envelopes or the contents thereof indicating that the communication relates to the collection of a debt.

[2] Copies of the Complaint, Decision and Order, filed with the original document.

Provided, however, nothing herein shall prohibit any contact in an effort solely to locate a debtor, whose whereabouts are unknown, and where the fact or existence of a debt or alleged debt is not disclosed in any manner, directly or indirectly, except that respondents may identify themselves as a collection agency.

It is further ordered, That respondents, their successors and assigns, shall, within thirty (30) days after this order becomes final, serve by mail or otherwise cause to be served on its creditor clients or assignors of claims:

(a) A copy of this Consent Order; and

(b) A copy of the letter attached hereto as Appendix A signed by the President of the appropriate respondent.

It is further ordered, That: (a) The respondent corporations, their successors and assigns, shall distribute a copy of this order to each of their operating divisions.

(b) Respondents, their successors and assigns, shall deliver a copy of this order to all present and future personnel engaged in collection procedures and secure a signed statement acknowledging receipt of said order from each such person. Furthermore, respondents shall instruct said employees or agents that the practices prohibited by this order are against respondents' business policy and that engagement in said practices will result in dismissal.

It is further ordered, That respondents, their successor and assigns, notify the Commission at least 30 days prior to any proposed change in the corporate respondents such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondents, their successors and assigns, shall within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

APPENDIX A

(RESPONDENTS' LETTERHEAD)

(*Date*)

DEAR CLIENT: We have entered into a consent agreement with the Federal Trade Commission which requires certain standards of collection practices. Our agreement with the Commission is for settlement purposes only and does not constitute an admission by us that the law has been violated. We are enclosing a copy of the Order for your information.

Very truly yours,

(*President*)

Enclosure.

The Decision and Order was issued by the Commission December 4, 1974.

[SEAL] CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7901 Filed 3-26-75;8:45 am]

[Docket C-2610]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

A. R. Knitwear Co., Inc., et al.

SUBPART—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements:* § 13.533–20 *Disclosures;* § 13.533–53 *Recall of merchandise, advertising material, etc.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1844 [1] *Care labeling of textile wearing apparel;* § 13.1895 *Scientific or other relevant facts.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

In the Matter of A. R. Knitwear Co., Inc., a Corporation, and Abe Rosenbluth, and Rose Rosenbluth, Individually and as Officers of Said Corporation.

Consent order requiring a New York City manufacturer and distributor of textile fiber products, among other things to cease failing to affix labels containing disclosures as to the proper care and washing instructions for its wearing apparel.

The Decision and Order, including further order requiring report of compliance therewith, is as follows: [2]

ORDER

It is ordered, That respondents A. R. Knitwear Co., Inc., a corporation, its successors and assigns, and its officers, and Abe Rosenbluth and Rose Rosenbluth, individually and as officers of said corporation and respondents' representatives, agents and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, offering for sale, sale or distribution of any textile product in the form of a finished article of wearing apparel, as the terms "textile product" and "finished article of wearing apparel" are defined in the Federal Trade Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel (16 CFR 423), in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Failing to provide, for any said article of wearing apparel, care instructions which when followed prevent excessive shrinkage of the article.

2. Failing to include the phrase "wash separately" in care instructions for the machine or hand washing of any said apparel whose dye would "run" or "bleed" onto, or stain other articles washed with said apparel.

3. Failing to provide instructions on a permanently affixed label which fully inform purchasers how to effect the regular care and maintenance of said apparel.

It is further ordered, That respondents notify by registered mail all of their customers who have purchased, or to whom have been delivered, the finished articles of wearing apparel which gave rise to this complaint of the excessive shrinkage and staining capacity of said products, and effect the recall of the products from the customers.

It is further ordered, That the respondents herein relabel said articles of wearing apparel to bring them into conformance with the requirements of the Federal Trade Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel (16 CFR Part 423).

It is further ordered, That in addition to the notification to customers required above, the respondents serve a copy of this order by registered mail, return receipt requested, on each customer who purchased the products which gave rise to this complaint.

It is further ordered, That respondents notify the Commission at least 30 days prior to any change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondents herein promptly notify the Commission of the discontinuance of their present business or employment and of their affiliation with a new business or employment. Such notice shall include respondents' current business and address, the nature of the business or employment in which they are engaged as well as a description of their duties and responsibilities.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist contained herein.

The Decision and Order was issued by the Commission December 9, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7936 Filed 3-26-75;8:45 am]

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[1] New.

[2] Copies of the Complaint, Decision and Order filed with the original document.

[Docket C-2609]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Beatrice Maggie Edwards t/a New Faces

Subpart—Advertising falsely or misleadingly: § 13.10 *Advertising falsely or misleadingly;* § 13.15 *Business status, advantages or connections;* § 13.15–225 *Personnel or staff;* § 13.15–250 *Qualifications and abilities;* § 13.135 *Nature of product or service;* § 13.170 *Qualities or properties of product or service;* § 13.170–24 *Cosmetic or beautifying;* § 13.170–30 *Durability or permanence;* § 13.170–63 *Non-toxic;* § 13.170–78 *Renewing, restoring;* § 13.190 *Results;* § 13.195 *Safety;* § 13.205 *Scientific or other relevant facts;* § 13.280 *Unique nature or advantages.* Subpart—Contracting for sale any evidence of indebtedness prior to specified time: § 13.527 *Contracting for sale any evidence of indebtedness prior to specified time.* Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements;* § 13.533–10 *Corrective advertising;* § 13.533–20 *Disclosures;* § 13.533–45 *Maintain records;* § 13.533–45(k) *Records, in general;* § 13.533–53 *Recall of merchandise, advertising material, etc.;* § 13.533–55 *Refunds, rebates, and/or credits.* Subpart—Misrepresenting oneself and goods—Business status, advantages or connections: § 13.1520. *Personnel or staff;* § 13.1535 *Qualifications* —Goods: § 13.1685 *Nature;* § 13.1710 *Qualities or properties;* § 13.1730 *Results;* § 13.1740 *Scientific or other relevant facts;* § 13.1760 *Terms and conditions;* § 13.1760–50 *Sales contract;* § 13.1770 *Unique nature or advantages.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1870 *Nature;* § 13.1885 *Qualities or properties;* § 13.1890 *Safety;* § 13.1892 *Sales contract, right-to-cancel provision;* § 13.1895 *Scientific or other relevant facts;* § 13.1905 *Terms and conditions;* § 13.1905–50 *Sales contract.* Subpart—Offering unfair, improper and deceptive inducements to purchase or deal: § 13.2063 *Scientific or other relevant facts.*

(Sec. 6, 38 Stat. 721; (15 U.S.C. 46). Interprets or applies sec. 5, 38 Stat. 719, as amended; (15 U.S.C. 45, 52)) [Cease and desist order, Beatrice Maggie Edwards t/a New Faces, Atlanta, Ga., Docket C-2609, Dec. 9, 1974.]

In the matter of Beatrice Maggie Edwards, an individual trading and doing business as New Faces.

Consent order requiring an Atlanta, Ga., promoter of a medical process involving the use of certain caustic chemical solutions on the face or body for the removal of wrinkles and blemishes, among other things to cease misrepresenting the nature, safety and results of its skin peeling process. Further, respondent is required to have prospective customers consult a physician prior to signing any contracts, 48 hours in which to cancel the contract with full refund rights. Further, respondent must devote 15 percent of its advertising and oral sales presentations to disclosures of the inherent dangers and other material facts involved with the treatment.

The Decision and Order, including further order requiring report of compliance therewith, is as follows: [1]

I

It is ordered, That respondent Beatrice Maggie Edwards, an individual trading and doing business as New Faces, her successors or assigns and respondent's agents, representatives, and employees, either directly or through any corporate or other device, or through any francisees or licensees, in connection with the advertising, offering for sale, sale, or dispensing of the New Faces treatment (hereinafter sometimes referred to as respondent's treatment) or any similar cosmetic chemosurgical process of face lifting or skin peeling, which involves the topical application of a caustic chemical solution containing carbolic acid (also known as phenol) or other substances on the face, neck, arms, hands or other parts of the human body for the purpose of inducing superficial skin burns, the result of which is the peeling or removal of the outer layers of skin, in commerce, as "commerce" is defined in the Federal Trade Commission Act, or by the United States mails within the meaning of section 12(a) (1) of the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing directly or by implication that:

1. Respondent's treatment or process is solely a cosmetic process, not a medical process, or does not involve chemical surgery.

2. Respondent's treatment or process is painless or involves no abrasives or caustic chemicals.

3. The potential discomfort possibly resulting from the application of respondent's treatment or process is no more severe than that normally associated with a sunburn.

4. Respondent's treatment is safe or free from possible serious side effects or complications.

5. Respondent's treatment or process will remove or significantly reduce acne scars, big pores, deep lines, deep wrinkles, or sagging, redundant folds of skin.

6. Respondent's treatment will produce or result in new, soft, fresh, clear, healthy, fine textured skin.

7. Respondent's process can be clinically recommended to or safely or successfully performed on men, young people, elderly people, or dark-skinned people.

8. Respondent is competently trained and qualified to: (a) examine, advise, and mentally prepare patients to undergo the treatment; (b) determine whether each patient is a proper subject for treatment; (c) administer or perform treatment without direction and supervision of a licensed medical practitioner; and (d) provide post-operative advice and care for patients.

9. Respondent's treatment is complete within any specified period of time.

10. Respondent's treatment will cause clients to appear any specified number of years younger than their actual chronological age.

11. Respondent's process is unique, new or special in the following or other ways:

(a) That it involves a secret formula or secret solution;

(b) That it or similar processes are only available through respondent;

(c) That it is not available through qualified plastic surgeons under more closely controlled hospital conditions in metropolitan areas across the country at a substantially lower cost.

B. Failing or refusing to make clear and conspicuous disclosures in all advertising and in all oral sale presentations, that:

1. The treatment is chemical skin-peeling, a serious medical procedure known as chemosurgery.

2. The treatment involves the application of an acid called phenol to the skin, causing a second-degree burn which peels off the outer layers of the skin and produces a change in skin appearance solely by the body's own wound-healing reactions.

3. The pain associated with the treatment can be very severe; thus patients are sedated or anesthetized during the application of acid. This pain, as well as other discomforts, such as burning, itching, and swollen shut eyes, may persist for days or weeks afterward, requiring medication to control.

4. The treatment has a number of known inherent dangers, including: (a) Poisoning of a person's entire system by the acid absorbed through the skin, which can be a serious, even fatal illness; (b) infection; (c) blindness, if the acid gets into a patient's eyes; (d) permanent scarring; and (e) other complications resulting from the traumatic nature of the procedure or the medications used.

5. A number of undesirable changes in the skin result from chemical skin-peeling, necessitating the continual use of cosmetics or medical techniques to protect, treat, or camouflage the skin. These may include: (a) Permanent scarring; (b) changes in overall color of the treated area; (c) mottling; (d) a line of demarcation at the edge of the treated area; (e) extreme redness; (f) abnormal sensitivity of sunlight; (g) and other traumatic skin reactions.

6. The most common sign of aging in the neck area, which is a stringy or "turkey-neck" condition of the skin and underlying tissues, is not improved by chemical skin-peeling.

7. Almost all plastic surgeons refuse to perform chemical skin-peeling on the neck because the neck is not likely to be improved by the process and is more likely to be worsened since the risks of undesirable side effects and skin changes described above are greater.

[1] Copies of the Complaint, Decision and Order, filed with the original document.

8. Only minor aspects of skin appearance, such as fine wrinkles and some skin blemishes, can be treated by the process.

9. Acne scars, big pores, deep lines, deep wrinkles, and sagging or redundant folds of skin are not removed or significantly reduced by the process, yet some of these conditions may be improved by other techniques of plastic surgery, such as dermabrasion or surgical face-lift.

10. Most men are not advised to undergo the process because of difficulties associated with beard growth and the necessity for continual use of cosmetics.

11. A young person whose skin has not matured should not undergo the process, because of the risk of permanent skin damage.

12. Dark-skinned persons should not undergo the process because of the probability of drastic pigmentation changes.

13. Only certain kinds of people with certain types of skin have a reasonable chance of receiving favorable results and avoiding adverse effects from chemical skin-peeling, and only a licensed medical practitioner familiar with such techniques of plastic surgery and able to evaluate complex physical, mental and emotional factors is qualified to examine, diagnose, advise, select, or mentally prepare patients for chemical skin-peeling, and only such a professional person can provide post-operative advice and care for patients.

14. Although a treatment of this serious nature is usually performed in a hospital, respondent only maintains space in her office for each patient's treatment and recuperation.

15. It may be weeks or months after the treatment before the skin is healed, during which time a treated person has an extremely red face, may suffer various discomforts, and must restrict public activities, avoid direct or reflected sunlight and use heavy cosmetics and sun screens.

16. If a more youthful appearance is achieved through the treatment, the result may not last more than a year or two, since part of the benefit is due to temporary swelling and since the natural aging processes begin all over again after treatment.

17. Chemical skin-peeling is available from qualified plastic surgeons under closely controlled hospital conditions in metropolitan areas across the country at substantially lower cost.

Respondent shall set forth the above disclosures separately and conspicuously from the balance of each advertisement and each presentation used in connection with the advertising, offering for sale, sale, or dispensing of respondent's cosmetic process, and shall devote no less than fifteen percent of each advertisement or presentation to such disclosures. *Provided however,* That in advertisements which consist of less than forty-eight column inches in newspapers or periodicals, and in radio or television advertisements with a running time of two minutes or less, respondent may substitute the following statement, in lieu of the above requirements:

WARNING: This is a medical procedure—basically a chemical burn which peels skin away. It is extremely painful, takes a long time to heal, and exposes a person to risks of poisoning, infection, permanent scarring, and other medical complications. If performed on the neck, the process may make it look worse. Many signs of aging are not improved by this process, and the benefit, if any, is mainly temporary. Only certain kinds of people can benefit from this process, and they should be diagnosed, selected, treated, and continually cared for by a qualified doctor under closely controlled medical conditions. (Statement required by order of the Federal Trade Commission.)

Respondent shall set forth the above disclosure separately and conspicuously from the balance of each advertisement, stating nothing to the contrary or in mitigation thereof, and shall devote no less than fifteen percent of each advertisement to such disclosure, and if such disclosure is made in print, it shall be in at least eleven-point type.

II

It is further ordered, That respondent:

1. Recall and retrieve, from each and every licensee and sales representative, all advertisements and material upon which advertisements or oral sales presentations are based, which contain any of the representations prohibited by Paragraph I(A) of this order or which fail to make the disclosures required by Paragraph I(B).

2. Deliver a copy of this order to each present and future franchisee, licensee, and sales representative, and to each licensed medical practitioner associated with respondent or her licensees; and obtain a written acknowledgement from each of the receipt thereof.

3. Obtain from each present and future franchisee, licensee, or sales representative an agreement in writing (a) to abide by the terms of this order, and (b) to the cancellation of their license or franchise for failure to do so; and that respondent cancel the license or franchise of any licensee or franchisee that fails to abide by the terms of this order.

III

It is further ordered, That respondent:

1. Provide prospective and present patients, as soon as possible after initial sales contact is made with such person and before such person signs any document relating to respondent's process, an information sheet which shall be furnished to the prospective patient and which contains nothing but the disclosures, numbered 1 to 17, set forth in Paragraph I(B). Respondent shall allow these persons ample, uninterrupted opportunity to read and consider the contents of this information sheet. Respondent shall retain a copy of this information sheet, after it is signed and dated by the person, for a period of two years.

2. Require that each such prospective patient, after receipt of the information sheet described above and before he or she signs any contract for respondent's treatment, consult with a licensed physician, who is not in any way associated with or recommended by the respondent, regarding the nature of chemical skin-peeling, its dangers, discomforts, limitations, and alternatives. Respondent shall obtain from each prospective patient a certificate, signed by the physician who was thus consulted, specifying that the physician:

a. Understands what respondent's treatment is and the conditions under which it will be performed;

b. Has explained to the prospective patient the nature of the treatment, its dangers, discomforts, limitations, and alternatives;

c. Has conducted or has examined the results of tests appropriate to determine prospective patient's physical fitness to undergo respondent's treatment and has discussed these results with the prospective patient; and

d. Has reviewed appropriate aspects of the prospective patient's medical history and has discussed these aspects with the propective patient.

This certificate shall specify the date and approximately time of the consultation, and respondent shall retain all such certificates for three years.

IV

It is further ordered That no contract for respondent's process shall become binding on the patient prior to forty-eight hours after the patient has consulted with the physician who will direct and supervise the performing of the treatment and inspected and approved the treatment and recuperation facilities, and that:

1. Respondent shall clearly and conspicuously disclose, orally prior to the time of sale, and in writing on any contract, promissory note or other instrument signed by the patient, that the purchaser may rescind or cancel any obligation incurred, with return of all monies paid, by mailing or delivering a notice of cancellation to the respondent's place of business prior to the end of this period.

2. Respondent shall provide a separate and clearly understandable form which the purchaser may use as a notice of cancellation.

3. Respondent shall return to such patient, within forty-eight hours after receipt of notice of cancellation, all monies paid.

4. Respondent shall not negotiate any contract, promissory note, or other instrument of indebtedness to a finance company or other third party prior to the time the patient is treated.

V

It is further ordered, That respondent cease and desist from the following unfair practice:

Failing or refusing to use a licensed medical practitioner, who is familiar with such techniques of plastic surgery, who is operating within the limits of his or her profession, and who is qualified to evaluate complex physical, mental and

emotional factors, to examine, diagnose, advise, select, or mentally prepare all prospective patients for chemical skin-peeling, to supervise and direct all administrations or applications of the treatment, and to provide post-operative advice or care for all such patients.

VI

It is further ordered, That respondent maintain at all times in the future, for a period of not less than three (3) years, complete business records relative to the manner and form of her continuing compliance with the above terms and provisions of this order.

VII

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of her present business or employment, and of her affiliation with a new business or employment, in the event of such discontinuance of affiliation. Such notice shall include respondent's current business address and a statement as to the nature of the business or employment in which she is engaged as well as a description of her duties and responsibilities.

VIII

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

IX

It is further ordered, That respondent notify the Commission at least 30 days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

X

It is further ordered, That the respondent herein shall within sixty (60) days after service upon her of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which she has complied with this order.

The Decision and Order was issued by the Commission December 9, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7904 Filed 3-26-75;8:45 am]

[Docket C-2611]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Bel-Mor Knitwear, Inc., et al.

Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements:* § 13.533-20 *Disclosures;* § 13.533-53 *Recall of merchandise, advertising material, etc.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1844[1] *Care labeling of textile wearing apparel;* § 13.1895 *Scientific or other relevant facts.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

In the Matter of Bel-Mor Knitwear, Inc., a Corporation, and Aaron Genicoff, Individually and as an Officer of Said Corporation

Consent order requiring a New York City manufacturer and distributor of textile products among other things to cease failing to provide instructions on a permanently affixed label which inform purchasers how to effect regular care and maintenance of respondents wearing apparel.

The Decision and Order, including further order requiring report of compliance therewith, is as follows:[2]

ORDER

It is ordered, That respondents Bel-Mor Knitwear, Inc., a corporation, its successors and assigns, and its officers, and Aaron Genicoff, individually and as an officer of said corporation and respondents' representatives, agents and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, offering for sale, sale or distribution of any textile product in the form of a finished article of wearing apparel, as the terms "textile product" and "finished article of wearing apparel" are defined in the Federal Trade Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel (16 CFR 423), in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Failing to provide, for any said article of wearing apparel, care instructions which when followed prevent excessive shrinkage of the article.

2. Failing to include the phrase "wash separately" in care instructions for the machine or hand washing of any said apparel whose dye would "run" or "bleed" onto, or stain other articles washed with said apparel.

3. Failing to provide instructions on a permanently affixed label which fully inform purchasers how to effect the regular care and maintenance of said apparel.

It is further ordered, That respondents notify by registered mail all of their customers who have purchased, or to whom have been delivered, the finished articles of wearing apparel which gave rise to this complaint of the excessive shrinkage and staining nature of said products, and effect the recall of said products from such customers.

It is further ordered, That the respondents herein relabel said articles of wearing apparel to bring them into conformance with the requirements of the Federal Trade Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel (16 CFR Part 423).

It is further ordered, That respondents notify the Commission at least 30 days prior to any change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondents herein promptly notify the Commission of the discontinuance of their present business or employment and of their affiliation with a new business or employment. Such notice shall include respondents' current business and address, the nature of the business or employment in which they are engaged as well as a description of their duties and responsibilities.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist contained herein.

The Decision and Order was issued by the Commission, December 9, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7995 Filed 3-26-75;8:45 am]

[Docket C-2615]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

C & C Distributing Co., Inc., et al.

Subpart—Advertising Falsely or misleadingly: § 13.10 *Advertising falsely or misleadingly;* § 13.15 *Business status, advantages or connections;* § 13.15-225 *Personnel or staff;* § 13.15-250 *Qualifications and abilities;* § 13.50 *Dealer or seller assistance;* § 13.60 *Earnings and profits;* § 13.135 *Nature of product or service;* § 13.143 *Opportunities;* § 13.160 *Promotional sales plans;* § 13.175 *Quality of product or service;* § 13.195 *Safety;* § 13.195-30 *Investment;* § 13.205 *Scientific or other relevant facts;* § 13.250 *Success, use or standing.* Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements;* § 13.533-20 *Disclosures.* Subpart—Delaying or withholding corrections, adjustments or action owed: § 13.675 *Delaying or withholding corrections, adjustments or action owed.* Subpart—Failing to maintain records: § 13.1051 *Failing to maintain records;* § 13.1051-10 *Accurate;* § 13.1051-30 *Formal regulatory and statutory requirements.* Subpart—Misrepresenting oneself and goods—Business status, advantages or

[1] New.

[2] Copies of the Complaint, Decision and Order filed with the original document.

connections: § 13.1490 *Nature;* § 13.1520 *Personnel or staff;* § 13.1535 *Qualifications;* §13.1540 *Reputation, success or standing.* —Goods: § 13.1608 *Dealer or seller assistance;* § 13.1615 *Earnings and profits;* § 13.1685 *Nature;* § 13.1697 *Opportunities in product or service;* § 13.1740 *Scientific or other relevant facts;* § 13.1755 *Success, use, or standing.* —Promotional sales plans: § 13.1830 *Promotional sales plans.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1855 *Identity;* § 13.1870 *Nature;* § 13.1889 *Risk of loss;* § 13.1892 *Sales contract, right-to-cancel provision;* § 13.1895 *Scientific or other relevant facts;* § 13.1905 *Terms and conditions;* § 13.1905–50 *Sales contract.* Subpart—Offering unfair, improper and deceptive inducements to purchase or deal: § 13.1935 *Earnings and profits;* § 13.1985 *Individual's special selection or situation;* § 13.2015 *Opportunities in product or service;* § 13.2045 *Sales assistance;* § 13.2063 *Scientific or other relevant facts.*

(Sec. 6, 38 Stat. 721; (15 U.S.C. 46). Interprets or applies sec. 5, 38 Stat. 719, as amended; (15 U.S.C. 45))

In the Matter of C & C Distributing Co., Inc., a Corporation, and William Thomas Hall, Individually and as an Officer of Said Corporation.

Consent order requiring a Terrell, Texas, seller and distributor of ladies' cologne and franchises in relation thereto, among other things to cease misrepresenting the nature of its franchises or distributorships; misrepresenting the risks involved in the investment; misrepresenting earnings and profits; failing to maintain accurate records substantiating representations made; failing to make certain disclosures as to the background and experience of respondent and the success of the franchises sold by respondent. Respondent is further required to allow future purchasers a 10-day cooling-off period in which to cancel the contract.

The order to cease and desist, including further order requiring report of compliance therewith, is as follows:[1]

It is ordered, That respondents C & C Distributing Company, Inc., a corporation, and its officers, and William Thomas Hall, individually and as an officer of said corporation and respondents' representatives, agents and employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale or distribution of perfume and ladies cologne and routes, licenses and franchies in relation thereto, or any other route, franchise, license, product, or service, in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing, directly or by implication, orally, in writing, or visually, that:

1. Exclusive franchises or distributorships for established retail and supermarket accounts are offered, or misrepresenting in any manner the nature of the franchises or distributorships.

2. Any amount invested is secured by inventory worth the amount invested and there is no risk of losing the money so invested or misrepresenting, in any manner, the amount of security provided by the inventory or the risk of losing all or any part of the investment.

3. Profitable accounts and routes are established. New accounts and routes, when the original location is not profitable are obtained, or misrepresenting in any manner, the establishing or quality of the accounts and routes.

4. Persons who purchase any such products or services and engage in business can or will derive any stated amount of sales, profits or earnings, or representing directly or by implication, the past or present sales, profits or earnings of purchasers of any such products or services, routes, licenses, franchises or distributorships unless in fact the past sales, or the profits and earnings represented, are those of a substantial number of purchasers and accurately reflect the average sales, profits or earnings of such purchases under circumstances similar to those of the franchisee or distributor or the prospective franchisee or distributor to whom the representation is made or misrepresenting, in any manner, the past, present, or future sales, profits or earnings from the engagement in business and resale of any such products or services.

5. Persons who purchase any such products or services and engage in business must have special qualifications or be specially selected to qualify for purchases of any such products or services and engage in business.

6. Continuing assistance and advice to their distributors or franchisees is offered, or misrepresenting, in any manner, the type and duration of assistance and advice offered.

B. Failing to maintain accurate records which substantiate that any past or present sales, profits or earnings represented are accurate and are those of a substantial number of franchisees or distributors and accurately reflect the average sales, profits or earnings, of such franchisees or distributors under circumstances similar to those of the franchisee or distributor or prospective franchisee or distributor to whom the representation is being made.

C. Failing to furnish any prospective franchisee with all of the following information, in a clear, permanent, and straight-forward form, at the time when contact is first established between such prospective franchisee and respondents or their representatives:

1. A factual description of the franchise offered or to be sold.

2. The business experience, stated individually, of each of the franchisor's directors, stockholders owning more than ten percent of the stock, and the chief executive officers for the past ten years; and biographical data concerning all such persons.

3. The business experience of the franchisor, including the length of time the franchisor has conducted a business of the type to be operated by the franchisee; has granted franchises for such business; and has granted franchises in other lines of business.

4. Where such is the case, a statement that the franchisor or any of its directors, stockholders owning more than ten percent of the stock, or chief executive officers:

a. Have been held liable in a civil action, convicted of a felony, or pleaded nolo contendere to a felony charge in any case involving fraud, embezzlement, fraudulent conversion, or misappropriation of property;

b. Are subject to any currently effective injunctive or restrictive order or ruling relating to business activity as a result of action by any public agency or department; or

c. Have filed bankruptcy or been associated with management of any company that has been involved in bankruptcy or reorganization proceedings; or

d. Are, or have been, a party to any cause of action brought by franchisees against the franchisor.

Such statement shall set forth the identity and location of the court, date of conviction or judgment, any penalty imposed or damages assessed, and the date, nature, and issuer of each such order or ruling.

5. The financial history of the franchisor, including balance sheets and profit and loss statements for the most recent five-year period; and a statement of any material changes in the financial condition of the franchisor since the date of such financial statements.

6. A description of the franchise fee; and a statement indicating whether all or part of the franchise fee may be returned to the franchisee and the conditions under which the fee will be refunded.

7. The formula by which the amount of such franchise fee is determined if the fee is not the same in all cases.

8. A statement of the number of franchises presently operating and the number proposed to be sold, indicating which existing franchises, if any, are company-owned and their addresses.

9. A statement of the number of franchises, if any, that operated at a loss during the previous year.

10. A statement of the conditions under which the franchise agreement may be terminated or renewal refused, or repurchased at the option of the franchisor, and a statement of the number of franchisees that fell into each of these categories during the past 12 months.

11. A statement of the conditions and terms under which the franchisor allows the franchisee to sell, lease, assign, or otherwise transfer his franchise, or any interest therein.

12. A statement of the conditions under which the franchisee agreement

[1] Copies of the complaint and decision and order filed with the original document.

may be terminated or renewal refused or repurchased at the option of the franchisor, and a statement of the number of franchisees that fell into each of these categories during the past 12 months.

13. A statement of the conditions and terms under which the franchisor allows the franchisee to sell, lease, assign or otherwise transfer his franchise, or any interest therein.

14. A statement of the terms and conditions of any financing arrangements offered directly or indirectly by the franchisor or affiliated persons, and a description of any payments received by the franchisor from any persons for the placement of financing with such persons.

15. A list of at least ten representative operating franchises with addresses and telephone numbers, similarly situated to the franchise offered and located in the same geographic area, if possible.

16. A statement of the average length of service of personnel who are responsible for assisting the franchisee at his location, and the average number of hours such personnel spent during the past year with each franchisee that was in business for less than one year.

17. If the franchisor informs the prospective franchisee that it intends to provide him with training, the franchisor must state the number of hours of instruction and furnish the prospective franchisee with a brief biography of the instructors who will conduct the training.

All of the foregoing information 1. to 17. is to be contained in a single disclosure statement, which shall not contain any promotional claims or other information not required by this order. The statement shall carry a distinctive and conspicuous cover sheet with the following notice (and no other) imprinted thereon in bold face type of not less than 10 point size:

INFORMATION FOR PROSPECTIVE FRANCHISEES REQUIRED BY FEDERAL TRADE COMMISSION DECISION AND ORDER

This information is provided for your own protection. It is in your best interest to study it carefully before making any commitment. If you do sign a contract, you may cancel it, and obtain a full refund of any money paid, for any reason, within ten business days after either signing such contract or receiving this disclosure statement, whichever occurs later. Details appear on the contract itself.

It is further ordered, That respondents shall cease and desist from making any claim:

1. In any advertising, promotional material, or disclosure statement, or in any oral sales presentation, solicitation, or discussion between a franchisor's representative and prospective franchisees for which the franchisor does not have substantiation in its possession, which substantiation shall be made available to prospective franchisees upon demand. This provision applies, but is not limited, to statements concerning the experience or qualifications, or lack of experience or qualifications, needed for success as a franchisee.

2. In any advertising or promotional material, or in any oral sales presentation, solicitation, or discussion between a franchisor's representatives and prospective franchisees, which (directly or by implication) contradicts or exceeds any of the statements required to be disclosed by para. (B) of this order.

It is further ordered, That respondents herein cease and desist from:

(a) Failing to include immediately above and on the same page as the franchisee's signature line of any contract establishing or confirming a franchise agreement, the following statement in bold face print at least 50 percent larger than any other print in the body of such contract, or in bold face print of a contrasting color:

NOTICE: YOU ARE ENTITLED TO CERTAIN IMPORTANT INFORMATION CONCERNING THIS TRANSACTION ENTITLED, "INFORMATION FOR PROSPECTIVE FRANCHISEES REQUIRED BY FEDERAL TRADE COMMISSION DECISION AND ORDER." IT IS IN YOUR BEST INTEREST TO DEMAND AND STUDY SUCH INFORMATION. *YOU MAY CANCEL THIS CONTRACT FOR ANY REASON WITHIN TEN BUSINESS DAYS AFTER EITHER SIGNING THIS CONTRACT OR RECEIVING THE REQUIRED INFORMATION, WHICHEVER OCCURS LATER.* If you do choose to cancel, you will be entitled to receive a full refund within ten business days after franchisor receives notice of your cancellation. You may use any reasonable method to notify franchisor of your cancellation within the grace period. For your protection you may wish to use certified mail with return receipt requested, or a telegram, either of which should be sent to the address below. (Franchisor will insert here the address and telephone number to which such notices should be sent.)

(b) Failing to cancel any contract for which a notice of cancellation was sent by any reasonable means within ten business days after either the contract's execution, or the franchisee's receipt of all required information, whichever occurs later, or to refund any money paid by franchisee within ten business days after the date of receipt of such notice of cancellation.

(c) Failing to furnish the prospective franchisee upon request at any time, and in the absence of any request, before consummation of any agreement, with a copy of the franchise agreement proposed to be used.

It is further ordered, That the individual respondent William Thomas Hall, promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business address and a statement as to the nature of the business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with this order.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in any of the corporate respondents such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That respondents deliver a copy of this order to cease and desist to all of their present and future personnel engaged in the offering for sale, or sale of franchises, services, or any other products or services, or in any aspect of preparation, creation, or placing of advertising, and that respondents secure a signed statement acknowledging receipt of said order from each such person.

The Decision and Order was issued by the Commission, December 17, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7903 Filed 3-26-75;8:45 am]

[Docket C-2618]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Credit Bureau of Greater Syracuse, Inc., et al.

Subpart—Collecting, assembling, furnishing or utilizing consumer reports: § 13.382 Collecting, assembling, furnishing or utilizing consumer reports: § 13.382-1 Confidentiality, accuracy, relevancy, and proper utilization: § 13.382-1(a) Fair Credit Reporting Act; § 13.382-5 Formal regulatory and/or statutory requirements: § 13.382-5(a) Fair Credit Reporting Act.

(Sec. 6, 38 Stat. 721; (15 U.S.C. 46). Interpret or apply sec. 5, 38 Stat. 719, as amended; 82 Stat. 146, 147, 84 Stat. 1127-36; (15 U.S.C. 1601), et seq.)

In the Matter of Credit Bureau of Greater Syracuse, Inc., a Corporation, and Richard W. Viale, Individually and as an Officer of Said Corporation

Consent order requiring a Syracuse, N.Y., credit bureau, among other things to cease furnishing credit reports on consumers to persons it had no reason to believe intended to use the information for a permissible purpose; failing to disclose to properly identified consumers information in their files; failing to reinvestigate disputed information within a reasonable period of time; and imposing fees for making required disclosures or when conducting a reinvestigation.

The Decision and Order, including further order requiring report of compliance therewith, is as follows: [1]

[1] Copies of the Complaint, Decision and Order, filed with the original document.

It is ordered, That respondent Credit Bureau of Greater Syracuse, Inc., a corporation, its successors and assigns, and its officer Richard W. Viale, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the collecting, assembling or furnishing of consumer reports, as "consumer report" is defined in section 603(d) of the Fair Credit Reporting Act (Pub. L. 91-508, 15 U.S.C. 1601 et seq.), shall forthwith cease and desist from:

1. Submitting consumer report information to persons whom respondents have no reason to believe intend to use the information for a permissible purpose as set out in section 604 of the Act.

2. Failing to disclose to any consumer, upon request and proper identification, the nature and substance of all information (including claims information, but excluding medical information) in respondents' files on the consumer at the time of the request, in accordance with section 609(a) of the Fair Credit Reporting Act.

3. Failing to make the disclosures required by section 609 of the Fair Credit Reporting Act by telephone as required by section 610 of the Act, or discouraging such disclosures.

4. Failing within ten working days to:

(a) Reinvestigate any item of information, the completeness or accuracy of which is disputed by the consumer and record the current status of the information unless they have reasonable grounds to believe the dispute is frivolous or irrelevant, as required by section 611(a) of the Act.

(b) Delete any information which is found to be inaccurate or can no longer be verified, as required by section 611(a) of the Act.

5. Failing to provide notification that an item of information has been deleted or corrected to recipients of previous reports (within the past two years for employment purposes and the past six months for any other purpose) when specifically requested to do so by the consumer, as required by section 611(d) of the Act.

6. Imposing a charge on consumers for making disclosures pursuant to section 609, and when furnishing consumer reports pursuant to section 611(d), when requested by consumers within 30 days after receipt of a notification pursuant to section 615 of some adverse action, in accordance with the requirements of section 612 of the Fair Credit Reporting Act.

7. Imposing a charge on consumers when conducting a reinvestigation of disputed information in a consumer's files as required by section 611(a) of the Fair Credit Reporting Act.

It is further ordered, That respondents herein shall deliver a copy of this order to cease and desist to all present and future personnel, including employees and representatives, engaged in the preparation of reports including consumer reports, and engaged in the disclosure and reinvestigation of all information in said reports, and that respondents secure a signed statement acknowledging receipt of said order from each such person.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business or employment in which he is engaged, as well as a description of his duties and responsibilities.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondents, such as dissolution, assignment or sale, resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondents herein shall within sixty (60) days after service upon them of this Order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with this Order.

The Decision and Order was issued by the Commission December 24, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7902 Filed 3-26-75;8:45 am]

[Docket C-2612]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Leon Birnbaum t/a Jolie Knitwear

Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements;* § 13.533-20 *Disclosures;* § 13.533-53 *Recall of merchandise, advertising material, etc.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1844 *Care labeling of textile wearing apparel;*[1] § 13.1895 *Scientific or other relevant facts.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45) [Cease and desist order, Leon Birnbaum t/a Jolie Knitwear, New York City, Docket C-2612, Dec. 9, 1974.]

In the Matter of Leon Birnbaum, an Individual Trading as Jolie Knitwear.

Consent order requiring a New York City manufacturer of textile fiber products, among other things to cease failing to label its merchandise with information relative to proper care and washing instructions of its wearing apparel.

The Decision and Order, including further order requiring report of compliance therewith, is as follows:[2]

It is ordered, That respondent, Leon Birnbaum, individually and trading as Jolie Knitwear or trading under any other name, his successors and assigns, and respondent's representatives, agents and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, offering for sale, sale or distribution of any textile product in the form of a finished article of wearing apparel, as the terms "textile product" and "finished article of wearing apparel" are defined in the Federal Trade Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel (16 CFR Part 423), in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Failing to provide, for any said article of wearing apparel, care instructions which when followed prevent excessive shrinkage of the article.

2. Failing to include the phrase "wash separately" in care instructions for the machine or hand washing of any said apparel whose dye would "run" or "bleed" onto, or stain other articles washed with said apparel.

3. Failing to provide instructions on a permanently affixed label which fully inform purchasers how to effect the regular care and maintenance of said apparel.

It is further ordered, That respondent notify by registered mail all of his customers who have purchased, or to whom have been delivered, the finished articles of wearing apparel which gave rise to this complaint of the excessive shrinkage and staining nature of said products, and effect the recall of said products from such customers.

It is further ordered, That the respondent herein relabel said articles of wearing apparel to bring them into conformance with the requirements of the Federal Trade Commission's Trade Regulation Rule relating to the Care Labeling of Textile Wearing Apparel (16 CFR Part 423).

It is further ordered, That in addition to the notification to customers required above, the respondent serve a copy of this order by registered mail, return receipt requested, on each customer who purchased the products which gave rise to this complaint.

It is further ordered, That the respondent promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business and address, the nature of the business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That respondent shall, within sixty (60) days after service upon him of this order, file with the Commission a report in writing setting forth in detail the manner and form in which he has complied with the order to cease and desist contained herein.

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[1] New.

[2] Copies of the Complaint, Decision and Order, filed with the original document.

The Decision and Order was issued by the Commission, December 9, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7994 Filed 3-26-75;8:45 am]

[Docket No. C-2134]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Plaza Club, Inc., et al.

Codification under Part 13 appears at 37 FR 4249, March 1, 1972.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45) [Modified order to cease and desist, Plaza Club, Inc., et al., Docket C-2134, Dec. 17, 1974]

In the Matter of Plaza Club, Inc., a Corporation, and Health Spa, Inc., a Corporation, and European Health Spa, Inc., a Corporation, and James R. Booker, Individually and as an Officer of Said Corporations, and George E. Shore, Individually and as a Stockholder of Said Corporations, and European Health Spa & Country Club, Inc., a Corporation, and James R. Booker and George E. Shore, Individually and as Officers of Said Corporation.

Order modifying subparagraph (J) of Paragraph I of a consent order issued against respondents, 80 F.T.C. 62, to except the use of negotiable instruments in consumer credit transactions in the State of Kansas.[1]

The ordering reopening proceedings and modifying order to cease and desist is as follows:

This matter is before the Commission upon a motion captioned "Petition to Reopen Docket," received October 29, 1974, filed by Spa Fitness Centers, Inc., Carl Lane, Kenneth Melby and Scott Rice, successors in interest to the above-captioned respondents. The Bureau of Consumer Protection has filed an answer dated November 26, 1974.

Petitioners point out that the law of Kansas, in which they transact business, now forbids the use of negotiable instruments in those consumer credit transactions in which they engage, and the law further preserves all defenses of a consumer against a third party to whom an instrument of indebtedness may have been negotiated in violation of the law. Therefore, the disclosure required by paragraph I (J) of the order in this matter is no longer necessary, and indeed may be misleading with respect to contracts governed by Kansas law. Respondents seek exemption from the requirement for their operations in Kansas, and the Bureau of Consumer Protection does not object.

The Commission has considered the arguments of the parties and has determined, in the exercise of its discretion, to grant the petition to reopen, and to modify the order as provided hereinafter:

It is ordered, That the proceedings in this matter be reopened and that subparagraph (J) of paragraph I of the Order to Cease and Desist issued against respondents on January 14, 1972, be modified to read as follows:

With the exception of contracts executed in the State of Kansas and to be performed in the State of Kansas, failing to incorporate the following statement on the face of all contracts executed by respondents' customers with such conspicuousness and clarity as is likely to be observed, read, and understood by the purchaser:

IMPORTANT NOTICE

If you are obtaining credit in connection with this contract, you will be required to sign a promissory note. This note may be purchased by a bank, finance company or other third party. If it is purchased by another party, you will be required to make your payments to the purchaser of the note. You should be aware that if this happens you may have to pay the note in full to the new owner of the note even if this contract is not fulfilled.

The order reopening proceedings and modifying order to cease and desist was issued by the Commission December 17, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7998 Filed 3-26-75;8:45 am]

[Docket 8827-o]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Standard Oil Company of California, et al.

Subpart—Advertising falsely or misleadingly: § 13.10 *Advertising falsely or misleadingly;* § 13.20 *Comparative data or merits;* § 13.160 *Promotional sales plans;* § 13.170 *Qualities or properties of product or service;* § 13.170-16 *Cleansing, purifying;* § 13.205 *Scientific or other relevant facts;* § 13.265 *Tests and investigations.* Subpart—Misrepresenting oneself and goods—Goods: § 13.1575 *Comparative data or merits;* § 13.1710 *Qualities or properties;* § 13.1730 *Results;* § 13.1740 *Scientific or other relevant facts;* § 13.1762 *Tests, purported.* —Promotional sales plans: § 13.1830 *Promotional sales plans.* Subpart—Offering unfair, improper and deceptive inducements to purchase or deal: § 13.2063 *Scientific or other relevant facts;* § 13.2075 *Television "mock ups," etc.* Subpart—Using deceptive techniques in advertising: § 13.2275 *Using deceptive techniques in advertising;* § 13.2275-70 *Television depictions.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45) [Final Order, Standard Oil Company of California, et al., San Francisco, Calif., Docket 8827-o, Nov. 26, 1974]

In the Matter of Standard Oil Company of California, a Corporation, and Batten, Barton, Durstine & Osborn, Inc., a Corporation

Consent order requiring a San Francisco, Calif., distributor of gasoline and other petroleum products and its New York City advertising agency, among other things to cease misrepresenting that the F-310 additive in its Chevron gasoline will produce pollution-free exhaust. The order further dismisses certain subparagraphs of Paragraphs five and six of the complaint.

The Final Order, including further order requiring report of compliance therewith, is as follows:[1]

This matter is before the Commission on the appeal of complaint counsel from the Administrative Law Judge's Initial Decision filed April 25, 1973. The Commission has received written briefs, heard oral arguments and considered the record in this matter, and has determined that complaint counsel's appeal should be granted in part. The Commission also has determined that, except as otherwise ordered herein, the Initial Decision should be set aside, and the findings and conclusions contained in the accompanying opinion should be adopted as the findings of fact and conclusions of law of the Commission, and that the cease-and-desist order contained herein should issue. After the October 15, 1973 oral argument on this appeal, three motions were filed with the Commission by parties hereto. Said motions shall be acted upon in the manner and for the reasons set forth herein. Accordingly,

It is ordered, That respondent Standard Oil Company of California's Motion to Strike Portions of Complaint Counsel's Briefs in this Docket and in Docket No. 8851 (Crown Central) filed on October 23, 1973 is denied for the reason that it is not improper for parties to adjudicative proceedings before the Commission to cite to Initial Decisions of Administrative Law Judges in other such proceedings in briefs on appeal to the Commission. Such citations have no evidentiary value and are considered by the Commission only as references to pre-existing adjudicative conclusions which may serve as precedents or guides to future decisions when similar or related issues are before the Commission for resolution. In addition, no prejudice has been shown as a result of the challenged references to the Initial Decision in question.

It is further ordered, That the Joint Motion to Correct the Record of Oral Argument filed by counsel for all the parties hereto on March 1, 1974 is granted and that a copy of said Motion shall be attached to the official copy of the transcript of the oral argument to provide a record of the agreed changes.

It is further ordered, That respondent Batten, Barton, Durstine & Osborn,

[1] Copies of the complaint, Initial Decision, final order and opinion filed with the original document.

[1] Copy of the Order Reopening Proceedings and Modifying Order to Cease and Desist filed with the original document.

Inc.'s Motion to Correct the Record filed February 25, 1974 is denied for the failure of the Motion to state persuasive reasons for a change on the grounds alleged. However, said Motion shall be considered a statement by said respondent in explanation of its counsel's remarks about its abilities to sell gasoline chemistry recorded at page 67 of the transcript of the oral argument.

It is further ordered, That only the following portions of the Administrative Law Judge's Initial Decision in this case are adopted as findings and conclusions of the Commission:

The lists of witnesses; the first two paragraphs following the witness lists; findings 1–6; all but the first full sentence of finding 7; finding 11; finding 15; paragraphs 1, 2, 5, 6 and 8 of finding 16; paragraphs 1, 2, 4 and 5 of finding 17; paragraph 2 of finding 18, all of finding 19 except the second and third sentences of paragraph 2; paragraph 1 of finding 20; paragraph 3 of finding 25; paragraph 1, all but the fifth sentence in paragraph 2, the first full sentence of paragraph 3 and paragraphs 5 and 6 of finding 26; finding 27; paragraph 3, the last two sentences of paragraph 5, all but the last sentence of paragraph 6 and the first two sentences of paragraph 7 of finding 28; paragraph 2 of finding 29; paragraph 2 of finding 30; paragraphs 1 and 2 and the first four sentences of paragraph 3 of finding 31; paragraphs 2 and 3 and the first two sentences of paragraph 4 of finding 32; and both paragraphs under the heading The Oral Argument.

All other findings and conclusions of the Initial Decision are hereby set aside, and the conclusions contained in the accompanying opinion are established together with the above listed sections of the Initial Decision and the Appendix to the opinion, as the findings of fact and conclusions of law of the Commission in this case.

It is further ordered, That the following cease and desist order shall be and it hereby is entered:

I. *It is ordered,* That respondent Standard Oil Company of California, a corporation, its successors and assigns, its officers, representatives, agents, employees directly or through any corporate or other device, in connection with the advertising, offering for sale, sale or distribution of Chevron gasolines, or the additive F–310, or any other product in commerce as "commerce' is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing directly or by implication that any such product:

(a) Will produce or result in motor vehicle exhaust which is pollution free or generally pollution free; or

(b) Will eliminate or reduce air pollution caused by motor vehicles; or

(c) Will eliminate or reduce emissions from all or any number or group of motor vehicles in which it is used;

or that:

(d) Any gasoline or gasoline additive product has any other quality, performance ability or other characteristic; or

(e) Tests, demonstrations, research or experiments have been conducted which prove or substantiate any of said representations;

Unless and only to the extent that each and every such representation is true and has been fully and completely substantiated by competent scientific tests. The results of said tests, the original data collected in the course thereof and a detailed description of how said tests were performed shall be kept, available in written form for at least three years following the final use of the representation.

2. Representing directly or by implication that:

(a) Automotive exhaust has certain observable or measurable characteristics in all or any number or group of motor vehicles when such is not the fact; or

(b) Any machines, measuring devices or technical instruments have particular characteristics or capacities when such is not the fact; or

(c) Any product has any effectiveness in reducing air pollution or any air pollutant or air pollutants without at the same time, in the same advertisement or other form of communication, conspicuously disclosing that not all of the harmful pollutants in automotive exhaust are affected by said product; or

(d) Any product will reduce any emissions of pollutants from automobile exhaust by any percentage or numerical quantity unless in connection therewith there is a clear, accurate and conspicuous disclosure of the type of vehicle which can expect to achieve reductions of such magnitude and the approximate percentage of such vehicles in the general car population.

II. *It is ordered,* That respondent Standard Oil Company of California, a corporation, its successor and assigns, its officers, representatives, agents, employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale, or distribution of Chevron gasolines, or the additive F–310 or any other product in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist directly or indirectly from:

1. Advertising by or through the use of or in conjunction with any test, experiment, or demonstration, or the result thereof, or any other information or evidence that appears or purports to confirm or prove, or is offered as confirmation, evidence, or proof of any fact, product characteristic or the truth of any representation, which does not accurately demonstrate, prove, or confirm such fact, product characteristic, or representation.

2. Using any pictorial or other visual means of communication with or without an accompanying verbal text which directly or by implication creates a misleading impression in the minds of viewers as to the true state of material facts which are the subject of said pictures or other visual means of communication.

3. Misrepresenting in any manner or by any means any characteristic, property, quality, or the result of use of any gasoline or gasoline additive product.

III. *It is ordered,* That respondent Batten, Barton, Durstine & Osborn, Inc., a corporation, its successors and assigns, its officers, representatives, agents, employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale or distribution of Chevron gasolines, or the additive F–310, or any other product in commerce as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing directly or by implication that any such product:

(a) Will produce or result in motor vehicle exhaust which is pollution free or generally pollution free; or

(b) Will eliminate or reduce air pollution caused by motor vehicles; or

(c) Will eliminate or reduce emissions from all or any number or group of motor vehicles in which it is used;

or that:

(d) Any gasoline or gasoline additive product has any other quality, performance ability or other characteristic; or

(e) Tests, demonstrations, research or experiments have been conducted which prove or substantiate any of said representations;

Unless and only to the extent that respondent has a reasonable basis for such representation based upon competent scientific tests by it or its client. The results of said tests and the data collected in the course thereof relied upon by respondent shall be kept available in written form for at least three years following the final use of the representation.

2. Representing directly or by implication that:

(a) Automotive exhaust has certain observable or measurable characteristics in all or any number or group of motor vehicles when such is not the fact; or

(b) Any machines, measuring devices or technical instruments have particular characteristics or capacities when such is not the fact; or

(c) Any product has any effectiveness in reducing air pollution or any air pollutant or air pollutants without at the same time, in the same advertisement or other form of communication, conspicuously disclosing that not all of the harmful pollutants in automotive exhaust are affected by said product; or

(d) Any product will reduce any emissions of pollutants from automobile exhaust by any percentage of numerical quantity unless in connection therewith there is a clear, accurate and conspicuous disclosure of the type of vehicle which can expect to achieve reductions of such magnitude and the approximate percentage of such vehicles in the general car population.

IV. *It is ordered,* That respondent Batten, Barton, Durstine & Osborn, Inc., a corporation, its successors and assigns, its officers, representatives, agents, employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale,

or distribution of Chevron gasolines, the additive F-310, or any other product in commerce as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist directly or indirectly from:

1. Advertising by or through the use of or in conjunction with any test, experiment, or demonstration, or the result thereof, or any other information or evidence that appears or purports to confirm or prove or is offered as confirmation, evidence or proof of any fact, product characteristic, or of the truth of any representation which does not accurately demonstrate, prove, or confirm such fact, product characteristic, or representation unless the respondent can establish it neither knew, nor had reason to know, nor upon reasonable inquiry could have known that such was the case.

2. Using any pictorial or other visual means of communication with or without an accompanying verbal text which directly or by implication creates a misleading impression in the minds of viewers as to the true state of material facts which are the subject of said pictures or other visual means of communication unless the respondent can establish it neither knew nor had reason to know nor upon reasonable inquiry could have known the true facts.

3. Misrepresenting in any manner or by any means any characteristic, property, quality, or the result of the use of any gasoline or gasoline additive product unless the respondent can establish it neither knew nor had reason to know nor upon reasonable inquiry could have known that such representations are false.

It is further ordered, That subparagraphs 1, 3, 4, 5, 7, 8, 9, 10(b), 10(c), and 11 of Paragraphs five and six of the complaint be, and they hereby are dismissed.

It is further ordered, That the respondent corporations shall forthwith distribute a copy of this order to each of their operating divisions.

It is further ordered, That respondents herein shall notify the Commission at least thirty (30) days prior to any proposed change in any of the corporate respondents such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondents shall, within sixty (60) days after service of the order upon them, file with the Commission a written report, signed by the respondents, setting forth in detail the manner and form of their compliance with the order to cease and desist.

Commissioners Hanford and Nye did not participate since oral argument was heard prior to their assumption of Office.

Final order issued by the Commission, November 26, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7993 Filed 3-26-75;8:45 am]

[Docket C-2607]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Statewide Interiors, Inc., et al.

Subpart—Advertising falsely or misleadingly: § 13.30 *Composition of goods:* § 13.30-75 *Textile Fiber Products Identification Act;* § 13.73 *Formal regulatory and statutory requirements:* § 13.73-90 *Textile Fiber Products Identification Act.* Subpart—Misbranding or Mislabeling: § 13.1185 *Composition:* § 13.1185-80 *Textile Fiber Products Identification Act;* § 13.1212 *Formal regulatory and statutory requirements:* § 13.1212-80 *Textile Fiber Products Identification Act.* Misrepresenting oneself and goods—Goods: § 13.1590 *Composition:* § 13.1590-70 *Textile Fiber Products Identification Act;* § 13.1623 *Formal regulatory and statutory requirements:* § 13.1623-80 *Textile Fiber Products Identification Act.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1845 *Composition:* § 13.1845-70 *Textile Fiber Products Identification Act;* § 13.1852 *Formal regulatory and statutory requirements:* § 13.1852-70 *Textile Fiber Products Identification Act.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended, 72 Stat. 1717; 15 U.S.C. 45, 70)

In the Matter of Statewide Interiors, Inc., a Nevada Corporation, Statewide Interiors, Inc., an Idaho Corporation, and Alfred F. Allen, Individually and as an Officer of Said Corporations

Consent order requiring two Nevada and Idaho distributors and retailers of upholstery fabrics, draperies and floor coverings, among other things to cease misbranding its textile fiber products.

The Decision and Order, including further order requiring report of compliance therewith, is as follows: [1]

ORDER

It is ordered, That respondents Statewide Interiors, Inc., a Nevada corporation, and Statewide Interiors, Inc., an Idaho corporation, their successors and assigns, and their officers, and Alfred F. Allen, individually and as an officer of said corporations, and respondents' agents, representatives, and employees, directly or through any corporate, subsidiary, division or other device (hereinafter in this and other paragraphs of this order, referred to as "respondents"), in connection with the introduction, delivery for introduction, sale, advertising, or offering for sale, in commerce, or the transportation or causing to be transported in commerce of any textile fiber product; or in connection with the sale, offering for sale, advertising, delivery, transportation or causing to be transported, of any textile fiber product which has been advertised or offered for sale in commerce; or in connection with the sale, offering for sale, advertising, delivery, transportation, or causing to be transported, after shipment in commerce, of any textile fiber product, whether in its original state or contained in other textile fiber products, as the terms "commerce" and "textile fiber product" are defined in the Textile Fiber Products Identification Act, do forthwith cease and desist from:

1. Misbranding textile fiber products by failing to affix a stamp, tag, label or other means of identification to each such textile fiber product showing in a clear, legible, conspicuous manner each element of information required to be disclosed by section 4(b) of the Textile Fiber Products Identification Act; or as an alternative to the foregoing, where properly labeled samples, swatches, or specimens are used to effect the sale of articles of wearing apparel or other household textile articles which are manufactured specifically for a particular customer after the sale is consummated, and the articles of wearing apparel or other household textile articles are of the same fiber content as the samples, swatches or specimens from which the sale was effected, failing to provide an invoice or other paper to accompany them showing the information otherwise required to appear on the label, as allowed by Rule 21(b) of the rules and regulations under the Textile Fiber Products Identification Act, effective March 3, 1960, as amended.

2. Misbranding textile fiber products by failing to affix a stamp, tag, label or other means of identification to samples, swatches or specimens used to effect the sale of a textile product as required by Rule 21(a) of the rules and regulations under the Textile Fiber Products Identification Act, effective March 3, 1960, as amended.

It is further ordered, That the respondent corporations shall forthwith distribute a copy of this order to each of their operating divisions.

It is further ordered, That the respondents shall forthwith distribute a copy of this order to all present and future personnel of respondents engaged in the offering for sale, or sale, of any floor covering or any other merchandise offered for sale by respondents, and that respondents secure a signed statement acknowledging receipt of said order from each such person.

It is further ordered, That respondents notify the Commission at least 30 days prior to any proposed change in the corporate respondents such as dissolution, assignment or sale resulting in the emergence of a successor corporation,

[1] Copies of the Complaint, Decision and Order, filed with the original document.

the creation or dissolution of subsidiaries or any other change in the corporations which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business address and a statement as to the nature of the business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

The Decision and Order was issued by the Commission December 4, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7997 Filed 3-26-75;8:45 am]

[Docket C-2619]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS.

Tomorrow's Heritage, Inc., t/a Heritage, et al.

Subpart—Advertising falsely or misleadingly: § 13.10 *Advertising falsely or misleadingly;* § 13.15 *Business status, advantages, or connections:* § 13.15–30 *Connections or arrangements with other;* § 13.15–80 *Government connection;* § 13.70 *Fictitious or misleading guarantees;* § 13.75 *Free goods or services;* § 13.105 *Individual's special selection or situation;* § 13.135 *Nature of product or service;* § 13.155 *Prices:* § 13.155–5 *Additional charges unmentioned;* § 13.155–35 *Discount savings;* § 13.155–40 *Exaggerated as regular and customary;* § 13.155–70 *Percentage savings;* § 13.155–100 *Usual as reduced, special, etc.;* § 13.160 *Promotional sales plans;* § 13.175 *Quality of product or service;* § 13.185 *Refunds, repairs, and replacements;* § 13.200 *Sample, offer or order conformance;* § 13.205 *Scientific or other relevant facts;* § 13.240 *Special or limited offers:* Subpart—Contracting for sale any evidence of indebtedness prior to specified time: § 13.527 *Contracting for any evidence of indebtedness prior to specified time.*

Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements:* § 13.533–20 *Disclosures;* § 13.533–55 *Refunds, rebates, and/or credits.* Subpart—Delaying or withholding corrections, adjustments or action owed: § 13.675 *Delaying or withholding corrections, adjustments or action owed;* § 13.677 *Delaying or failing to deliver goods or provide services or facilities.* Subpart—Enforcing dealings or payments wrongfully: § 13.1045 *Enforcing dealings or payments wrongfully.* Subpart—Failing to maintain records: § 13.1051 *Failing to maintain records:* § 13.1051–20 *Adequate.* Subpart—Misrepresenting oneself and goods—Business status, advantages or connection: §13.1395 *Connections and arrangements with others;* —Goods: § 13.1625 *Free goods or services;* § 13.1647 *Guarantees;* § 13.1663 *Individual's special selection or situation;* § 13.1685 *Nature;* § 13.1715 *Quality;* § 13.1725 *Refunds;* § 13.1740 *Scientific or other relevant facts;* § 13.1747 *Special or limited offers;* § 13.1760 *Terms and conditions:* § 13.1760–50 *Sales contract;* —Prices: § 13.1778 *Additional costs unmentioned;* § 13.1805 *Exaggerated as regular and customary;* § 13.1825 *Usual as reduced or to be increased;* —Promotional sales plans: § 13.1830 *Promotional sales plans;* —Services: § 13.1835 *Cost;* § 13.1843 *Terms and conditions.* Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1855 *Identity;* § 13.1870 *Nature;* § 13.1882 *Prices:* § 13.1882–10 *Additional costs unmentioned;* § 13.1886 *Quality, grade or type;* § 13.1892 *Sales contract, right-to-cancel;* § 13.1895 *Scientific or other relevant facts;* § 13.1905 *Terms and conditions:* § 13.1905–50 *Sales contract.* Subpart—Offering, unfair, improper and deceptive inducements to purchase or deal: § 13.1980 *Guarantee, in general;* § 13.1985 *Individual's special selection or situation;* § 13.2010 *Money back guarantee;* § 13.2063 *Scientific or other relevant facts.* Subpart—Securing orders by deception: § 13.2170 *Securing orders by deception.* Subpart—Securing signatures wrongfully: § 13.2175 *Securing signatures wrongfully.* Subpart—Substituting product inferior to offer: § 13.2263 *Substituting product inferior to offer.* Subpart—Threatening suits, not in good faith: § 13.2264 *Delinquent debt collection.*

(Sec. 6, 38 Stat. 721, 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

In the Matter of Tomorrow's Heritage, Inc., a Corporation, Doing Business as Heritage and Ben H. Garfinkel, and Robert R. Silvers, Individually and as Officers of Said Corporation

Consent order requiring a Beverly Hills, Calif., seller and distributor of photograph albums, coupon books and certificates, sold in connection with photo enlargement and studio portrait plans, among other things to cease misrepresenting the business relationship between respondents and others; misrepresenting the usual and customary prices for its products or services; failing to maintain adequate records; misrepresenting special or limited offers; misrepresenting guarantees and failing to make refunds on a money-back guarantee.

The order to cease and desist, including further order requiring report of compliance therewith, is as follows: [1]

[1] Copies of the Complaint, Decision and Order, filed with the original document.

ORDER

It is ordered, That respondents Tomorrow's Heritage, Inc., a corporation, doing business as Heritage, or under any other name, its successors and assigns, and Ben H. Garfinkel and Robert R. Silvers, individually and as officers of said corporation, and respondents' officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of photograph albums, photograph enlargement plans, studio portrait plans, or any other type of photography plan, in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

I. 1. Representing, directly or indirectly, orally or in writing, that respondents have a business relationship with Eastman Kodak Company apart from the purchase or use of Eastman Kodak Company products; or misrepresenting, in any manner, the business relationship between respondents and any company, firm, organization, or individual.

2. Representing, directly or indirectly, orally or in writing, that any amount is the usual and customary retail price for products or services, whether purchased from respondents or elsewhere, unless such amount is the price at which the products or services have been usually and customarily sold at retail by respondents, or any other person or persons, for a substantial period of time in the recent and regular course of business; or misrepresenting in any manner, the value of products or services sold by respondents.

3. Failing to keep adequate records:

(a) Which disclose the facts upon which any retail price claims, comparative value claims, or other representations of the type described in Subparagraph 2 of this Order are based; and

(b) From which the validity of any retail price claims, comparative value claims, or other representations of the type described in Subparagraph 2 of this Order can be determined.

4. Representing, directly or indirectly, orally or in writing, that the $1.00 charge, accompanying each enlargement request, covers only the cost of "postage and handling;" or misrepresenting in any manner the purpose or use of any charges exacted for products or services.

5. Representing, directly or indirectly, orally or in writing, that enlargements can and will be made from any clear negative under the terms of any agreement with respondent or respondents' representatives in cases where respondents or respondents' agents, cannot or will not, make such enlargements under the terms of the agreement; or misrepresenting, in any manner, the services provided by respondents' enlargement plan.

6. Failing to disclose, in a clear and conspicuous manner, both in the written sales agreement entered into with purchasers and any and all written or oral communications describing the services

provided by the respondents' enlargement plan, any and all conditions, qualifications, limitations or terms which would affect full use and enjoyment of the enlargement service by any purchaser entering into written agreement with respondents or respondents' representatives, including, but not limited to, the unavailability of enlargement services for certain types of camera and negatives.

7. Representing, directly or indirectly, orally or in writing, that respondents make no profit on the sale of the enlargement plan; or misrepresenting, in any manner, the business reason for any offer made by respondent, or its representatives.

8. Failing to reveal, clearly and unqualifiedly, at the outset of the initial and all subsequent contacts or solicitations of purchasers or prospective purchasers that the purpose of such contact or solicitation is to make a sales presentation to the prospective purchaser with regard to the sale of products or services.

9. Failing to disclose any and all charges or costs to customers in the purchase of any product or service whenever respondents, or respondents' representatives, discuss any charges, costs or savings in the purchase of products or services; or misrepresenting, in any manner, the amount of savings available to purchasers of respondents' products or services.

10. Failing, clearly, conspicuously and unqualifiedly, to disclose in respondents' sales contract used in connection with the sale of their photograph enlargement plan, that any charges, in addition to the amount being financed by the customer required to obtain full use and enjoyment of the program, are not included in the credit disclosure portion of the contract and represent an additional cost over and above the "cash price" of the plan.

11. Representing, directly or indirectly, orally or in writing, that the studio portrait plan entitles the customer to color portraits unless, in fact, such studio designated by respondents offers color portraits without additional charge or expense to the customer.

12. Representing, directly or indirectly, orally or in writing, that the studio designated to perform respondents' obligations under the contract will not exact a sitting fee, service charge, or any other charge, unless, in fact, the contract for service is performed without cost or obligation whatsoever to the customer.

13. Substituting a means of performance, in cases where, due to no fault of the customer, respondents or their agents cannot perform their original obligation, according to the original terms of the agreement, unless such substitute or alternative performance on the part of respondents is freely and voluntarily consented to by the customer at the time the substituted performance is to be made. Respondents or their agents will not be deemed to be unable to perform their obligations to a customer in those situations where the customer unilaterally and by his own decision changes his position or circumstances making performance by respondents of their original contractual obligations to the customer impossible.

14. Failing, in cases where respondents or their agents cannot perform their obligations to a customer, due to no fault of the customer, to refund pro rata, an amount equal to the unperformed portion of the contract, unless the customer freely and voluntarily elects to accept a substitute means of performance in lieu of the original contract. Such proportion used to determine the amount of refund shall be derived by dividing the unused portraits to which the customer is entitled by the total number of portraits specified in the contract, without regard to any other products or materials received by the customer. Respondents or their agents will not be deemed to be unable to perform their obligations to a customer in those situations where the customer unilaterally and by his own decision changes his position or circumstances making performance by respondents of their original contractual obligations to the customer impossible.

15. Representing, directly or indirectly, orally or in writing, that any offer to sell said products or services is being made only to specially selected persons, or is not available, on the same terms, to all persons; or misrepresenting, in any manner, the persons, or class of persons, afforded the opportunity of purchasing respondents' products or services.

16. Representing, directly or indirectly, orally or in writing, that any price of a product or service is promotional or reduced, unless such price is below the amount at which such product or service has been sold by respondents for a reasonably substantial period of time in the recent and regular course of their business.

17. Representing, directly or indirectly, orally or in writing, that the offer being made is a special, or one-time offer, or that the offer is for a limited duration; or misrepresenting, in any manner, the duration or availability of any offer.

18. Representing, directly or indirectly, orally or in writing, that any person will receive a free gift, unless respondents actually tender such a gift at the time the representation is made, and make clear that there is no condition or obligation upon the customer or prospective customer for acceptance of such item.

19. Representing, directly or indirectly, orally or in writing, that any product or service is a prize, gift, or bonus, or is being offered at a reduced cost, in connection with the purchase of, or agreement to purchase any product or service, or combination of products or services, unless this stated price of the product or service, or combination thereof, required to be purchased in order to obtain such prize, gift, bonus, or reduced cost is the same as or less than, the customary and usual price at which such product or service, or combination thereof, required to be purchased, has been sold separately from such prize, gift, bonus, or reduced cost item, for a substantial number of sales, at the stated price, for a substantial period of time in the trade area where the representation is made.

20. Failing to make a complete refund to any customers, upon request, who have received, directly or indirectly, orally or in writing, a money-back satisfaction guarantee from respondents or their representatives.

21. Representing that respondents' agents or representatives are from, or connected with, the "Newlywed Game;" or misrepresenting, in any manner, the connection between respondents and any other television or radio program.

22. Representing, directly or indirectly, orally or in writing, that respondents' agents or representatives are considering persons for participation in the Newlywed Game television program; or misrepresenting, in any manner, the purpose of respondents' agents or representatives contact with any prospective customer.

23. Representing, directly or indirectly, orally or in writing, that customers are being given a money-back guarantee, unless such guarantee is honored according to its terms, which must be clearly and conspicuously disclosed in writing, and is limited by no more than the following conditions:

(a) The guarantee be exercisable immediately and valid for not less than a one year period following receipt of all initial parts of the purchased package;

(b) Respondents may demand return of consideration given by them.

II. *It is further ordered*, That respondents Tomorrow's Heritage, Inc., a corporation, doing business as Heritage, or under any other name, its successors and assigns, and Ben H. Garfinkel and Robert R. Silvers, individually, and as officers of said corporation, and respondents' officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the collection or attempted collection of any allegedly delinquent accounts in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing, directly or indirectly, orally or in writing, that any account or alleged debt is being, or has been, transferred to any attorney with instructions to institute suit or to take any other legal step involving court process, unless respondents are able to establish by adequate records that a prior determination had been made in good faith to institute such legal action.

2. Instituting, or threatening to institute, suits except in the county where defendant resides at the commencement of the action, or in the county where the defendant signed the contract sued upon. This provision shall not preempt any rule of law which further limits choice of forum or which requires, in actions involving real property or fixtures attached to real property, that suit be instituted in a particular county.

3. Using forms, or any other items of printed or written matter, which mislead, or have the tendency to mislead,

the recipient to believe that such form was sent by a government body or public agency.

4. Using forms, or any other items of printed or written matter, which mislead, or have the tendency to mislead, the recipient to believe that he is obligated or instructed to appear at any place in connection with the account or alleged debt, or waive any claims he may have against respondents.

III. *It is further ordered,* That respondents Tomorrow's Heritage, Inc., a corporation, doing business as Heritage, or under any other name, its successors and assigns, and Ben H. Garfinkel and Robert R. Silvers, individually and as officers of said corporation, and respondents' agents, representatives, and employees directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of photograph albums, photograph enlargement plans, studio portrait plans, or any other type of photography plan, in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Failing to furnish the buyer with a fully completed receipt or copy of any contract pertaining to such sale at the time of its execution, which is in the same language, e.g., Spanish, as that principally used in the oral sales presentation and which shows the date of the transaction and contains the name and address of the seller, and in immediate proximity to the space reserved in the contract for the signature of the buyer or on the front page of the receipt if a contract is not used and in bold face type of a minimum size of 10 points, a statement in substantially the following form:

You, the buyer, may cancel this transaction at any time prior to midnight of the third business day after the date of this transaction. See the attached notice of cancellation form for an explanation of this right.

2. Failing to furnish each buyer, at the time he signs the door-to-door sales contract or otherwise agrees to buy consumer goods or services from the seller, a completed form in duplicate, captioned "Notice of Cancellation", which shall be attached to the contract or receipt and easily detachable, and which shall contain in 10 point bold face type the following information and statements in the same language, e.g., Spanish, as that used in the contract

NOTICE OF CANCELLATION

(enter date of transaction)

date

You may cancel this transaction without any penalty or obligation within 3 business days from the above date.

If you cancel, any property traded in, any payments made by you under the contract or sale, and any negotiable instrument executed by you will be returned within 10 business days following receipt by the seller of your cancellation notice, and any security interest arising out of the transaction will be cancelled.

If you cancel, you must make available to the seller at your residence, in substantially as good condition as when received, any goods delivered to you under this contract or sale; or you may, if you wish, comply with the instructions of the seller regarding the return shipment of the goods at the seller's expense and risk.

If you do make the goods available to the seller and the seller does not pick them up within 20 days of the date of your notice of cancellation, you may retain or dispose of the goods without any further obligation. If you fail to make the goods available to the seller, or if you agree to return the goods to the seller and fail to do so, then you remain liable for performance of all obligations under the contract.

To cancel this transaction, mail or deliver a signed and dated copy of this cancellation notice or any other written notice, or send a telegram, to _____
(name of seller)

at _____
(address of seller's place of business)

not later than midnight of _____
(date)

I hereby cancel this transaction.

_____
(date)

_____
(buyer's signature)

3. Failing, before furnishing copies of the "Notice of Cancellation" to the buyer, to complete both copies by entering the name of the seller, the address of the seller's place of business, the date of the transaction, and the date, not earlier than the third business day following the date of the transaction, by which the buyer may give notice of cancellation.

4. Including in any door-to-door contract or receipt a waiver of any of the rights to which the buyer is entitled under this Section including specifically his right to cancel the sale in accordance with the provisions of this section. Respondents further agree not to include in any door-to-door contract or receipt any confession of judgment.

5. Failing to inform each buyer orally, at the time he signs the contract or purchases the goods or services, of his right to cancel.

6. Misrepresenting in any manner the buyer's right to cancel.

7. Failing or refusing to honor any valid notice of cancellation by a buyer and within 10 business days after the receipt of such notice, to: (a) Refund all payments made under the contract or sale; (b) return any goods or property traded in, in substantially as good condition as when received by the seller; (c) cancel and return any negotiable instrument executed by the buyer in connection with the contract or sale and take any action necessary or appropriate to terminate promptly any security interest created in the transaction.

8. Negotiating, transferring, selling, or assigning any note or other evidence of indebtedness to a finance company or other third party prior to midnight of the fifth business day following the day the contract was signed or the goods or services were purchased.

9. Failing, within 10 business days of receipt of the buyer's notice of cancellation, to notify him whether the seller intends to repossess or to abandon any shipped or delivered goods.

IV. *It is further ordered,* That respondents shall forthwith distribute a copy of this order to each of their operating divisions.

It is further ordered, That respondents shall:

a. Provide each of their present and future branch managers, and other supervisory personnel engaged in the sale or supervision of persons engaged in the sale of respondents' products or services, written instructions with respect to the provisions of this Order which are applicable to the functions of each such person;

b. Require each person so described in paragraph (a) above to clearly and fully explain the applicable provisions of this Order to all sales agents, representatives and other persons engaged in the sale of the respondents' products or services;

c. Provide each person so described in paragraphs (a) and (b) above with a form returnable to the respondents clearly stating his intention to be bound by, and to conform his business practices to, the applicable provisions of this Order, retain said statement during the period said persons is so engaged and make said statement available to the Commission's staff for inspection and copying upon request;

d. Inform each person described in paragraphs (a) and (b) above that respondents shall not use any third party, or the services of any third party, if such third party will not agree to so file and does not file notice with the respondents that such third party will be bound by the applicable provisions of this Order;

e. If such third party will not agree to so file notice with respondents and be bound by the applicable provisions of the Order, not use such third party, or the services of such third party, to sell respondents' products or services;

f. Inform the persons described in paragraphs (a) and (b) above that respondents are obligated by this Order to discontinue dealing with those persons who continue on their own the deceptive acts or practices prohibited by this Order;

g. Institute a reasonable program of surveillance or investigation to ascertain whether the business operations of each said person described in paragraphs (a) and (b) above comply with the applicable provisions of this Order;

h. Discontinue dealing with the persons so engaged, revealed by the aforesaid program of surveillance, who continue on their own the deceptive acts or practices prohibited by the applicable provisions of this Order;

i. Upon receiving information or knowledge from any source concerning two or more bona fide complaints prohibited by the applicable provisions of this Order against any of their sales agents or representatives during any one-month period, be responsible for either ending said practices or securing the termination of the employment of the offending sales agent or representative;

j. Submit to the Commission a detailed report every six (6) months for a period of three years from the effective date of this Order demonstrating the effectiveness of the steps or actions taken with regard to the aforesaid surveillance program.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent, such as dissolution, assignment or sale, resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the Order.

It is further ordered, That the individual respondents named herein promptly notify the Commission of the discontinuance of their present business or employment and of their affiliation with a new business or employment. Such notice shall include respondents' current business and employment name and address, as well as a description of their duties and responsibilities.

It is further ordered, That the respondents herein shall within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

The Decision and Order was issued by the Commission December 31, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7992 Filed 3-26-75;8:45 am]

[Docket C-2617]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Victor H. Graber, et al.

Subpart—Advertising falsely or misleadingly: § 13.73 *Formal regulatory and statutory requirements:* § 13.73–92 *Truth in Lending Act;* § 13.155 *Prices:* § 13.155–95 *Terms and conditions;* § 13.155–95(a) *Truth in Lending Act.* Subpart—Misrepresenting oneself and goods—Prices: § 13.1823 *Terms and conditions:* § 13.1823–20 *Truth in Lending Act.* Subpart—*Neglecting, unfairly or deceptively, to make material disclosure:* § 13.1852 *Formal regulatory and statutory requirements:* § 13.1852–75 *Truth in Lending Act;* § 13.1905 *Terms and conditions:* § 13.1905–60 *Truth in Lending Act.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 712, as amended, 82 Stat. 146, 147; (15 U.S.C. 45, 1601–1605))

In the matter of Victor H. Graber, Jewelers Distributing Co., Kelly Graber Co., Steven Jewelry Co., Vissala Corp., Barkell, Inc., Milbourn, Corp., Reyla Jewelry Co., Lisa Corp., Vicgray Corp., Market Corp., Corporations, Each Also Known as Crescent Jewelers Company, and Victor H. Graber, Individually and as an Officer of Said Corporations.

Consent order requiring 11 California corporations, all of which are also known under the common name of Crescent Jewelers Company, retailing jewelry, appliances and related products, among other things to cease violating the Truth in Lending Act by failing to disclose to consumers, in connection with the extension of consumer credit, such information as required by Regulation Z of the said Act.

The Decision and Order, including further order requiring report of compliance therewith, is as follows: [1]

ORDER

It is ordered, That respondent corporations, their successors and assigns, and their officers, and Victor H. Graber, individually and as an officer of said corporations, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with any advertisement to aid, promote or assist directly or indirectly any extension of consumer credit, as "consumer credit," and "advertisement" are defined in Regulation Z (12 CFR 226) of the Truth in Lending Act (Pub. L. 90–321, 15 U.S.C. 1601 et seq.), do forthwith cease and desist from:

1. Representing, directly or by implication, in any advertisement to promote the sale of jewelry, appliances, and related products, as "advertisement" is defined in Regulation Z the amount of the downpayment required or that no downpayment is required, the amount of any installment payment, the dollar amount of any finance charge, the number of installments or the period of repayment, or that there is no charge for credit, unless all of the following items are stated in terminology prescribed under § 226.8 of Regulation Z, as required by § 226.10 (d) (2) thereof:

a. The cash price;

b. The amount of the downpayment required or that no downpayment is required, as applicable;

c. The number, amount, and due dates or period of payments scheduled to repay the indebtedness if the credit is extended;

d. The amount of the finance charge expressed as an annual percentage rate;

e. The deferred payment price.

2. Failing in any consumer credit transaction or advertisement to make all disclosures determined in accordance with §§ 226.4 and 226.5 of Regulation Z, at the time and in the manner, form, and amount required by §§ 226.6, 226.8 and 226.10 of Regulation Z.

It is further ordered, That respondents deliver a copy of this order to cease and desist to each operating retail outlet and to all present and future personnel of respondents engaged in the consummation of any extension of consumer credit, and that respondents secure a signed statement acknowledging receipt of said order from each such person.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondents such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporations which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondents shall, within sixty (60) days after service upon them of this Order, file with the Commission a report in writing, setting forth in detail the manner and form in which they have complied with this order.

The Decision and Order was issued by the Commission December 23, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7905 Filed 3-26-75;8:45 am]

[1] Copies of the Complaint, Decision and Order, filed with the original document.

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Recodification Editorial and Transfer Amendments

The Food and Drug Administration is in the process of recodifying all of Chapter I of Title 21 of the Code of Federal Regulations, for the purposes of providing orderly development of such regulations, furnishing ample room for expansion in the years ahead, and providing the public and affected industries with regulations that are easy to find, read and understand.

The eighth and ninth in a series of recodification documents, which reorganize and recodify regulations on animal drugs and drugs having general applicability, are published elsewhere in this issue of the FEDERAL REGISTER. These regulations now appear in Subchapter C—Drugs: General, and Subchapter E—Animal Drugs, Feeds, and Related Products.

To provide uniformity and continuity during the recodification, the Commissioner concludes that the references to the recodified material should be amended at this time.

Due to the complexity and volume of cross references involved in the recodification of these regulations, if necessary, supplemental documents will be issued at a later date.

Therefore, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

SUBCHAPTER A—GENERAL

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

§ 1.1 [Amended]

1. Section 1.1(c) is amended by changing the references to "§§ 1.7, 1.101a,

and 701.10", "§§ 1.8b(f), 1.102d(e), and 701.13(f)", "§§ 1.8b(i), 1.102(h), and 701.13(i)", "§§ 1.8b (j) and (m), 1.102d (i) and (k), and 701.13 (j) and (m)", "§§ 1.102d(m) and 701.13(o)", "§§ 1.102d (n) and 701.13(p)", "§§ 1.8b(o), 1.102d (o), and 701.13(q)" to read "§§ 1.7, 201.60 and 701.10 of this chapter", "§§ 1.8b(f), 201.62(e), and 701.13(f) of this chapter", "§§ 1.8b(i), 201.1(h), and 701.13(i) of this chapter", "§§ 1.8b-(j) and (m), 201.62 (i) and (k), and 701.13 (j) and (m) of this chapter", "§§ 201.62(m) and 701.13(o) of this chapter", "§§ 201.62(n) and 701.13(p) of this chapter", "§§ 1.8b (o), 201.62(o), and 701.13(q) of this chapter", respectively.

§ 1.1c [Amended]

2. Section 1.1c(b)(1) is amended by changing the references to "§ 1.102d (b), (i), and (j)" and "§ 1.102d(i)" to read "§ 201.62 (b), (i), and (j) of this chapter" and "§ 201.62(i) of this chapter" respectively.

PART 2—ADMINISTRATIVE FUNCTIONS, PRACTICES AND PROCEDURES

§ 2.121 [Amended]

3. Section 2.121(u)(3) is amended by changing the reference to "§ 135.3" to read "§ 511.1".

PART 4—PUBLIC INFORMATION

§ 4.100 [Amended]

4. Section 4.100 is amended as follows:

a. In paragraph (c)(9) the reference to "§ 132.9" is changed to read "§ 207.37".

b. In paragraph (c)(10) the reference to "§ 135.33" is changed to read "§ 514.-12".

c. In paragraph (c)(11) the reference to "§ 135.33a" is changed to read "§ 514.10".

d. In paragraph (c)(12) the reference to "§ 146.16" is changed to read "§ 514.-10".

§ 4.116 [Amended]

5. Section 4.116 is amended by changing the reference to "§ 132.9" to read "§ 207.37".

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

§ 121.10 [Amended]

6. Section 121.10 is amended by changing the reference to "§ 3.27" to read "§ 250.203".

§ 121.75 [Amended]

7. Section 121.75(b) is amended by changing the reference to "§ 135.3" to read "§ 511.1".

§ 121.208 [Amended]

8. Section 121.208 is amended as follows:

a. In paragraph (d), Table 1, item 16 the reference in the "Limitations" column to "sponsor No. 004, see § 135.501 (c)" is changed to read "No. 010042, see § 510.600(c)".

b. In paragraph (d), Table 1, item 17, the references in the "Limitations" and "Indications for use" columns to "§ 135e.66(f) table items 3, 4, and 5" are changed to read "§ 558.515(f)".

§ 121.210 [Amended]

9. Section 121.210 is amended as follows:

a. In paragraph (c), Table 1, item 7.1, a.7.1, the references in the "Limitations" column to "Code No. 028 in § 135.501(c)" and "firm No. 023 as identified in § 135.501(c)" are changed to read "No. 000794 in § 510.600(c)" and "No. 000006 as identified in § 510.600(c)".

b. In paragraph (c), Table 1, item 7.1, b.7.1, the references in the "Limitations" column to "code No. 031 in § 135.501(c)" and "firm No. 023 as identified in § 135.501(c)" are changed to read "No. 017210 in § 510.600(c)" and "No. 000006 as identified in § 510.600(c)".

c. In paragraph (c), Table 1, item 9.1, the references in the "Limitations" column to "code No. 023 in § 135.501(c)", "code No. 028 in § 135.501(c)", "code No. 031 in § 135.501(c)", and "firm No. 023 as identified in § 135.501(c)" are changed to read "No. 000006 in § 510.600(c)", "No. 000794 in § 510.600(c)", "No. 017210 in § 510.600(c)", and "No. 000006 as identified in § 510.600(c)".

§ 121.251 [Amended]

10. Section 121.251(d), Table 1, item 13 is amended by changing the reference in the "Limitations" column to "code No. 030 in § 135.501(c)" to read "No. 000069 in § 510.600(c)".

§ 121.262 [Amended]

11. Section 121.262 is amended as follows:

a. In paragraph (c), Table 1, item 1.18, 1.11 the reference in the "Limitations" column to "code No. 009 in § 135.501(c)" is changed to read "No. 012769 in § 510.600(c)".

b. In paragraph (c), Table 1, item 1.19, the reference in the "Limitations" column to "sponsor No. 067, see § 135.501 (c)" is changed to read "No. 000947 in § 510.600(c)".

c. In paragraph (c), Table 1, item 1.23, the references in the "Limitations" column to "code No. 031, § 135.501(c)", "code No. 014, § 135.501(c)", "code No. 037, § 135.501(c)", "firm No. 037 as identified in § 135.501(c)" are changed to read "No. 017210 in § 510.600(c)", "No. 000986 in § 510.600(c)", "No. 000009 in § 510.600(c)", "No. 000009 as identified in § 510.600(c)".

d. In paragraph (c), Table 1, item 1.24, the reference in the "Limitations" column to "sponsor No. 031; see § 135.501 (c)" is changed to read No. 017210 in § 510.600(c)".

e. In paragraph (e) the reference to "code No. 019 in § 135.501(c)" is changed to read "No. 011801 in § 510.600(c)".

SUBCHAPTER C—DRUGS[1]

PART 141c—CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS FOR VETERINARY USE; TESTS AND METHODS OF ASSAY

§§ 141c.201 and 141c.218 [Revoked]

12. § 141c.201 Chlortetracycline hydrochloride, veterinary, and § 141c.218 Tetracycline hydrochloride, veterinary are revoked.

PART 146a—CERTIFICATION OF PENICILLIN AND PENICILLIN-CONTAINING DRUGS FOR VETERINARY USE

§§ 146a.61 and 146a.68 [Revoked]

13. § 146a.61 Potassium phenoxymethyl penicillin (potassium phenoxymethyl penicillin salt) veterinary and § 146a.68 Benzathine penicillin G (benzathine penicillin G salt), veterinary are revoked.

PART 146b—CERTIFICATION OF STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) AND STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) CONTAINING DRUGS FOR VETERINARY USE

§ 146b.101 [Revoked]

14. § 146b.101 Streptomycin sulfate veterinary; streptomycin hydrochloride veterinary; streptomycin phosphate veterinary; streptomycin trihydrochloride calcium chloride (streptomycin calcium chloride complex) veterinary is revoked.

PART 146c—CERTIFICATION OF CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS FOR VETERINARY USE

§§ 146c.201, 146c.218, 146c.220, and 146c.232 [Revoked]

15. § 146c.201 Chlortetracycline hydrochloride (chlortetracycline hydrochloride salt), veterinary, § 146c.218 Tetracycline hydrochloride, veterinary, § 146c.220 Tetracycline, veterinary, and § 146c.232 Tetracycline phosphate complex veterinary are revoked.

PART 146e—CERTIFICATION OF BACITRACIN AND BACITRACIN-CONTAINING DRUGS FOR VETERINARY USE

§ 146e.401 [Revoked]

16. § 146e.401 Bacitracin, veterinary is revoked.

SUBCHAPTER D—DRUGS FOR HUMAN USE

17. Part 300—General is established and former § 3.86 is transferred to § 300.50 in Subpart B—Combination Drugs as set forth below:

[1] Now Subchapter C—Drugs: General, recodified elsewhere in this issue of the FEDERAL REGISTER.

PART 300—GENERAL

Subpart A [Reserved]

Subpart B—Combination Drugs

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended; (21 U.S.C. 371), unless otherwise noted.

§ 300.50 Fixed-combination prescription drugs for humans.

The Food and Drug Administration's policy in administering the new-drug, antibiotic, and other regulatory provisions of the Federal Food, Drug, and Cosmetic Act regarding fixed combination dosage form prescription drugs for humans is as follows:

(a) Two or more drugs may be combined in a single dosage form when each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. Special cases of this general rule are where a component is added:

(1) To enhance the safety or effectiveness of the principal active component

(2) To minimize the potential for abuse of the principal active component

(b) If a combination drug presently the subject of an approved new-drug application or antibiotic monograph has not been recognized as effective by the Commissioner of Food and Drugs based on his evaluation of the appropriate National Academy of Sciences-National Research Council panel report, or if substantial evidence of effectiveness has not otherwise been presented for it, then formulation, labeling, or dosage changes may be proposed and any resulting formulation may meet the appropriate criteria listed in paragraph (a) of this section.

(c) A fixed-combination prescription drug for humans that has been determined to be effective for labeled indications by the Food and Drug Administration, based on evaluation of the NAS–NRC report on the combination, is considered to be in compliance with the requirements of this section.

(Secs. 502, 505, 507, 52 Stat. 1050–53, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 355, 357)

PART 314—NEW DRUG APPLICATIONS

§ 314.1 [Amended]

18. Section 314.1(c)(2) is amended by changing the reference in Form FD–356H to "§ 1.106(b) (21 CFR 1.106(b))" to read "§ 201.100 (21 CFR 201.100)".

§ 314.8 [Amended]

19. Section 314.8(d)(4) is amended by changing the reference to "§ 3.81" to read "§ 201.200".

§ 314.9 [Amended]

20. Section 314.9(a) (1) and (3) is amended by changing the references to "§ 1.106 (b) or (c)" to read "§§ 201.100 or 201.105".

PART 328—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

§ 328.10 [Amended]

21. Section 328.10 is amended as follows:

a. In paragraph (a)(5) the reference to "§ 133.13" is changed to read "§ 211.60".

b. In paragraph (b)(5)(iv) the reference to "§ 133.13" is changed to read "§ 211.60".

c. In paragraph (c)(4) the reference to "§ 132.5" is changed to read "§ 207.25".

(d) In paragraph (d)(1)(v) the reference to "§133.13" is changed to read "§ 211.60".

§ 328.20 [Amended]

22. Section 328.20 is amended as follows:

a. In paragraph (a) the reference to "Part 132" is changed to read "Part 207".

b. In paragraph (b) the phrase "Part 133 of this chapter, 'Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding,' should be followed as a guideline" is changed to read "Parts 210, 211, 225, 226 and 229 of this chapter should be followed as a guideline".

PART 329—HABIT-FORMING DRUGS

§ 329.10 [Amended]

23. Section 329.10 is amended by changing the reference in the cross-reference note to "§ 1.108" to read "§§ 201.16(b)".

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

§ 330.1 [Amended]

24. Section 330.1 is amended as follows:

a. In paragraph (a) the reference to "Part 133" is changed to read "Parts 210, 211, 225, 226 and 229".

b. In paragraph (b) the references to "Part 132" are changed to read "Part 207".

c. In paragraph (c) the references to "§ 1.100" and "§ 1.102a(b)" are changed to read "Subchapter C" and "§ 20.61(b)".

d. In paragraph (f) the reference to "§ 133.9" is changed to read "§ 211.55".

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER

§ 369.4 [Amended]

25. Section 369.4 is amended by changing the reference to "Part 3" to read "Subchapter C".

§ 369.20 [Amended]

26. Section 369.20 is amended as follows:

a. The parenthetical sentence following the heading "ACETOPHENETIDIN-CONTAINING PREPARATIONS" is amended by changing the reference "§ 3.37" to read "§ 201.309".

b. The parenthetical sentence following the heading "ANTIHISTAMINICS, ORAL" is amended by changing the reference "§ 3.29" to read "§ 201.307".

c. The parenthetical sentence following the heading "COBALT PREPARATIONS" is amended by changing the reference "§ 3.48" to read "§ 250.106".

d. The parenthetical sentence following the heading "MINERAL OIL LAXATIVES" is amended by changing the reference to "§ 3.4" to read "§ 201.302".

e. The parenthetical sentence following the heading "OPHTHALMIC PREPARATIONS" is amended by changing the reference "§ 3.28" to read "§ 200.50".

f. The parenthetical sentence following the heading "POTASSIUM PERMANGANATE AQUEOUS SOLUTIONS (CONTAINING NOT MORE THAN 0.04 PERCENT POTASSIUM PERMANGANATE)" is amended by changing the reference "§ 3.7" to read "§ 250.108".

g. The parenthetical sentence following the heading "SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF AMINOSALICYLIC ACID AND ITS SALTS)" is amended by changing the reference "§ 3.509" to read "§ 201.314".

h. The parenthetical sentence following the heading "SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL)" is amended by changing the reference "§§ 3.35 and 3.509" to read "§§ 201.303 and 201.314".

i. The parenthetical sentence following the heading, "THROAT PREPARATIONS FOR TEMPORARY RELIEF OF MINOR SORE THROAT: LOZENGES, TROCHES, WASHES, GARGLES, ETC." is amended by changing the reference "§ 3.510" to read "§ 201.315".

§ 369.21 [Amended]

27. Section 369.21 is amended as follows:

a. The parenthetical sentence following the heading "ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE, MECLIZINE HYDROCHLORIDE DOXYLAMINE SUCCINATE, CHLOROTHEN CITRATE, CYCLIZINE HYDROCHLORIDE, AND CHLORCYCLIZINE HYDROCHLORIDE PREPARATIONS)" is amended, by changing the reference "§ 3.29" to read "§ 201.307".

b. The parenthetical sentence following the heading "BACITRACIN-CONTAINING OINTMENTS" is amended by changing the reference "§ 146e.402" to read "§ 548.313b".

c. The parenthetical sentence following the heading "BACITRACIN (ZINC BACITRACIN)-POLYMYXIN OINTMENT; BACITRACIN-POLYMYXIN-NEOMYCIN OINTMENT" is amended by changing the reference "§ 146e.422" to read "§ 448.510c(a)".

d. The parenthetical sentence following the heading "IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING"

is amended by changing the reference "§ 3.30" to read "§ 201.308".

e. The parenthetical sentence following "SODIUM GENTISATE" is amended by changing the reference "§ 3.509" to read "§ 201.314".

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

28. Part 429 is amended in the cross reference note of the table of contents by changing the reference "§§ 1.115, 3.506, and 3.507" to read "§§ 200.11, 200.15, and 201.17".

§ 429.11 [Amended]

29. The footnote for § 429.11(h)(1) is amended by changing the reference to "§ 1.108" to read "§§ 201.16(a) and 290.6".

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

§ 431.16 [Amended]

30. Section 431.16 is amended as follows:

a. In paragraph (a) the reference to "§ 3.81" is changed to read "§ 201.200".

b. In paragraph (b) the reference to "§ 1.106(b)" is changed to read "§ 201.100".

§ 431.51 [Amended]

31. Section 431.51(e) is amended by changing the reference to "Part 133" to read "Parts 210, 211, 225, 226, and 229".

§ 431.53 [Amended]

32. Section 431.53(g) is amended by changing the reference to "§ 144.26" to read "§ 510.515".

PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

33. Part 432 is amended in the cross reference note in the table of contents by changing the reference "§ 1.107" to read "§ 201.150".

§ 432.5 [Amended]

34. Section 432.5(a)(1) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

§ 433.17 [Amended]

35. Section 433.17 is amended by changing the references to "§ 135.3" to read "§ 511.1".

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

§ 436.504 [Amended]

36. Section 436.504(a)(1) is amended by changing the reference to "§ 141a.8(a)" to read "§ 540.380a(b)(1)".

§ 436.505 [Amended]

37. Section 436.505(a)(1) is amended by changing the reference to "§ 141a.35(a)" to read "§ 536.501(a)".

§ 436.509 [Amended]

38. Section 436.509 is amended as follows:

a. In paragraph (a)(1) the reference to "§ 141a.8(a)" is changed to read "§ 540.380a(b)(1)".

b. In paragraph (a)(2) the reference to "§ 141b.129(a)(1)" is changed to read "§ 544.373c(b)(1)(i)".

§ 436.510 [Amended]

39. Section 436.510(a)(1) is amended by changing the reference to "§ 141a.35(a)(1)" to read "§ 536.501(a)(1)".

§ 436.511 [Amended]

40. Section 436.511 is amended as follows:

a. In paragraph (a)(1) the reference to "§ 141a.8(a)" is changed to read "§ 540.380a(b)(1)".

b. In paragraph (a)(2) the reference to "§ 141a.65(a)(2) of this chapter" is changed to read "§ 436.105".

c. In paragraph (a)(3) the reference to "§ 141a.65(a)(3) of this chapter" is changed to read "§ 436.105".

d. In paragraph (a)(5) the reference to "§ 141a.65(a)(4)(ii) of this chapter" is changed to read "§ 436.105".

§ 436.514 [Amended]

41. Section 436.514(b) is amended by changing the reference to "§ 141b.117(c)" to read "§ 536.513(c)".

§ 436.516 [Amended]

42. Section 436.516(c) is amended by changing the reference to "§ 141b.117(c)" to read "§ 536.513(c)".

PART 440—PENICILLIN ANTIBIOTIC DRUGS

§ 440.80a [Amended]

43. Section 440.80a(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.153 [Amended]

44. Section 440.153(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.155c [Amended]

45. Section 440.155c(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.160 [Amended]

46. Section 440.160(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.166 [Amended]

47. Section 440.166(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.171b [Amended]

48. Section 440.171b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.174 [Amended]

49. Section 440.174(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.180a [Amended]

50. Section 440.180a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.180b [Amended]

51. Section 440.180b is amended as follows:

a. In paragraph (b)(1)(ii) the reference to "§ 141a.36(a)(2)" is changed to read "§ 536.502(a)(2)".

b. In paragraph (b)(1)(iii) the reference to "§ 141a.36(a)(3)" is changed to read "§ 536.502(a)(3)".

§ 440.180e [Amended]

52. Section 440.180e(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.180f [Amended]

53. Section 440.180f(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.253 [Amended]

54. Section 440.253(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.255b [Amended]

55. Section 440.255b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.259 [Amended]

56. Section 440.259(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.261 [Amended]

57. Section 440.261(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.265a [Amended]

58. Section 440.265a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.265b [Amended]

59. Section 400.265b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.274a [Amended]

60. Section 440.274a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.274b [Amended]

61. Section 440.274b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.280c [Amended]

62. Section 440.280c(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.280d [Amended]

63. Section 440.280d(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 440.563 [Amended]

64. Section 440.563(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

§ 444.70a [Amended]

65. Section 444.70a(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 444.170a [Amended]

66. Section 444.170a is amended as follows:

a. In paragraph (a)(3) the reference to "§ 1.106(b)" is changed to read "§ 201.100".

b. In paragraph (b)(1)(i)(a) the reference to "§ 141b.109(a)(1)" is changed to read "§ 544.173a(b)(1)(i)".

§ 444.270b [Amended]

67. Section 444.270b(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 444.270c [Amended]

68. Section 444.270c(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 444.570a [Amended]

69. Section 444.570a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 444.570b [Amended]

70. Section 444.570b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

PART 446—TETRACYCLINE ANTIBIOTIC DRUGS

§ 446.110b [Amended]

71. Section 446.110b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.111 [Amended]

72. Section 446.11(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.181c [Amended]

73. Section 446.181c(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.281b [Amended]

74. Section 446.281b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.310a [Amended]

75. Section 446.310a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.510a [Amended]

76. Section 446.510a(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.510b [Amended]

77. Section 446.510b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 446.567e [Amended]

78. Section 446.567e(b)(2) is amended by changing the reference to "§ 141b.117(c)" to read "§ 536.513(c)".

§ 446.581a [Amended]

79. Section 446.581a is amended as follows:

a. In paragraph (a)(3) the reference to "§ 1.106(b)" is changed to read "§ 201.100".

b. In paragraph (b)(3) the reference to "§ 141b.117(c), is changed to read "§ 536.513(c)".

§ 446.581b [Amended]

80. Section 446.581b is amended as follows:

a. In paragraph (b)(1)(i) the reference to "§ 141c.237(a)(2)" is changed to read "§ 546.312a(b)(1)(ii)".

b. In paragraph (b)(3) the reference to "§ 141c.237(a)(3)" is changed to read "§ 546.312a(b)(1)(iii)".

§ 446.610 [Amended]

81. Section 446.610(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

PART 448—PEPTIDE ANTIBIOTICS

§ 448.10a [Amended]

82. Section 448.10a(a)(3)(i) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 448.110a [Amended]

83. Section 448.110a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 448.310a [Amended]

84. Section 448.310a(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 448.310b [Amended]

85. Section 448.310b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 448.510a [Amended]

86. Section 448.510a is amended as follows:

a. In paragraph (a)(3)(i) the reference to "§ 1.106(b)" is changed to read "§ 201.100".

b. In paragraph (b)(1) the reference to "§ 141a.8(a)" is changed to read "§ 540.380a(b)(1)".

§ 448.510d [Amended]

87. Section 448.510d(b)(1)(ii) is amended by changing the reference to "§ 141a.8(a)" to read § 540.380a(b)(1)".

§ 448.510f [Amended]

88. Section 448.510f(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

PART 455—CERTAIN OTHER ANTIBIOTIC DRUGS

§ 455.310b [Amended]

89. Section 455.310b(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

§ 455.410 [Amended]

90. Section 455.410(a)(3) is amended by changing the reference to "§ 1.106(b)" to read "§ 201.100".

SUBCHAPTER F—BIOLOGICS

PART 601—LICENSING

§ 601.11 [Amended]

91. Section 601.11(a) is amended by changing the reference to "Part 132" to read "Part 207".

§ 601.25 [Amended]

92. Section 601.25(d)(5) is amended by changing the reference to "§ 1.106" to read "Subpart D of Part 201".

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation.

Dated: March 21, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-7957 Filed 3-26-75;8:45 am]

Title 39—Postal Service

CHAPTER I—U.S. POSTAL SERVICE

SUBCHAPTER D—ORGANIZATION AND ADMINISTRATION

PART 222—DELEGATIONS OF AUTHORITY

Extension of Authority To Administer Oaths of Office in Conjunction With Transfers of Accountability

This document amends 39 CFR 222.5 to provide to Postal System Examiners the authority to administer oaths of office for employment in conjunction with transfers of accountability upon the appointment of new postmasters. This change is effective immediately.

Section 222.5 of title 39, CFR, is amended by adding at the end thereof the following new paragraph (c):

§ 222.5 Authority to approve personnel actions and administer oaths of office for employment.

* * * * *

(c) *Transfers of accountability.* Inaddition to other personnel authorized under this section, Postal System Examiners may administer oaths of office for employment at any post office in conjunction with transfers of accountability.

(39 U.S.C. 401, 1011)

ROGER P. CRAIG,
Deputy General Counsel.

[FR Doc.75-8014 Filed 3-26-75;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 337-7]

SUBCHAPTER C—AIR PROGRAMS

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Georgia: Permit System Regulations

On May 31, 1972 (37 FR 10842), the Administrator approved portions of the Georgia plan to attain and maintain the national ambient air quality standards. Section 110(a)(2)(D) of the Clean Air Act requires that such a plan include a

procedure for reviewing, prior to construction or modification, any source to which performance standards apply in order to determine whether such construction or modification might be expected to cause a violation of any standard.

The Georgia plan as originally submitted provided for such review. The State, however, subsequently amended its permit regulations to allow for issuing compliance schedules and to prescribe conditions for operation, and submitted the affected portions, section 391-3-1-.03(2), Operating Permits, and 391-3-1-.03(3), Revocation of Permits, as plan revisions on May 20, 1974. The requirements of 40 CFR 51.4 and 51.6 pertaining to public hearings and plan revisions had been met. The Administrator announced the proposed changes in Georgia regulations on July 25, 1974 (39 FR 27149).

As revised, section 391-3-1-.02(3) of the Georgia regulations requires an operating permit of any source of air contaminant emissions, whereas the previous regulation required this only of sources for which a construction permit had been obtained, i.e., of new or modified sources. Sources affected by the new requirements can continue to operate until the State acts on their application for an operating permit, but there is now no set deadline for the State's action as in the original regulation. Provision is made in the new regulation for delayed submittal of supporting information, formerly required at the time of application. Operating permits now contain specific conditions designed to assure compliance with applicable State regulations and statutes, and sources can now be required to monitor and report operations as well as conduct the performance tests previously required. The State can now grant Temporary Operating Permits in cases where time was needed to correct deficiencies in an existing facility; in such cases, the permit would contain a specific schedule for compliance within the shortest practical time period.

Section 391-3-1-.03(3), Revocation of Permits, provides for the periodic review and possible modification of permits already issued.

Two comments were received in response to the July 25, 1974, proposal of these changes. Section 391-3-1-.03(2)(e) states that for sources subject to regulations effective prior to January 1, 1973, schedules for achieving final compliance cannot extend past July 31, 1975. Section 391-3-1-.03(3) states that no modification or revocation of a permit for sources subject to regulations effective prior to January 1, 1973, shall extend the time for compliance beyond July 31, 1975. The Natural Resources Defense Council, Inc., raised the question as to whether a source subject to a regulation effective after January 1, 1973 could be granted an extension beyond July 31, 1975. No existing Georgia regulation has an effective date later than January 1, 1973. Moreover, the Administrator on September 26 (39 FR 34533) disapproved all State plans insofar as their regulations permit deferral of compliance beyond the statutory attainment date of the Clean Air Act. However, for the sake of clarity, the proposed permit regulations are approved as part of the implementation plan without the two qualifying clauses just mentioned. The State Highway Department asked if the regulations were intended to apply to motor vehicles, since they are not excluded by the Georgia definition of an air pollution source. The Georgia air pollution control agency has clarified this issue orally, indicating that its permit regulations are intended to apply to stationary sources only.

In the judgement of the Administrator, the approval of the proposed plan revision will enhance the attainment and maintenance of the national ambient air quality standards in the State of Georgia, and it is hereby approved.

This action is effective immediately. The Administrator finds that good cause exists for making these changes immediately effective since the regulations in question have been in effect in Georgia since September, 1973, and the Administrator's approval of these imposes no additional regulatory burden on affected facilities.

(Section 110(a), Clean Air Act, as amended (42 USC 1857c-5(a))

Dated: March 20, 1975.

JOHN QUARLES,
Acting Administrator.

Part 52 of Chapter I, Title 40, Code of Federal Regulations, is amended as follows:

Subpart L—Georgia

In § 52.570(c), subparagraph (4) is amended to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c) * * *

(4) May 17 and 20, 1974, by the Director of the Environmental Protection Division of the Georgia Department of Natural Resources.

Section 52.582 is added as follows:

§ 52.582 Rules and regulations.

The following portions of the State's permit regulations are disapproved to the extent that they could be construed in some cases as permitting deferral of compliance with emission limitations of the plan beyond the statutory dates set forth in the Clean Air Act: Part of the last sentence of section 391-3-.03(2)(e), viz., "In the case of sources subject to regulations effective prior to January 1, 1973, . . ." and part of the last sentence of section 391-3-1-.03(3), viz., "for sources subject to such regulations effective prior to January 1, 1973."

[FR Doc.75-7891 Filed 3-26-75;8:45 am]

SUBCHAPTER E—PESTICIDE PROGRAMS

[FRL 351-1; OPP-262315]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Benomyl

On January 3, 1975, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (40 FR 2448) a notice of proposed rulemaking to establish a tolerance for combined residues of the fungicide benomyl (methyl 1-(butylcarbamoyl)-2-benzimidazolecarbamate) and its metabolites containing the benzimidazole moiety (calculated as benomyl) in or on the raw agricultural commodity blueberries at 7 parts per million. This notice of proposed rulemaking to amend § 180.294 was published in response to a petition (PP 4E1479) submitted to Dr. C. C. Compton, Coordinator, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers University, New Brunswick, N.J. 08903, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Florida, Michigan, New Jersey, North Carolina, Oregon, and Washington; the North American Blueberry Council; and the State of New Jersey Department of Agriculture.

No comments or requests for referral to an advisory committee were reviewed by the Agency on this proposal. Therefore, it is concluded that the proposed amendment should be adopted without change.

Any person adversely affected by this regulation may on or before April 28, 1975, file written objections with the Hearing Clerk, Environmental Protection Agency, 401 M Street SW., East Tower, Room 1019, Washington, D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed objectionable and the grounds for the objection. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on March 27, 1975, Part 180, Subpart C, Section 180.294, is amended as follows.

(Section 403(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)))

Dated: March 20, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

Part 180, § 180.294, is amended by revising the paragraph "7 parts per million in or on blackberries . . ." to read as set forth below.

§ 180.294 Benomyl; tolerances for residues.

* * * * *

7 parts per million in or on blackberries, blueberries, boysenberries, dewberries, loganberries and raspberries.

* * * * *

[FR Doc.75-7896 Filed 3-26-75;8:45 am]

[FRL 350-8; OPP-262816]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Carbofuran

On December 27, 1974, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (39 FR 44777) a notice of proposed rulemaking to establish a tolerance for combined residues of the insecticide carbofuran (2,3 - dihydro-2,2-dimethyl-7 - benzofuranyl-N-methylcarbamate); its carbamate metabolite 2,3-dihydro-2,2- dimethyl-3-hydroxyy-7 - benzofuranyl-N-methyl-carbamate; and its phenolic metabolites 2,3-dihydro-2,2-dimethyl-7-benzofuranol and 2,3-dihydro-2,2-dimethyl-3-oxo-7-benzofuranol and 2,3-dihydro-2,2-dimethyl-3,7-benzofuranadiol in or on the raw agricultural commodity coffee beans at 0.1 parts per million. This notice of proposed rulemaking to amend § 180.254 was published in response to a petition (PP 4E1483) submitted by FMC Corp., 100 Niagara St., Middleport, N.Y. 14115.

No comments or requests for referral to an advisory committee were received. Therefore, it is concluded that the proposed amendment to § 180.254 should be adopted without change.

Any person adversely affected by this regulation may on or before April 28, 1975, file written objections with the Hearing Clerk, Environmental Protection Agency, 401 M Street SW., East Tower, Room 1019, Washington, D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed objectionable and the grounds for the objection. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on March 27, 1975. Part 180, Subpart C, Section 180.254, is amended as follows:

(Section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)).)

Dated: March 20, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator, for Pesticide Programs.

Part 180, Subpart C, § 180.254 is amended by revising the paragraph "0.1 part per million in or on bananas . . ." to read as set forth below.

§ 180.254 Carbofuran: tolerances for residues.

* * * * *

0.1 part per million in or on bananas (negligible residue), coffee beans, sorghum grain, sugar beets, and sugarcane.

* * * * *

[FR Doc.75-7895 Filed 3-26-75;8:45 am]

[FRL 351-4; OPP-262808]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

2,4-D

On November 27, 1974, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (39 FR 41385) a notice of proposed rulemaking 1) to extend the established tolerance for residues of 2,4-D sodium salt, calculated as 2,4-D (2,4-Dichlorophenoxyacetic acid), in or on asparagus at 5 parts per million to include the alkanolamine salts (of the ethanol and isopropanol series), and 2) to consolidate section 180.165 with the other established tolerances for 2,4-D in section 180.142. On December 26, 1974, the EPA published in the FEDERAL REGISTER (39 FR 44668) a notice of proposed rulemaking to establish a tolerance for residues of the herbicide 2,4-D (2,4-dichlorophenoxyacetic acid) from the application of its alkanolamine salts (of the ethanol and isopropanol series) in or on strawberries at 0.05 part per million. Both notices of proposed rulemaking were published in response to petitions (PP 5E1475 and PP 5E1544) submitted by Dr. C. C. Compton, Coordinator, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers University, New Brunswick, NJ 08903, on behalf of the IR-4 Technical Committee and several other Agricultural Experiment Stations.

An adverse comment which objected to the use of 2,4-D and other pesticides in our environment was received by the Agency from the same individual on each of these proposals. However, neither comment provided further insight into the toxicity of 2,4-D or the safety of the proposed use. Rather, the comments urged development of alternative biological controls since 2,4-D does not occur naturally in the human body, or in any part of the environment. These comments are available for public inspection in the office of the Federal Register Section, Office of Pesticide Programs, Environmental Protection Agency, Room 423, East Tower, 401 M Street SW., Washington D.C. 20460.

Based on the data submitted in the petitions and other relevant material, it is concluded that the proposed amendments to the regulations should be adopted without change.

Any person adversely affected by this regulation may on or before April 28, 1975, file written objections with the Hearing Clerk, Environmental Protection Agency, 401 M Street SW., East Tower, Room 1019, Washington D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on March 27, 1975. Part 180, Subpart C, is amended to delete Section 180.165 and amend Section 180.142 as follows.

(Section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346(e)).)

Dated: March 21, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

Part 180 is amended by deleting § 180.165 and by adding two new paragraphs to § 180.142 after paragraph (c) as follows.

§ 180.142 2,4-D; tolerances for residues.

* * * * *

(d) A tolerance of 5 parts per million is established for residues of 2,4-D sodium salt and alkanolamine salts (of the ethanol and isopropanol series), calculated as 2,4-D (2,4-dichlorophenoxyacetic acid), in or on asparagus.

(e) A tolerance of 0.05 part per million is established for residues of 2,4-D (2,4-dichlorophenoxyacetic acid) from application of its alkanolamine salts (of the ethanol and isopropanol series) in or on strawberries.

[FR Doc.75-7899 Filed 3-26-75;8:45 am]

[FRL 352-6; OPP-262818]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

6-methyl-1,3-dithiolo[4,5-b] quinoxalin-2-one

On January 22, 1975, notice was given (40 FR 3492) that Chemagro Division of Mobay Chemical Corp., PO Box 4913, Kansas City, MO 64120 had filed a petition (PP 5F1577) for a pesticide tolerance with the Environmental Protection Agency (EPA). This petition proposed establishment of a tolerance for negligible residues of the fungicide and insecticide 6 - methyl - 2,3 - quinoxalinedithiol cyclic *S,S,*-dithiocarbonate in or on the raw agricultural commodities apples and pears at 0.05 part per million. The standardized chemical name for this pesticide is 6-methyl-1,3-dithiolo[4,5b]quinoxalin-2-one.

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purposes for which the tolerance is sought. The established tolerances are adequate to cover residues, if any, resulting from the proposed and existing uses in meat and milk, and there is no reasonable expectation of residues in eggs or poultry, and § 180.6(a) (3) applies. The tolerance established by this amendment to the regulation will protect the public health.

Any person adversely affected by this regulation may on or before April 28, 1975, file written objections with the Hearing Clerk, Environmental Protection Agency, 401 M Street, SW., East Tower, Room 1019, Washington, D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions for the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on March 27, 1975. Part 180, Subpart C, is amended by amending § 180.338.

Dated: March 25, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

STATUTORY AUTHORITY: Sec. 408(d) (2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(d) (2)).

Section 180.338 is amended by revising the heading and introductory paragraph and adding the new paragraph "0.05 part per million (negligible residue) * * *" after the paragraph "0.1 part per million * * *" to read as follows.

§ 180.338 6-methyl-1,3-dithiolo [4,5-b] quinoxalin-2-one, tolerances for residues.

Tolerances are established for residues of the fungicide and insecticide 6-methyl-1,3-dithiolo [4,5-*b*] quinoxalin-2-one in or on raw agricultural commodities as follows:

* * * * *

0.05 part per million (negligible residue) in or on apples and pears.

* * * * *

[FR Doc.75-8126 Filed 3-26-75;8:45 am]

Title 41—Public Contracts and Property Management

CHAPTER 5A—FEDERAL SUPPLY SERVICE, GENERAL SERVICES ADMINISTRATION

PART 5A-7—CONTRACT CLAUSES

Warranty of Pesticides

This change to the General Services Administration Procurement Regulations (GSPR) provides a clause for use in all solicitations for pesticides to provide a warranty if the Administrator, Environmental Protection Agency (EPA), under Pub. L. 92-516, as amended, takes action against a pesticide which is under Government contract.

1. The table of contents for Part 5A-7 is amended to add the following:

Sec.
5A-7.103-94 Warranty of pesticides.

Subpart 5A-7.1—Fixed-Price Supply Contracts

2. Section 5A-7.103-94 is added as follows:

§ 5A-7.103-94 Warranty of pesticides.

The following clause shall be inserted in all solicitations involving the procurement of pesticides. The clause is mandatory for procurement of any substance or mixture of substances for preventing, destroying, repelling, or mitigating pests; e.g., insecticides, insect repellants, fungicides, rodenticides, sanitizers, germicides, disinfectants, plant regulators, defoliants, and desiccants. In addition, procurement agents shall provide space in the item description for bidders to insert the brand name and the EPA Registration Number of the item solicited.

WARRANTY OF PESTICIDES

(a) Notwithstanding acceptance of pesticides by the Government, the contractor warrants that for the period of 1 year after the date of shipment, all pesticides furnished under this contract shall meet the regulatory requirements of Public Law 92-516, as amended, and shall be registered with the Administrator, Environmental Protection Agency (EPA).

(b) If EPA takes action to stop sale, stop use, remove, seize, or cancel registration of a pesticide within 1 year after date of shipment, the contractor shall immediately notify the contracting officer. The notification shall include: 1. Contract Number; 2. Identification of the pesticide; 3. Reason for EPA action against the pesticide; and 4. List of Government activities and addresses to which delivery had been made. (End of clause.)

(Sec. 205(c), 63 Stat. 390; (40 U.S.C. 486 (c)))

Effective date, These regulations are effective on the date shown below.

Dated: March 12, 1975.

M. J. TIMBERS,
Commissioner,
Federal Supply Service.

[FR Doc.75-7912 Filed 3-26-75;8:45 am]

Title 46—Shipping

CHAPTER I—COAST GUARD, DEPARTMENT OF TRANSPORTATION

[CGD 73-43R]

MARINE INVESTIGATION REGULATIONS

Disclosure of Records and Information

The Freedom of Information Act, as recently amended, (5 U.S.C. 552) and the Department of Transportation regulations (49 CFR Part 7) supersede the present Coast Guard regulations on release of investigative records and of suspension and revocation information, as well as on disclosure of information regarding shipments and discharges of merchant mariners.

Therefore, the Coast Guard has decided to revoke its separate standards in Parts 4, 5, and 14 and replace them by references to DOT regulations.

Since the amendments in this document are general statements of policy, they are excepted from notice of public rulemaking and may be made effective in less than 30 days.

In consideration of the foregoing, Parts 4, 5, and 14, of Title 46 of the Code of Federal Regulations are amended as follows:

PART 4—MARINE INVESTIGATION REGULATIONS

1. In Part 4, Subpart 4.13 is hereby revised to read as follows:

Subpart 4.13—Availability of Records

Sec.
4.13-1 Public Availability of Records.

AUTHORITY: The provisions of this Subpart 4.13 issued under 5 U.S.C. 552(a) (1) (A), 46 U.S.C. 239, 49 U.S.C. 1655(b) (1); 49 CFR 1.46(b).

§ 4.13-1 Public availability of records.

Coast Guard records are made available to the public in accordance with 49 CFR Part 7.

PART 5—SUSPENSION AND REVOCATION PROCEEDINGS

2. In Part 5, Subpart 5.50 is hereby revised to read as follows:

Subpart 5.50—Disclosure of Information

Sec.
5.50-1 Availability of Information to the Public.

AUTHORITY: The provisions of this Subpart 5.50 issued under 5 U.S.C. 552(a) (1) (A), 46 U.S.C. 214, 216b, 226, 228, 229, 232, 234, 239, 239b, 240, 49 U.S.C. 1655(b) (1); 49 CFR 1.46 (b).

§ 5.50-1 Availability of information to the public.

The Coast Guard makes information available to the public in accordance with 49 CFR Part 7.

PART 14—SHIPMENT AND DISCHARGE OF SEAMEN

3. In Part 14, Subpart 14.15 is hereby revised to read as follows:

Subpart 14.15—Disclosure of Information Regarding Shipments and Discharges of Merchant Mariners

Sec.
14.15-1 Availability of Information to the Public.

AUTHORITY: The provisions of this Subpart 14.15 issued under 5 U.S.C. 552(a) (1) (A), 14 U.S.C. 633, 49 U.S.C. 1655(b) (1); 49 CFR 1.46 (b).

§ 14.15-1 Availability of information to the public.

The Coast Guard makes information available to the public in accordance with 49 CFR Part 7.

Effective date. These amendments are effective on May 12, 1975.

Dated: March 21, 1975.

O. W. SILER,
Admiral, U.S. Coast Guard,
Commandant.

[FR Doc.75-7985 Filed 3-26-75;8:45 am]

Title 49—Transportation

CHAPTER I—DEPARTMENT OF TRANSPORTATION

SUBCHAPTER B—OFFICE OF PIPELINE SAFETY

[Docket No. OPS-18; Amdt. 192-20]

PART 192—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE: MINIMUM FEDERAL SAFETY STANDARDS

Line Markers for Mains and Transmission Lines

This amendment revises the existing requirement in § 192.707 for marking the location of gas transmission lines and establishes new marking requirements for gas distribution mains under that section. The purpose of this amendment is to alleviate a major cause of failures in gas pipelines—interference with pipelines by persons outside the gas pipeline industry conducting excavation-related activities. Installation of line markers in accordance with these revised requirements should increase the likelihood that outsiders will seek assistance in locating underground lines before excavating. Also the revised requirements should influence operators to encourage State or local governments to adopt programs for preventing interference with underground pipelines.

On May 19, 1972, the Director issued a notice of proposed rule making to amend § 192.707 (37 FR 10578; May 25, 1972) to specify locations for line markers and the information to be inscribed on them. Due to the large number of persons interested in the proceeding, the original deadline for submitting written information, views, or arguments was extended to August 17, 1972, (37 FR 13351; July 7, 1972). The comments received as a result of the notice have been fully considered by the Office of Pipeline Safety (OPS) in developing the final rule.

There were 126 persons who commented on the notice. A majority of the commenters recognize the need to reduce the number of pipeline failures due to interference by outsiders, but believe that the costs of implementing the proposed line marking program would far outweigh any benefits that might be obtained.

OPS believes that the final rule alleviates the objection to the proposal expressed by these commenters. Compliance with the revised line marking requirement will involve capital expenditure, but much less than would have been required by the proposed rule. Furthermore, the revised standard should benefit the public by reducing risk of harm, and benefit operators by reducing losses, claims for damage, and expense of service interruptions. Unfortunately, because data is not available on the effectiveness of existing line markers in preventing damage to pipelines, the amount of future benefits from line marking under the revised rule cannot be determined with precision.

The final rule is modified to improve economic practicability in many respects. First, the proposed requirement that each marker be visible from preceding and following markers is deleted. Secondly, lead times for compliance are provided both for existing markers, as proposed, and for installing line markers not required by the existing rule. Lastly, markers are not required in Class 3 and Class 4 locations where operators are successful in encouraging State or local governments to enact programs for preventing damage to pipelines by outsiders, and where placement of markers is impractical.

A large number of commenters suggested that carrying out programs other than line marking would be much more effective in reducing the number of accidents caused by outsiders. Some of the suggested programs involve a "one call" system, a construction permit system, education, better communication between operators and outsiders, and legislation.

OPS agrees with these comments. Line marking is only a partial solution for the problem of pipeline failures caused by damage during excavation. Line marking, however, is an important step which operators can take as part of their responsibility to prevent that type of damage in the absence of a more effective program. Programs which are enforceable under law against outsiders and provide them with information as to the location of underground pipelines are probably the best means of reducing damage caused by outside parties. OPS has encouraged the development of one such program by drafting and distributing to State and local governments a model statute aimed at preventing excavation-type damage through a construction permit system. The promulgation of this amendment is in furtherance of this prior effort. The revised standard not only attacks the problem of interference with pipelines by outsiders directly through regulation of gas operators but also encourages the development of other damage prevention programs.

Several commenters remarked that statistics, reports, and experience show that: (1) Most incidents occur where pipelines are marked. (2) Outsiders fail to call or check with the operator as requested on markers. (3) Contractors have a careless attitude toward protecting underground lines. (4) A significant amount of damage occurs at new construction sites before markers are installed. On the basis of these factors, the commenters conclude that increasing the number of pipeline markers would not significantly reduce damage caused by outsiders.

OPS does not concur with this conclusion. While it is true that, for example, in the year 1972, approximately two-thirds of reported leaks caused by outside parties on distribution lines occurred where pipelines were marked, the reports do not reflect the accuracy or adequacy of the markers involved. Operators use various kinds of permanent and temporary line markers. Data is not available on the effectiveness of these markers in properly warning outsiders of the presence of underground pipelines. Furthermore, the statistic is misleading because, due to a lack of pertinent data, it cannot be compared with the percentage of excavation-related activities conducted by outsiders near marked distribution lines. In the absence of either type of information, OPS believes it is reasonable to conclude that markers which are properly placed, maintained, and inscribed will alert outsiders to the presence of underground lines and thus reduce the potential for damage.

As for the failure of outsiders to notify operators before excavating, OPS expects that markers worded as required by the final rule will increase the likelihood that outsiders will seek assistance in determining the location of pipelines. More markers with uniform wording could also affect an outsider's attitude toward interference with pipelines during excavation activities. With respect to damage in areas undergoing new construction, the requirement to mark underground pipelines is binding on operators as soon as the lines are buried and in operation. The rule does not provide an exception for circumstances involving construction by outsiders. One method of compliance in this situation would be to install temporary markers until outside construction is complete. Then, the temporary markers could be removed and replaced by permanent ones.

Some commenters asked why the notice did not provide an exemption for offshore pipelines from the proposed line marking requirements. The existing requirement of § 192.707 for marking transmission lines applies to offshore as well as onshore pipelines. OPS is currently considering the need to amend the existing standards in Part 192 as they relate to the transportation of gas offshore. The desirability of marking offshore pipelines is an issue which was raised for public discussion in an OPS advance notice of proposed rule making on offshore pipeline facilities: Docket No. OPS-30, Notice No. 74-6 (39 FR 34568; September 26, 1974). As a result of that proceeding, OPS will publish a notice of its decision whether to propose an amendment to the line marking requirement with respect to offshore pipelines.

A number of changes have been made in the proposed rule on the basis of comments received. The major changes, as well as the response by OPS to comments which did not result in changes, are discussed below.

Paragraph (a), buried pipelines. The notice proposed that line markers be placed "over" each buried main and transmission line at certain locations. Many commenters noted that from a

compliance standpoint, line markers cannot always be placed directly "over" a pipeline. For example, in swamps and marshes and at navigable waterway crossings, line markers are often offset from a pipeline so the marker can be properly supported. OPS realizes this practice may be contrary to a notion held by some that a pipeline lies directly underneath a marker. Yet, it is consistent with the primary purpose of line markers to warn the public of the presence of a pipeline and to provide a telephone number to call for more specific information.

OPS agrees that requiring markers directly over a pipeline in all cases would be too restrictive. The final rule, therefore, prefaces the word "over" by the phrase "as close as practical." This change provides operators flexibility to offset markers a reasonable distance from a pipeline wherever necessary. For instance, offsetting may be necessary to obtain support for the marker, avoid an obstruction, or facilitate maintenance.

The proposed requirement that a marker be visible from the immediately preceding and following marker is not included in the final rule. This proposal was intended as an aid to outsiders in determining the route of a pipeline. Commenters remarked, however, that compliance could entail costly construction of towers or many additional markers at locations not otherwise warranted by safety considerations. Compliance could also spoil the natural beauty of many areas. The OPS believes that these adverse consequences would outweigh the possible advantages contemplated by the proposal. OPS believes that deleting the requirement from the final rule does not weaken the intention or effectiveness of the remaining provisions of paragraph (a).

After considering objections raised by a majority of the Technical Pipeline Safety Standards Committee (TPSSC), the proposal under § 192.707(a) (2) in the notice is not adopted. This proposal would have required line markers at fences and property boundaries. OPS now believes that placement of markers at these numerous locations would be costly and not yield a commensurate safety benefit.

Wording is added at the conclusion of § 192.707(a) to provide operators of existing buried mains or transmission lines approximately 3 years' lead time (until January 1, 1978) to comply with the new line marking requirements imposed by this amendment. The 3-year period was recommended by the TPSSC. The lead time does not apply to transmission lines under § 192.707(a) (2) because that section merely restates the existing requirement of § 192.707. This additional time beyond the general effective date for this amendment should be used by operators to prepare for compliance or, in accordance with § 192.707(b) (1) (ii), to seek enactment of alternative damage prevention programs at the State or local level.

Paragraph (b), exceptions for buried pipelines. The notice included exceptions from the proposed marking requirements for buried lines in heavily developed areas. These exceptions provided that line markers would not be required for transmission lines, where both placement is impracticable and the local government maintains current substructure records, and for distribution mains, where either criterion for exemption respecting transmission lines occurs. One reason for the exceptions was to give operators limited but necessary discretion as to placement of markers based on practicability. The primary purpose, however, was to influence operators to encourage local governments to establish construction permit systems in heavily developed areas related to currently maintained records of underground pipelines.

In the final rule, the proposed exceptions for marking buried pipelines are modified slightly. The exception for situations where placement is "impracticable" is changed to apply where placement is "impractical." Many commenters objected that since "impracticable" means impossible, the proposed exception would have extremely limited application.

Also, the proposed exceptions in heavily developed areas for situations where a local government maintains current substructure records are broadened under § 192.707(b) (1) to apply equally to mains and transmission lines in Class 3 or Class 4 locations "where a program for preventing interference with underground pipelines is established by law." The change from "heavily developed areas" to "Class 3 or Class 4 locations" is made for clarity. The exceptions apply in these locations because of the difficulty in placing markers there, the esthetic objections to markers in these areas, and because Class 3 and Class 4 areas have the greatest need for government enacted programs to prevent interference with underground pipelines.

In the final rule, a government enacted damage prevention program qualifies as an exemption under the new line marking requirement even though it is not related to government maintenance of underground substructure records. OPS agrees with commenters who pointed out that local governments may not wish to maintain these records and that operators are better able to keep current records of pipelines. Also, there are currently various types of damage prevention programs in effect. This change, therefore, adds flexibility to the final rule by exempting placement of markers, for example, where an operator participates in a government program by answering calls from contractors on the basis of the operator's own records. The broadened exemption also has the benefit of encouraging State controlled programs in Class 3 or Class 4 areas for prevention of damage to pipelines rather than just encouraging programs on a local level.

Many commenters and the TPSSC pointed out that most of the current damage prevention programs are conducted by the operators themselves, although not under the auspices of a State or local government. They also pointed out the difficulty in obtaining timely governmental action on an operator-sponsored program as an alternative to line marking. As a result, these commenters and the TPSSC believe an operator-run program for prevention of excavation-type damage is just as satisfactory as one run by a State or local government. OPS does not entirely agree.

The primary objective of a damage-prevention program is to notify outside contractors preparing to excavate of the location of underground pipelines. Once a contractor is aware of the existence of a pipeline, the contractor must exercise care in excavating near the line. Although an operator-run program, which may include advertising, can be a vital part in preventing damage by outsiders, it would not provide as strong an incentive for outsiders to learn the precise locations of pipelines as would a program backed by government sanctions. This does not mean there is no room for operators in a government program. After all, operators are the ones most likely to have up-to-the-minute information on pipeline locations. Undoubtedly, a government-run program must heavily rely on operator cooperation.

A program under §192.707(a) (2) may be as simple or as complex as a government considers necessary. In fact, a simple requirement that outsiders contact operators for information before excavating would suffice. Alternatively, an industry-run "one call" program backed by State or local law could be used. When operators are so notified before excavation, they should respond with assistance in locating underground lines in the area of excavation. OPS anticipates that criteria for programs serving as an alternative to line marking may be the subject of a future rule-making proceeding.

A further question arises that if an exception to line marking applies in Class 3 and Class 4 locations because of a government enacted program, should the same exception apply in Class 1 and Class 2 locations where a government program exists? The TPSSC recommended that the exemption apply regardless of location. OPS has not adopted the recommendation for two reasons. First, the risk of encountering underground utilities during excavation is less in rural locations than in more developed areas. As a consequence, outsiders in rural areas are probably less likely to anticipate the existence of underground utilities or to be aware of a government enacted program. Secondly, a government program in less developed areas might not apply to farming activities. Thus, in most of these cases, farmers would not be made aware of the location of underground pipelines in the absence of line markers.

Likewise, the TPSSC recommended that the exception to the line marking requirement for impractical situations be extended to apply in Class 1 and Class 2 locations. This recommendation was not

adopted because, as proposed, the exception is intended to facilitate placement of markers in heavily developed areas. OPS does not believe that rural areas need the same considerations.

OPS still recognizes the difficulties in installing line markers over gas mains in urbanized areas. Yet, in the absence of alternative programs established by a State or local government, OPS considers line marking the most effective means for protecting against interference with buried lines by outsiders.

In the final rule, one last change is made to the exceptions for buried pipelines. After considering comments made by the TPSSC, OPS adopted the exception that in the case of navigable waterway crossings, a line marker is not required within 100 feet of a line marker which is placed and maintained at that waterway in accordance with the requirements of § 192.707. This change alleviates the proliferation of signs which would otherwise result under § 192.707 where multiple pipelines cross a waterway in proximity.

Paragraph (c), pipelines aboveground. This paragraph is not changed, except editorially, from the way it was proposed in the notice.

Paragraph (d), markers other than at navigable waterways. This paragraph sets forth requirements for line markers which are not at navigable waterways. Each marker must have written on it the word "Warning," "Caution," or "Danger." The requirement is changed from the notice which proposed that only the word "Warning" be used. Many commenters objected that existing line markers which have words with a similar meaning would have to be changed unnecessarily. OPS agrees that the words "Caution" and "Danger" notify the public of the hazard involved as sufficiently as the word "Warning." Providing a selection of words allows an operator to choose the one traditionally used in certain areas.

The notice proposed certain minimum sizes for lettering the word "Warning" and, in the case of markers at navigable waterway crossings, the words "Do Not Anchor or Dredge." Commenters objected to this proposal because of the various sizes and types of markers in existence and the additional cost of compliance for relettering or installing new signs to accommodate the minimum letter sizes.

The size of lettering is only one factor among many determining visibility and legibility of words by a viewer. Another is the contrast of colors between the words and their background. OPS does not believe that safety and the intention of this proceeding necessitate a precise standard for all factors governing visibility or legibility of the inscription on markers. However, certain minimum requirements are necessary in the public interest to judge the quality of notice provided by a line marker, and to ensure a standard of maintenance. OPS recognizes, however, the difficulty in meeting a minimum letter requirement for markers in urban areas, as, for example, on paving inserts. In the final rule, therefore, the performance standard for color contrasts and, except for markers in urban areas, the proposed specification for letter sizes are adopted for line markers not at navigable waterways. Criteria for visibility and legibility applicable to markers at navigable waterways is discussed hereafter. The lead time for compliance of existing line markers permitted by paragraph (f) should alleviate some of the objections concerning cost of compliance.

Paragraph (e), markers at navigable waterways. In the final rule, a new paragraph (e) is added to provide more detailed requirements for line markers at navigable waterways. The United States Coast Guard is concerned that signs intended to warn mariners of pipeline crossings would not be readily recognized unless they conform to a standard system for providing navigational information. OPS agrees. Line markers at navigable waterways are primarily intended to warn vessel operators of a potential danger. Therefore, they should be constructed according to a format generally understood by mariners. One widely adopted format for aids to navigation is the Uniform State Waterway Marking System (USWMS). This system is set forth in 33 CFR Subpart 66.10.

In the final rule, § 192.707(e) is written to ensure that line markers at navigable waterways conform to the USWMS. Compliance with the revised standard should not be construed, however, to satisfy Federal statutes or regulations pertaining to the marking of pipelines which obstruct navigation. The intended effect of the OPS marking requirements is not to equal or supersede similar requirements of the U.S. Coast Guard or the U.S. Army Corps of Engineers, but to be compatible with them. Thus, where a marker is required at a navigable waterway by these agencies, a single sign which complies with § 192.707 can be used.

There are notable differences between markers required at navigable waterways and elsewhere. At waterways, markers must be rectangular white signs with an international orange border. All lettering on the sign must be black and in block style. The size of the sign and lettering on it are governed by a requirement that in overcast daylight the sign be visible, and prescribed writing be legible, from approaching or passing vessels that may damage or interfere with the pipeline. In planning aids to navigation, the Coast Guard uses a rule of thumb that the distance in feet at which a sign may be read is approximately 40 times the letter height in inches. This rule of thumb could be used in placing markers at navigable waterways under § 192.707(e).

In submitting material to the TPSSC for this proceeding, OPS proposed that a diamond shape outlined in international orange be centered on the rectangular signs at navigable waterway crossings. This proposal, which was in conformity with the USWMS, would have resulted in an unnecessary expense to operators. In this regard, the minority views of one member of the Committee, which explain the problem in greater detail, were adopted and are set forth below.

Paragraph (f), existing markers. The proposal provided a 3-year lead time for operators to bring their existing markers into compliance with the proposed inscription requirements. The lead time was considered necessary because of the various sizes and shapes of markers in use which might have to be replaced to accommodate the proposed inscription. The lead time would allow temporary use of these markers.

Many commenters pointed out that normal sign attrition is much longer than 3 years. Having to replace recently installed signs within 3 years would be an unnecessary cost burden ultimately met by the public. These commenters suggested a requirement that existing markers without proper inscriptions be replaced in a normal maintenance cycle. Since a "normal" maintenance cycle undoubtedly varies from operator to operator, OPS does not concur with this suggestion. However, in light of the comments and recommendations by the TPSSC, the final rule permits existing markers which meet the location requirements to be used until January 1, 1980.

Report of the Technical Pipeline Safety Standards Committee. Section 4(b) of the Natural Gas Pipeline Safety Act of 1968 requires that all proposed standards and amendments to such standards be submitted to the Committee and that the Committee be afforded a reasonable opportunity to prepare a report on the "technical feasibility, reasonableness, and practicability of each such proposal." This amendment to Part 192 was submitted to the Committee as Item 4 in a list of five proposed amendments. The Committee has made a favorable report which is set forth below. Also, the two Committee members who disagreed with the majority of the Committee on Item 4 submitted statements of their views which are set forth following the report.

JANUARY 17, 1975.

Memorandum to: The Secretary of Transportation. Attention: Joseph C. Caldwell, Director, Office of Pipeline Safety.

From: Secretary, Technical Pipeline Safety Standards Committee.

Subject: Proposed Changes to 49 CFR Part 192, Minimum Federal Safety Standards for Transportation of Natural and Other Gases by Pipeline.

The following letter and attachments represent an official report by the Technical Pipeline Safety Standards Committee concerning the Committee's action related to five proposed amendments to 49 CFR Part 192, Minimum Federal Safety Standards for Transportation of Natural and Other Gases by Pipeline.

The Committee reviewed the proposals of the Office of Pipeline Safety at a meeting, held in Washington, D.C., on October 30 and 31, 1974, and through an informal balloting procedure recommended certain modifications, some of which were acceptable to the Office of Pipeline Safety. A formal ballot, reflecting the suggested changes, was prepared and distributed to the Committee members, by the undersigned on December 5, 1974.

Formal ballots have been submitted by all fourteen members of the Committee. The

majority of the Committee approved all five items on the ballot as being technically feasible, reasonable, and practicable. Negative votes were cast by one member against Items 1, 2, and 3, by two members against Item 4 and by four members against Item 5. Another member, who had been unable to attend the meeting and participate in the discussions, abstained from voting.

Attachment A sets forth the minority opinions submitted in support of the negative votes on Items 4 and 5.

LOUIS W. MENDONSA.

DECEMBER 16, 1974.

Mr. LOUIS W. MENDONSA,
Federal Power Commission,
Washington, D.C.

DEAR MR. MENDONSA: Attached is my executed letter ballot on five proposed amendments to 49 CFR Part 192 relative to the Agenda for the Technical Pipeline Safety Standards Committee meeting held on October 30–31, 1974.

I have voted affirmatively on Items 1, 2, and 3 and negatively on Items 4 and 5. My reasons for the negative votes are as follows:

Item 4. My objection is restricted to proposed § 192.707(d) (1) with the clause "except for markers in heavily developed urban areas." This clause leaves the size of the lettering of a marker in such areas completely unregulated in those areas most subject to pipeline damage with the greatest exposure to life and property.

Moreover, "heavily developed urban areas" was not defined. To many, including myself, it describes metropolitan areas of large cities. To others, and this was borne out at the meeting, it would include residential areas of high-priced homes.

Moreover, proposed § 192.707(b) (1), and possibly (b) (2), would probably result in no markers in such areas anyway.

Therefore, I see no need for the exception in § 192.707(d) (1).

Item 5. * * *

Sincerely,

W. L. WALLS,
Member, TPSSC.

REASONS FOR DISAPPROVAL OF ITEM 4; MARKING MAINS AND TRANSMISSION LINES GEORGE W. WHITE

My disapproval of Item 4 is centered on the required use of the diamond symbol in § 192.707(e) (1), which I believe to be inappropriate. This symbol is taken from the U.S. Coast Guard regulation on aids to navigation, 33 CFR 66.10—Uniform State Waterway Marking System, and is found in § 66.10–5(c) (1). In my opinion, this symbol, read in the context of § 66.10–1(a) and § 66.10–15(a) is to indicate "the presence of either natural or artificial obstructions or hazards" to navigation and the operator should not approach the marker in order to read any wording on it. I believe the square or rectangular symbol found in § 66.10–5(c) (4), which is for the purpose of providing "directions or information" is the appropriate symbol to use.

The additional advantage to using the square or rectangular symbol is that a majority of the thousands of existing navigable waterway crossing signs could remain in place, with minor modification, beyond the January 1, 1980, date. If the diamond symbol is adopted, all existing signs must be replaced with larger signs to provide room for the diamond. These existing markers are large, expensive, long-life signs, installed on piling, and, to the best of my knowledge, are adequately performing their function of warning boat or dredge operators. There is no evidence that damage to pipelines crossing navigable waterways is a safety problem, therefore, the continued use of existing signs with an international orange border (rectangular or square), however modified to meet the proposed wording is practical and consistent with pipeline safety.

At the October 30–31, 1974, Technical Pipeline Safety Standards Committee Meeting the substance of the proposed § 192.707(e) was not discussed, but it was agreed that OPS would consider if the proposed requirements are compatible with the present U.S. Corps of Engineers requirements. All present pipeline crossing markers on navigable waterways were approved by the Corps and the use of the rectangular symbol is much more compatible with these signs than the diamond symbol.

Would you please reconsider the use of the diamond symbol and substitute for it a rectangle or square one with the lettering (as proposed) inside the square or rectangle. This could be issued as an amendment to the letter ballot and voted on again by the Committee.

The proposed § 192.707(e) could be modified as follows:

Markers at navigable waterways. Each line marker at a navigable waterway must have the following characteristics:

(1) A sign, rectangular or square in shape, with a narrow strip along each edge, colored international orange and the area between lettering on the sign and boundary strips colored white.

(2) Written on the sign in block style, black letters—

(i) The word "Warning," "Caution," or "Danger," followed by the words "Do Not Anchor or Dredge," and the words "Gas Pipeline Crossing"; and

(ii) The name of the operator and the telephone number (including area code) where the operator can be reached at all times.

(3) In overcast daylight, the orange border is visible and the writing required by paragraph (e) (2) (i) of this section is legible, from approaching or passing vessels that may damage or interfere with the pipeline.

If the ballot is changed as I have suggested, I would approve of the entire Item 4.

Effective date. Section 3(e) of the Natural Gas Pipeline Safety Act of 1968 requires that standards and amendments thereto prescribed under the Act be effective 30 days after the date of issuance unless the Secretary determines good cause exists for an earlier or later effective date as a result of the period reasonably necessary for compliance. Accordingly, the revised § 192.707 will become effective 30 days after issuance. As provided in § 192.707(a), this effective date is not relevant, however, to existing buried mains and to existing buried transmission lines at public road, railroad, and navigable waterway crossings. As discussed hereinabove, in view of the period reasonably necessary to bring those existing buried pipelines into compliance with the revised requirements, § 192.707(a) does not become applicable to them until January 1, 1978.

In consideration of the foregoing, § 192.707 of Title 49 of the Code of Federal Regulations is revised to read as follows, effective April 21, 1975:

§ 192.707 Line markers for mains and transmission lines.

(a) *Buried pipelines.* Except as provided in paragraph (b) of this section, a line marker must be placed and maintained as close as practical over each buried main and transmission line—

(1) At each crossing of a public road, railroad, and navigable waterway; and

(2) Wherever necessary to identify the location of the transmission line or main to reduce the possibility of damage or interference.

However, until January 1, 1978, paragraphs (a) (1) and (a) (2) of this section do not apply to mains installed before April 21, 1975, and until January 1, 1978, paragraph (a) (1) of this section does not apply to transmission lines installed before April 21, 1975.

(b) *Exceptions for buried pipelines.* Line markers are not required for buried mains and transmission lines—

(1) In Class 3 or Class 4 locations—

(i) Where placement of a marker is impractical; or

(ii) Where a program for preventing interference with underground pipelines is established by law; or

(2) In the case of navigable waterway crossings, within 100 feet of a line marker placed and maintained at that waterway in accordance with this section.

(c) *Pipelines aboveground.* Line markers must be placed and maintained along each section of a main and transmission line that is located aboveground in an area accessible to the public.

(d) *Markers other than at navigable waterways.* The following must be written legibly on a background of sharply contrasting color on each line marker not placed at a navigable waterway:

(1) The word "Warning," "Caution," or "Danger" followed by the words "Gas Pipeline" all of which, except for markers in heavily developed urban areas, must be in letters at least one inch high with one-quarter inch stroke.

(2) The name of the operator and the telephone number (including area code) where the operator can be reached at all times.

(e) *Markers at navigable waterways.* Each line marker at a navigable waterway must have the following characteristics:

(1) A sign, rectangular in shape, with a narrow strip along each edge colored international orange and the area between lettering on the sign and boundary strips colored white.

(2) Written on the sign in block style, black letters—

(i) The word "Warning," "Caution," or "Danger," followed by the words "Do Not Anchor or Dredge" and the words "Gas Pipeline Crossing;" and

(ii) The name of the operator and the telephone number (including area code) where the operator can be reached at all times.

(3) In overcast daylight, the sign is visible and the writing required by paragraph (e) (2) (i) of this section is legible, from approaching or passing vessels that may damage or interfere with the pipeline.

(f) *Existing markers.* Line markers installed before April 21, 1975, which do not comply with paragraph (d) or (e) of this section may be used until January 1, 1980.

(Sec. 3, Natural Gas Pipeline Safety Act of 1968 (49 USC 1672); § 1.58(d) of the regulations of the Office of the Secretary of Transportation (49 CFR 1.58(d)), and the redelegation of authority to the Director, Office of Pipeline Safety, set forth in Appendix A to Part 1 of the regulations of the Office of the Secretary of Transportation (49 CFR Part 1))

Issued in Washington, D.C., on March 21, 1975.

JOSEPH C. CALDWELL,
Director,
Office of Pipeline Safety.

[FR Doc.75-7917 Filed 3-26-75;8:45 am]

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[Corrected Revised SO No. 1207]

PART 1033—CAR SERVICE

Lehigh Valley Railroad Company (Robert C. Haldeman, Trustee) Directed To Operate Certain Portions of Lehigh and New England Railway Company

At a Session of the Interstate Commerce Commission, Division 3, held at its office in Washington, D.C., on the 17th day of March, 1975.

It appearing, That the Lehigh and New England Railway Company (LNE) has notified the Commission that, on or before January 24, 1975, it will be unable to transport the traffic offered it because its cash position makes continued operation impossible; and that, accordingly, the LNE has placed its embargo No. 1-75 against all traffic, effective January 7, 1975;

It further appearing, That the imminent cessation of all transportation services by the LNE constitutes an emergency situation such as that contemplated by section 1(16)(b) of the Interstate Commerce Act (49 U.S.C. 1(16)), as amended, by section 601(e) of the Regional Rail Reorganization Act of 1973 (P.L. 93-236); and that section authorizes the Commission under certain prescribed conditions, to direct a carrier or carriers by railroad to perform essential transportation services which another carrier is no longer able to perform;

It further appearing, That the legislative history to section 1(16)(b) indicates that its purpose is to assure the continuance of essential rail service for a period of sixty days, or in extraordinary circumstances for an extended period not to exceed 240 days, in the event that a railroad is required to cease operation under conditions described in the Act; and that such authority was intended as an interim emergency measure and not as a permanent solution;

It further appearing, That in determining whether the LNE should be operated pursuant to the authority of section 1(16)(b) and in its planning therefore, the Commission, consistent with Congressional intent and the provisions of the Emergency Rail Services Act of 1970 (45 U.S.C. 661), has coordinated its activities with the Department of Transportation and has been in consultation with representatives of the United States Railway Association, among others;

It further appearing, That the Commission has determined that based upon the statute and the directives contained in the legislative history of section 1(16)(b) of the Act, the operation of the lines of the LNE is necessary and such operation is in the public interest; that the Commission considered many factors, including but not limited to: the transportation requirements of the patrons of the LNE, the economic impact of a discontinuance of service, the amount of originating and terminating traffic on individual lines, transportation requirements of connecting carriers, condition of track, alternative carriers and transportation modes, and net operating revenues attributable to individual lines; and that, the Commission should direct a carrier to operate over the lines of the LNE;

It further appearing, That the Lehigh Valley Railroad Company (Robert C. Haldeman, Trustee) (LV) should be directed to provide the services herein determined to be essential in the public interest, which were formerly performed by the LNE, because, among other things, the LV's proximity to the lines of the LNE, the volume of the traffic LNE interchanges with the LV, its familiarity with the operation of the LNE and its willingness and ability to perform the services required for shippers;

It further appearing, That the performance of the operations directed herein will not substantially impair the LV's ability adequately to serve its own patrons or to meet its outstanding common carrier obligations; that the performance of the directed operation should not violate the provisions of the Federal Railroad Safety Act of 1970 (45 U.S.C. 421);

It further appearing, That in light of the emergency situation which would result from a cessation of all transportation service by the LNE, public notice and hearings are impractical and not required by the procedures set forth in section 1(15) of the Act; that the public interest requires the continuation of operation over certain lines of the LNE by the LV for a period of operation of 150[1] days as provided by section 1(16)(b) of the Act; and that good cause exists for making this order effective upon the date served;

It further appearing, That the LV is presently a railroad in reorganization under section 77 of the Bankruptcy Act (11 U.S.C. 205) subject to the jurisdiction of the United States District Court for the Eastern District of Pennsylvania; and that, accordingly, approval of said court may be necessary for the implementation of this order; and

It further appearing, and the Division so finds, that this decision is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969;

It further appearing, and the Division so finds, that cessation of service by the LNE would have serious economic consequences not only to the patrons of the LNE but also to the communities located within the area; and for good cause appearing therefore:

§ 1033.1207 Service Order No. 1207.

(a) *Lehigh Valley Railroad Company (Robert C. Haldeman, Trustee) Directed To Operate Certain Portions of Lehigh and New England Railway Company. It is ordered,* That the Lehigh Valley Railroad Company, debtor (Robert C. Haldeman, Trustee), be, and it is hereby directed to enter upon the railroad properties presently operated by the Lehigh and New England Railway Company, except the Tamaqua branch, extending between Tamaqua, Pennsylvania, and Hauto, Pennsylvania, and to operate such railroad and facilities subject to any necessary approval of the reorganization court of the United States District Court for the Eastern District of Pennsylvania, for the purpose of handling, routing, and moving the traffic of the Lehigh and New England Railway Company in accordance with the lawful instructions of shippers and consignees and in compliance with the rules and regulations of the Commission, and subject to the rates and charges prescribed in tariffs lawfully published and filed in accordance with law and applicable to freight traffic transported over the lines of the Lehigh and New England Railway Company; that such entry and operations shall commence on or before 12:01 a.m., January 24, 1975, and shall continue for a period of 150 days, unless such period is reduced by order of the Commission or unless further extended by order of the Commission, for cause shown, for an additional designated period; and that a certified copy of the order of the court authorizing the Lehigh Valley Railroad Company, debtor, to perform the directed service pursuant to the order of the Commission shall be filed with this Commission, with appropriate reference to this proceeding;

(b) *It is further ordered,* That the Lehigh and New England Railway Company shall, on the date of service of this order inform all persons who were given notice of its embargo No. 1-75, that said embargo shall no longer be applicable to service over its lines;

(c) *It is further ordered,* That the Lehigh Valley Railroad Company, debtor, shall (1) collect all revenues attributable to the handling, routing, and movement of freight traffic including all agents' and conductors' accounts and all

[1] Correction.

payments from other carriers collected after the commencement of directed operations; (2) distribute such revenues in accordance with divisional agreements presently applicable, collecting and paying to the Lehigh and New England Railway Company the divisions of joint revenues payable to the Lehigh and New England Railway Company pursuant to such division agreements which are derived from services performed and events occurring prior to January 24, 1975, and collecting and retaining for the Lehigh Valley Railroad Company, debtor, on a segregated basis all such divisions of joint revenues payable to the Lehigh and New England Railway Company pursuant to such division agreements which are derived from services performed by the Lehigh Valley Railroad Company, debtor, in the place and stead of the Lehigh and New England Railway Company and from events occurring on or after January 24, 1975;

(d) *It is further ordered,* That all carriers are hereby directed to pay to the Lehigh Valley Railroad Company, debtor, such sums as otherwise would be payable to the Lehigh and New England Railway Company including interline freight revenues, per diem, and all other interline accounts of whatsoever kind and nature coming due under normal accounting rules and procedures for the settlement of interline transactions and accounts between carriers during the period this order is in effect and thereafter coming due for services performed and events occurring during the period of directed service;

(e) *It is further ordered,* That the Lehigh Valley Railroad Company, debtor, shall pay to all carriers amounts received by it but due to them for services performed by them, for per diem, and for events occurring either prior to the commencement of operations directed herein or during the period this order is in effect, all in accordance with established procedures for the settlement of interline transactions and accounts between carriers;

(f) *It is further ordered,* That the Lehigh Valley Railroad Company, debtor, be, and it is hereby, authorized to act on behalf of the Lehigh and New England Railway Company in all matters pertaining to the establishment of rates, routes and divisions applicable to that portion of the LINE operated by the IV as defined in paragraph (a) herein, including the publication or amendment of tariffs, division sheets, etc;

(g) *It is further ordered,* That in executing the directions of this Commission as provided for in this order, all carriers involved in the movement of traffic to the lines of the Lehigh and New England Railway Company shall proceed even though in some instances, no contracts, agreements or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic; that in the event reroutings are necessary pursuant to the directives of this and subsequent orders, the divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers, or upon failure of the carriers to so agree said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act;

(h) *It is further ordered,* That, in carrying out the operations directed herein, the Lehigh Valley Railroad Company, debtor, shall hire employees of the Lehigh and New England Railway Company to the extent such employees had previously performed the directed service and shall assume all existing employment obligations and practices of the Lehigh and New England Railway Company relating thereto, including, but not limited to, agreements governing rates of pay, rules, working conditions, and all current employee protective conditions, for the duration of the directed service;

(i) *It is further ordered,* That the Lehigh Valley Railroad Company, debtor, and the Lehigh and New England Railway Company shall, if possible, negotiate an agreement (hereinafter called the agreement) on all aspects of the directed operation subject to their determination, including, but not limited to use of and rental for equipment, use of, and compensation for, existing inventories of fuel, materials, and supplies, and rental for the use of rights-of-way and other rail facilities; that the Commission shall be represented at all such discussions; that the agreement shall be subject to approval by the Commission upon such procedure as the Commission shall later specify; and that in the event the Lehigh Valley Railroad Company, debtor, and the Lehigh and New England Railway Company fail to agree upon the terms for such use and compensation, the directed service shall continue pending a Commission determination to establish such terms as it may find to be just and reasonable;

(j) *It is further ordered,* That in the event the parties achieve agreement, any funds to be paid the Lehigh and New England Railway Company thereunder shall be paid into an escrow account until the agreement is given approval by the Commission; and that in the event the parties are unable to reach agreement, any monies the Lehigh Valley Railroad Company, debtor, holds for the account of the Lehigh and New England Railway Company to compensate it for the use of its equipment and facilities and properties, in lieu of a final agreement, shall be paid into an escrow account until a determination has been made by the Commission a to what terms are just and reasonable;

(k) *It is further ordered,* That the Lehigh Valley Railroad Company, debtor, shall record the revenues earned and the costs incurred in and for the performance of the operations directed herein over the lines of the Lehigh and New England Railway Company, in a manner to be prescribed by the Commission, that the information so recorded, and supporting data where specifically required, shall be submitted by the Lehigh Valley Railroad Company, debtor, to the Commission for audit and evaluation immediately upon completion of the directed operation, or at such intervals, during the period of the directed operation, as the Commission may request; and that, if, for the period during which this order shall be effective, the cost to the Lehigh Valley Railroad Company, debtor, of handling, routing, and moving the traffic over the lines of the Lehigh and New England Railway Company shall exceed the direct revenues therefor, payment shall be made to the Lehigh Valley Railroad Company, debtor, in the manner provided by section 1(16)(b) of the Act;

(l) *It is further ordered,* That the Commission shall retain jurisdiction to modify, supplement or reconsider this order at any time and for such purposes as it may consider necessary consistent with the legislative intent and the express provision of section 1(16)(b) of the Interstate Commerce Act, as amended;

(m) *It is further ordered,* That this order shall be served upon the United States Department of Transportation, the United States Railway Association, the Rail Planning Services Office of the Interstate Commerce Commission, the governor of the State of Pennsylvania, Pennsylvania Public Utilities Commission, the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

(n) *It is further ordered,* That this order shall be effective upon the date of service; that the operations which the Lehigh Valley Railroad Company, debtor, is herein directed to perform shall commence on or before 12:01 a.m., January 24, 1975; and that such operations shall cease 150 days from the date the directed service shall be instituted by the Lehigh Valley Railroad Company, debtor, at 11:59 p.m., unless otherwise extended, modified, changed, or suspended by subsequent order of the Commission.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended (49 U.S.C. 1, 12, 15, and 17(2)). Interprets or applies secs. 1(10–17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; (49 U.S.C. 1(10–17), 15(4), and 17(2)).)

By the Commission, Division 3.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-8027 Filed 3-26-75;8:45 am]

[Corrected Revised SO No. 1208]

PART 1033—CAR SERVICE

Reading Company, Andrew L. Lewis, Jr., and Joseph L. Castle, Trustees, Directed To Operate Certain Portions of Lehigh and New England Railway Company

At a session of the Interstate Commerce Commission, Division 3, held at its office in Washington, D.C., on the 17th day of March, 1975.

It appearing, That the Lehigh and New England Railway Company (LNE) has notified the Commission that, on or before January 24, 1975, it will be unable to transport the traffic offered it because its cash position makes continued operation impossible; and that, accordingly, the LNE has placed its embargo No. 1–75 against all traffic, effective January 7, 1975;

It further appearing, That the imminent cessation of all transportation services by the LNE constitutes an emergency situation such as that contemplated by section 1(16)(b) of the Interstate Commerce Act (49 U.S.C. 1(16)), as amended, by section 601(e) of the Regional Rail Reorganization Act of 1973 (P.L. 93–236); and that section authorizes the Commission under certain prescribed conditions, to direct a carrier or carriers by railroad to perform essential transportation services which another carrier is no longer able to perform;

It further appearing, That the legislative history to section 1(16)(b) indicates that its purpose is to assure the continuance of essential rail service for a period of sixty days, or in extraordinary circumstances for an extended period not to exceed 240 days, in the event that a railroad is required to cease operation under conditions described in the Act; and that such authority was intended as an interim emergency measure and not as a permanent solution;

It further appearing, That in determining whether the LNE should be operated pursuant to the authority of section 1(16)(b) and in its planning therefore, the Commission, consistent with Congressional intent and the provisions of the Emergency Rail Services Act of 1970 (45 U.S.C. 661), has coordinated its activities with the Department of Transportation and has been in consultation with representatives of the United States Railway Association, among others;

It further appearing, That the Commission has determined that based upon the statute and the directives contained in the legislative history of section 1(16)(b) of the Act, the operation of the lines of the LNE is necessary and such operation is in the public interest; that the Commission considered many factors, including but not limited to: the transportation requirements of the patrons of the LNE, the economic impact of a discontinuance of service, the amount of originating and terminating traffic on individual lines, transportation requirements of connecting carriers, condition of track, alternative carriers and transportation modes, and net operating revenues attributable to individual lines; and that, the Commission should direct a carrier to operate over the lines of the LNE;

It further appearing, That the Reading Company, Andrew L. Lewis, Jr., and Joseph L. Castle, Trustees (Rdg) should be directed to provide the services herein determined to be essential in the public interest, which were formerly performed by the LNE, because, among other things, the Rdg's proximity to the lines of the LNE, the volume of the traffic LNE interchanges with the Rdg, its familiarity with the operation of the LNE and its willingness and ability to perform the services required for shippers;

It further appearing, That the performance of the operations directed herein will not substantially impair the Rdg's ability adequately to serve its own patrons or to meet its outstanding common carrier obligations; that the performance of the directed operation should not violate the provisions of the Federal Railroad Safety Act of 1970 (45 U.S.C. 421);

It further appearing, That in light of the emergency situation which would result from a cessation of all transportation service by the LNE, public notice and hearings are impractical and not required by the procedures set forth in section 1(15) of the Act; that the public interest requires the continuation of operation over certain lines of the LNE by the Rdg for a period of operation of 150[1] days as provided by section 1(16)(b) of the Act; and that good cause exists for making this order effective upon the date served;

It further appearing, That the Rdg is presently a railroad in reorganization under section 77 of the Bankruptcy Act (11 U.S.C. 205) subject to the jurisdiction of the United States District Court for the Eastern District of Pennsylvania; and that, accordingly, approval of said court may be necessary for the implementation of this order; and

It further appearing, and the Division so finds, that this decision is not a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969;

It further appearing, and the Division so finds, that cessation of service by the LNE would have serious economic consequences not only to the patrons of the LNE but also to the communities located within the area; and for good cause appearing therefore:

§ 1033.1208 Reading Company, Andrew L. Lewis, Jr., and Joseph L. Castle, Trustees, Directed To Operate Certain Portions of Lehigh and New England Railway Company.

(a) *It is ordered,* That the Reading Company, Andrew L. Lewis, Jr., and Joseph L. Castle, Trustees (Rdg), be, and it is hereby directed to enter upon that portion of the Tamaqua branch of the Lehigh and New England Railway (LNE) extending between milepost 2.20 west of Hauto, Pennsylvania, and a connection with the Reading Company at milepost 6.55 in the vicinity of Tamaqua, Pennsylvania, and to operate such railroad and facilities subject to any necessary approval of the reorganization court of the United States District Court for the Eastern District of Pennsylvania, for the purpose of handling, routing, and moving the traffic of the Lehigh and New England Railway Company in accordance with the lawful instructions of shippers and consignees and in compliance with the rules and regulations of the Commission, and subject to the rates and charges prescribed in tariffs lawfully published and filed in accordance with law and applicable to freight traffic transported over the lines of the Lehigh and New England Railway Company; that such entry and operations shall commence on or before 12:01 a.m., January 24, 1975, and shall continue for a period of 150 days, unless such period is reduced by order of the Commission or unless further extended by order of the Commission, for cause shown, for an additional designated period; and that a certified copy of the order of the court authorizing the Reading Company to perform the directed service pursuant to the order of the Commission shall be filed with this Commission, with appropriate reference to this proceeding;

(b) *It is further ordered,* That the Lehigh and New England Railway Company shall, on the date of service of this order inform all persons who were given notice of its embargo No. 1–75, that said embargo shall no longer be applicable to service over its lines;

(c) *It is further ordered,* That the Reading Company shall (1) collect all revenues attributable to the handling, routing, and movement of freight traffic including all agents' and conductors' accounts and all payments from other carriers collected after the commencement of directed operations; (2) distribute such revenues in accordance with divisional agreements presently applicable, collecting and paying to the Lehigh and New England Railway Company the divisions of joint revenues payable to the Lehigh and New England Railway Company pursuant to such division agreements which are derived from services performed and events occurring prior to January 24, 1975, and collecting and retaining for the Reading Company on a segregated basis all such divisions of joint revenues payable to the Lehigh and New England Railway Company pursuant to such division agreements which are derived from services performed by the Reading Company in the place and stead of the Lehigh and New England Railway Company and from events occurring on or after January 24, 1975;

(d) *It is further ordered,* That all carriers are hereby directed to pay to the Reading Company, such sums as otherwise would be payable to the Lehigh and New England Railway Company including interline freight revenues, per diem, and all other interline accounts of whatsoever kind and nature coming due under normal accounting rules and procedures

[1] Correction.

for the settlement of interline transactions and accounts between carriers during the period this order is in effect and thereafter coming due for services performed and events occurring during the period of directed service;

(e) *It is further ordered,* That the Reading Company shall pay to all carriers amounts received by it but due to them for services performed by them, for per diem, and for events occurring either prior to the commencement of operations directed herein or during the period this order is in effect, all in accordance with established procedures for the settlement of interline transactions and accounts between carriers;

(f) *It is further ordered,* That the Reading Company be, and it is hereby, authorized to act on behalf of the Lehigh and New England Railway Company in all matters pertaining to the establishment of rates, routes and divisions applicable to that portion of the LNE operated by the Rdg as defined in paragraph (a) herein, including the publication or amendment of tariffs, division sheets, etc.;

(g) *It is further ordered,* That in executing the directions of this Commission as provided for in this order, all carriers involved in the movement of traffic to the lines of the Lehigh and New England Railway Company shall proceed even though in some instances, no contracts, agreements or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic; that in the event reroutings are necessary pursuant to the directives of this and subsequent orders, the divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers, or upon failure of the carriers to so agree said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act;

(h) *It is further ordered,* That, in carrying out the operations directed herein, the Reading Company shall hire employees of the Lehigh and New England Railway Company to the extent such employees had previously performed the directed service and shall assume all existing employment obligations and practices of the Lehigh and New England Railway Company relating thereto, including, but not limited to, agreements governing rates of pay, rules, working conditions, and all current employee protective conditions, for the duration of the directed service;

(i) *It is further ordered,* That the Reading Company and the Lehigh and New England Railway Company shall, if possible, negotiate an agreement (hereinafter called the agreement) on all aspects of the directed operation subject to their determination, including, but not limited to use of and rental for equipment, use of, and compensation for, existing inventories of fuel, materials, and supplies, and rental for the use of rights-of-way and other rail facilities; that the Commission shall be represented at all such discussions; that the agreement shall be subject to approval by the Commission upon such procedure as the Commission shall later specify; and that in the event the Reading Company and the Lehigh and New England Railway Company fail to agree upon the terms for such use and compensation, the directed service shall continue pending a Commission determination to establish such terms as it may find to be just and reasonable;

(j) *It is further ordered,* That in the event the parties achieve agreement, any funds to be paid the Lehigh and New England Railway Company thereunder shall be paid into an escrow account until the agreement is given approval by the Commission; and that in the event the parties are unable to reach agreement, any monies the Reading Company holds for the account of the Lehigh and New England Railway Company to compensate it for the use of its equipment and facilities and properties, in lieu of a final agreement, shall be paid into an escrow account until a determination has been made by the Commission as to what terms are just and reasonable;

(k) *It is further ordered,* That the Reading Company shall record the revenues earned and the costs incurred in and for the performance of the operations directed herein over the lines of the Lehigh and New England Railway Company, in a manner to be prescribed by the Commission, that the information so recorded, and supporting data where specifically required, shall be submitted by the Reading Company to the Commission for audit and evaluation immediately upon completion of the directed operation, or at such intervals, during the period of the directed operation, as the Commission may request; and that, if, for the period during which this order shall be effective, the cost to the Reading Company of handling, routing, and moving the traffic over the lines of the Lehigh and New England Railway Company shall exceed the direct revenues therefor, payment shall be made to the Reading in the manner provided by section 1(16)(b) of the Act;

(l) *It is further ordered,* That the Commission shall retain jurisdiction to modify, supplement or reconsider this order at any time and for such purposes as it may consider necessary consistent with the legislative intent and the express provision of section 1(16)(b) of the Interstate Commerce Act, as amended;

(m) *It is further ordered,* That this order shall be served upon the United States Department of Transportation, the United States Railway Association, the Rail Planning Services Office of the Interstate Commerce Commission, the governor of the State of Pennsylvania, Pennsylvania Public Utilities Commission, the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

(n) *It is further ordered,* That this order shall be effective upon the date of service; that the operations which the Reading Company is herein directed to perform shall commence on or before 12:01 a.m., January 24, 1975; and that such operations shall cease 150 days from the date the directed service shall be instituted by the Reading Company at 11:59 p.m., unless otherwise extended, modified, changed, or suspended by subsequent order of the Commission.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended (49 U.S.C. 1, 12, 15, and 17(2)). Interprets or applies secs. 1(10–17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; (49 U.S.C. 1(10–17), 15(4), and 17(2)).)

By the Commission, Division 3.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-8028 Filed 3-26-75;8:45 am]

Title 7—Agriculture

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Navel Orange Reg. 345]

PART 907—NAVEL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Limitation of Handling

This regulation fixes the quantity of California-Arizona Navel oranges that may be shipped to fresh market during the weekly regulation period Mar. 28–Apr. 3, 1975. It is issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 907. The quantity of Navel oranges so fixed was arrived at after consideration of the total available supply of Navel oranges, the quantity currently available for market, the fresh market demand for Navel oranges, Navel orange prices, and the relationship of season average returns to the parity price for Navel oranges.

§ 907.645 Navel Orange Regulation 345.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 907, as amended (7 CFR Part 907), regulating the handling of Navel oranges grown in Arizona and designated part of California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Navel Orange Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby

found that the limitation of handling of such Navel oranges, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for this regulation to limit the respective quantities of Navel oranges that may be marketed from District 1, District 2, and District 3 during the ensuing week stems from the production and marketing situation confronting the Navel orange industry.

(i) The committee has submitted its recommendation with respect to the quantities of Navel oranges that should be marketed during the next succeeding week. Such recommendation, designed to provide equity of marketing opportunity to handlers in all districts, resulted from consideration of the factors enumerated in the order. The committee further reports that the fresh market demand for Navel oranges continued to exhibit strength over the past week. Prices f.o.b. averaged $3.57 per carton on a reported sales volume of 1,581 carlots last week, compared with an average f.o.b. price of $3.56 per carton and sales of 1,229 carlots a week earlier. Track and rolling supplies at 554 cars were down 63 cars from last week.

(ii) Having considered the recommendation and information submitted by the committee, and other available information, the Secretary finds that the respective quantities of Navel oranges which may be handled should be fixed as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date of this regulation until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this regulation is based became available and the time this regulation must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for Navel oranges and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such Navel oranges; it is necessary, in order to effectuate the declared policy of the act, to make this regulation effective during the period herein specified; and compliance with this regulation will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on March 25, 1975.

(b) *Order.* (1) The respective quantities of Navel oranges grown in Arizona and designated part of California which may be handled during the period March 28, 1975, through April 3, 1975 are hereby fixed as follows:

(i) District 1: 1,275,000 cartons;

(ii) District 2: 225,000 cartons;

(iii) District 3: Unlimited movement."

(2) As used in this section, "handled," "District 1," "District 2," "District 3," and "carton" have the same meaning as when used in said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; (7 U.S.C. 601–674))

Dated: March 26, 1975.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-8184 3-26-75;12:43 am]

[Valencia Orange Reg. 490]

PART 908—VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Limitation of Handling

This regulation fixes the quantity of California-Arizona Valencia oranges that may be shipped to fresh market during the weekly regulation period Mar. 28–Apr. 3, 1975. It is issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 908. The quantity of Valencia oranges so fixed was arrived at after consideration of the total available supply of Valencia oranges, the quantity of Valencia oranges currently available for market, the fresh market demand for Valencia oranges, Valencia orange prices, and the relationship of season average returns to the parity price for Valencia oranges.

§ 908.790 Valencia Orange Regulation 490.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 908, as amended (7 CFR Part 908), regulating the handling of Valencia oranges grown in Arizona and designated part of California, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and upon the basis of the recommendations and information submitted by the Valencia Orange Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such Valencia oranges, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for this regulation to limit the respective quantities of Valencia oranges that may be marketed from District 1, District 2, and District 3 during the ensuing week stems from the production and marketing situation confronting the Valencia orange industry.

(i) The committee has submitted its recommendation with respect to the quantities of Valencia oranges that should be marketed during the next succeeding week. Such recommendation, designed to provide equity of marketing opportunity to handlers in all districts, resulted from consideration of the factors enumerated in the order. The committee further reports that the fresh market demand for Valencia oranges continues to be very slow. Prices f.o.b. averaged $3.17 per carton on a reported sales volume of 71 carlots last week, compared with an average f.o.b. price of $3.04 per carton and sales of 29 carlots a week earlier. Track and rolling supplies at 49 cars were down 3 cars from last week.

(ii) Having considered the recommendation and information submitted by the committee, and other available information, the Secretary finds that the respective quantities of Valencia oranges which may be handled should be fixed as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule-making procedure, and postpone the effective date of this regulation until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this regulation is based became available and the time when this regulation must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for Valencia oranges and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this regulation, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such Valencia oranges; it is necessary, in order to effectuate the declared policy of the act, to make this regulation effective during the period herein specified; and compliance with this regulation will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on March 25, 1975.

(b) *Order.* (1) The respective quantities of Valencia oranges grown in Arizona and designated part of California which may be handled during the period March 28, 1975, through April 3, 1975, are hereby fixed as follows:

(i) District 1: Unlimited;

(ii) District 2: Unlimited;

(iii) District 3: 125,000 cartons.

(2) As used in this section, "handled", "District 1", "District 2", "District 3", and "carton" have the same meaning as when used in said amended marketing agreement and order.

(Secs. 1–19, 48 Stat. 31, as amended; (7 U.S.C. 601–674))

Dated: March 26, 1975.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-8183 Filed 3-26-75;12:43 am]

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 917]

FRESH PEARS, PLUMS, AND PEACHES GROWN IN CALIFORNIA

Proposed Rulemaking

This notice invites written comments relative to amending the container marking requirements of Plum Regulation 5 (§ 917.419; 35 FR 7064). Said regulation currently specifies, among other things, that the size of the plums packed in the various containers shall be marked in accordance with (1) the arrangement of the plums in the style of container involved, such as "4x4" and "4x5" in four-basket crates and "6 row" and "8 row" in cartons or lug boxes, or (2) the number of plums in each container, i.e., the count, unless marked with the equivalent size designation for such plums in four-basket crates.

The Plum Commodity Committee established pursuant to the marketing agreement, as amended, and Order No. 917, as amended (7 CFR Part 917), has proposed certain changes in the language of the regulation which would (1) cause it to conform to certain requirements of the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) applicable to the disclosure of the size of the contents of containers by appropriate labeling of the containers and (2) add a requirement to the regulation which would cause the net weight of certain containers to be marked thereon. With regard to the first change, the word "size" would be added to the current size designations. For example, designations such as "4x5," "6 row," and others, would be changed to "4x5 size," "6 row size," and other corresponding terms. Thus any connotation of size which derives from the arrangement of the plums, in a particular container, would be specified directly as a size by including the word "size." Plums whose size is indicated by the number of them in the container, such as 88 or 162, would be in containers marked as "88 size" or "162 size" and such numbers would denote the minimum number of plums in the filled container. With regard to the second change, certain containers of loose-fill, loose-pack, or tight-fill plums (not packed in rows) would be marked to show the 28-pound minimum net weight thereof. The specification of a 28-pound net weight for such containers would forestall confusion in the industry by assuring a uniform net weight for those containers. Such container marking also would comply with other applicable labeling laws.

Accordingly, notice is hereby given that the Department is considering proposed amendment, as hereinafter set forth, of Plum Regulation 5 currently in effect pursuant to said marketing agreement and order which regulate the handing of fresh pears, plums, and peaches grown in California. This is a regulatory program effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674).

The amendment would add a new paragraph (a) (5) to § 917.419 and revise paragraph (a) (4) thereof to read as set forth below:

§ 917.419 Plum Regulation 5.

(a) * * *

(4) Each package or container of plums shall bear on one outside end, in plain sight and in plain letters, the size description of the contents which description shall conform to the following, as applicable:

(i) The size of plums in four-basket crates shall be indicated in accordance with the arrangement of the plums in the top layer of the baskets, such as "4x4 size," "4x5 size," etc.

(ii) The size of the plums in face and fill packs in cartons or lug boxes shall be indicated in accordance with the number of rows in the face, such as "6 row size," "8 row size," etc.

(iii) The size of plums packed or filled in other packages or containers shall be indicated as the number of plums in the package or container, such as "88 size," "178 size," etc., or by the equivalent size designation for such plums when packed in four-basket crates.

(5) Each package or container of loose-fill, loose-pack, or tight-fill plums (not packed in rows) shall bear on one outside end, in plain sight and in plain letters, the words "28 pounds net weight."

All persons who desire to submit written data, views, or arguments for consideration in connection with the proposed amendment shall file the same, in quadruplicate, with the Hearing Clerk, United States Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than April 17, 1975. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Dated: March 21, 1975.

CHARLES R. BRADER,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-7958 Filed 3-26-75;8:45 am]

[7 CFR Part 908]

HANDLING OF VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

Proposed Rulemaking With Respect to Size Regulation for Valencia Oranges

This proposal would extend through January 15, 1976, the current size requirement for Valencia oranges grown in District 3 of the California-Arizona production area. Shipments of such Valencia oranges are currently regulated through April 27, 1975, pursuant to Valencia Orange Regulation 487. The proposed extension of the period of Valencia Orange Regulation 487 is designed to continue in effect the current minimum diameter requirement of 2.20 inches for such fruit consistent with the objective of the act of promoting orderly marketing and protecting the interest of consumers.

Notice is hereby given that the Department is considering a proposed amendment of the size regulation for Valencia oranges grown in District 3, pursuant to the applicable provisions of the marketing agreement, as amended, and Order No. 908, as amended (7 CFR Part 908) regulating the handling of Valencia oranges grown in Arizona and designated part of California. This regulatory program is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The proposed amendment was recommended by the Valencia Orange Administrative Committee, established under said amended marketing agreement and order as the agency to administer the terms and provisions thereof.

The proposed regulation is designed to permit shipment during the period April 28, 1975, through January 15, 1976, of ample supplies of Valencia oranges of the more desirable sizes in the interest of both growers and consumers. The proposal is designed to maintain orderly marketing conditions, provide consumer satisfaction, and guard against the shipment of undesirable sizes of Valencia oranges, which tend to weaken the market for such fruit. The proposed extension of the effective period of Valencia Orange Regulation 487 is consistent with the size composition and estimated crop of Valencia oranges in District 3.

The proposal is as follows:

Amend paragraph (a) of Valencia Orange Regulation 487 (40 FR 8772) to read as follows:

§ 908.787 Valencia Orange Regulation 487.

* * * * * *

Order. (a) During the period April 28, 1975, through January 15, 1976, no han-

dler shall handle any Valencia oranges grown in District 3 which are of a size smaller than 2.20 inches in diameter, which shall be the largest measurement at a right angle to a straight line running from the stem to the blossom end of the fruit: *Provided*, That not to exceed 5 percent, by count, of the Valencia oranges contained in any type of container may measure smaller than 2.20 inches in diameter.

* * * * * *

All persons who desire to submit written data, views, or arguments for consideration in connection with the proposed amendment shall file same, in quadruplicate, with the Hearing Clerk, United States Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than April 14, 1975. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Dated: March 21, 1975.

CHARLES R. BRADER,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-7959 Filed 3-26-75;8:45 am]

[7 CFR Part 1251]

[Docket No. ERPA-1]

EGG RESEARCH AND PROMOTION

Hearing on Proposed Order

Notice is hereby given of a public hearing on a proposed national research and promotion order for eggs. The hearing will be held at each of the five locations beginning on the dates listed below:

1. May 6, 1975—Atlanta, GA 30309, Townhouse Motor Inn, 100-10th Street, N.W.
2. May 12, 1975—Philadelphia, PA 19106, Room 3306-3310, William J. Green, Jr. Federal Building, 600 Arch Street
3. May 15, 1975—Des Moines, IA 50309, Ramada Inn, 929 3rd Street
4. May 19, 1975—Dallas, TX 75235, Executive Inn, 3232 West Mockingbird Lane
5. May 22, 1975—South San Francisco, CA 94080, Holiday Inn, 245 South Airport Blvd.

Each day's session of the hearing will commence at 9:30 a.m., local time, unless the judge otherwise specifies during the course of the hearing. The hearing is called pursuant to the Egg Research and Consumer Information Act (88 Stat. 1171-1179, (7 U.S.C. 2701 et seq.)), and in accordance with the applicable rules of practice and procedure governing proceedings to formulate an order (7 CFR Part 1250).

The public hearing is for the purpose of: (a) receiving evidence, with respect to the economic and marketing conditions which relate to the proposed order, hereinafter set forth, and to any appropriate modifications thereof; (b) determining the extent of need for an order to implement a nationwide coordinated egg research and promotion program; and (c) determining whether provisions specified in the proposed order or some other provisions appropriate to the terms of the Egg Research and Consumer Information Act (88 Stat. 1171-1179 (7 U.S.C. 2701 et seq.)) will tend to effectuate the declared policy of the Act.

The proposed order, set forth below, has not received the approval of the Secretary of Agriculture.

The proposed order was submitted to the Secretary of Agriculture, with a request for a public hearing thereon, by:

Alabama Poultry and Egg Association
American Egg Board
Georgia Poultry Federation
Georgia Egg Association
Indiana State Poultry Association
Kentucky Poultry Federation
Midwest Poultry Federation
Minnesota Poultry and Hatchery Association
Northeastern Poultry Producers Council
Ohio Egg Marketing Association
Ohio Poultry Association
Pacific Egg and Poultry Association
Poultry and Egg Institute of America
South Carolina Egg Board
Southeastern Poultry and Egg Association
Tennessee Egg and Poultry Association
Texas Poultry Federation and Affiliates
United Egg Producers
Virginia Egg Council

The provisions of the proposed Egg Research and Promotion Order are:

PART 1251—EGG RESEARCH AND PROMOTION ORDER

DEFINITIONS

Sec.
1251.301 Secretary.
1251.302 Act.
1251.303 Fiscal period.
1251.304 Egg Board.
1251.305 Egg producer.
1251.306 Commercial eggs or eggs.
1251.307 Person.
1251.308 United States.
1251.309 Handler.
1251.310 Promotion.
1251.311 Research.
1251.312 Marketing.
1251.313 Eligible organization.
1251.314 Plans and projects.
1251.315 Part and subpart.

EGG BOARD

1251.316 Establishment and membership.
1251.317 Term of office.
1251.318 Nominations.
1251.319 Selection.
1251.320 Acceptance.
1251.321 Vacancies.
1251.322 Alternative members.
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1251.324 Compensation and reimbursement.
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RESEARCH, EDUCATION, AND PROMOTION

1251.327 Research, education, and promotion.

EXPENSES AND ASSESSMENTS

Sec.
1251.328 Expenses.
1251.329 Assessments.
1251.330 Collecting handlers and collection.
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1251.332 Influencing governmental action.

REPORTS, BOOKS, AND RECORDS

1251.333 Reports.
1251.334 Books and records.
1251.335 Confidential treatment.

CERTIFICATION OF ORGANIZATIONS

1251.336 Certification of organizations.

MISCELLANEOUS

1251.337 Suspension and termination.
1251.338 Proceedings after termination.
1251.339 Effect of termination or amendment.
1251.340 Personal liability.
1251.341 Separability.

DEFINITIONS

§ 1251.301 Secretary.

"Secretary" means the Secretary of Agriculture or any other officer or employee of the Department of Agriculture to whom there has heretofore been delegated, or to whom there may hereafter be delegated, the authority to act in his stead.

§ 1251.302 Act.

"Act" means the Egg Research and Consumer Information Act (Pub. L. 93-428).

§ 1251.303 Fiscal period.

"Fiscal period" means the calendar year unless the Egg Board, with the approval of the Secretary, selects some other budgetary period.

§ 1251.304 Egg Board.

"Egg Board" or "Board" means the administrative body established pursuant to § 1251.316.

§ 1251.305 Egg producer.

"Egg producer" or "producer" means the person owning laying hens engaged in the production of commercial eggs.

§ 1251.306 Commercial eggs or eggs.

"Commercial eggs" or "eggs" means eggs from domesticated chickens which are sold for human consumption either in shell egg form or for further processing into egg products.

§ 1251.307 Person.

"Person" means any individual, group of individuals, partnership, corporation, association, cooperative, or any other entity.

§ 1251.308 United States.

"United States" means the 48 contiguous States of the United States of America and the District of Columbia.

§ 1251.309 Handler.

"Handler" means any person, specified in this subpart or the rules and regulations issued thereunder, who receives or otherwise acquires eggs from an egg producer, and processes, prepares for marketing, or markets, such eggs, including eggs of his own production.

§ 1251.310 Promotion.

"Promotion" means any action, including paid advertising, to advance the image or desirability of eggs, egg products, spent fowl, or products of spent fowl.

§ 1251.311 Research.

"Research" means any type of research to advance the image, desirability, mar-

ketability, production, or quality of eggs, egg products, spent fowl, or products of spent fowl.

§ 1251.312 Marketing.

"Marketing" means the sale or other disposition of commercial eggs, egg products, spent fowl, or products of spent fowl in any channel of commerce.

§ 1251.313 Eligible organization.

"Eligible organization" means any organization, association, or cooperative certified by the Secretary pursuant to § 1251.336.

§ 1251.314 Plans and projects.

"Plans" and "projects" mean those research, consumer and producer education, advertising, marketing, product development, and promotion plans, studies, or projects pursuant to § 1251.327.

§ 1251.315 Part and subpart.

"Part" means the Egg Research and Promotion Order and all rules, regulations, and supplemental order issued pursuant to the act and the order, and the aforesaid order shall be a "subpart" of such part.

EGG BOARD

§ 1251.316 Establishment and membership.

There is hereby established an Egg Board, hereinafter called the "Board", composed of 18 egg producers or representatives of egg producers, each of whom shall have an alternate, appointed by the Secretary from nominations submitted by eligible organizations, associations or cooperatives or by other producers pursuant to § 1251.318.

§ 1251.317 Term of office.

The members of the Board, and their alternates, shall serve for terms of 2 years, except initial appointments shall be, proportionately, for terms of 2 and 3 years. Each member and alternate member shall continue to serve until his successor is appointed by the Secretary and has qualified. No member shall serve for more than three consecutive terms.

§ 1251.318 Nominations.

All nominations authorized under § 1251.316 shall be made in the following manner:

(a) Within 30 days of the approval of this order by referendum, nominations shall be submitted to the Secretary by eligible organizations, associations, or cooperatives certified pursuant to § 1251.336, or, if the Secretary determines that a substantial number of egg producers are not members of, or their interests are not represented by, any such eligible organization, association, or cooperative, then from nominations made by such egg producers in the manner authorized by the Secretary.

(b) After the establishment of the initial Board, the nominations for subsequent Board members and alternates shall be submitted to the Secretary not less than 60 days prior to the expiration of the terms of the members and alternates previously appointed to the Board.

(c) Where there is more than one eligible organization, association, or cooperative within each geographic area, as defined by the Secretary, they may caucus for the purpose of jointly nominating two qualified persons for each member and for each alternate member to be appointed. If joint agreement is not reached with respect to any such nominations, or if no caucus is held within a defined geographic area, each eligible organization, association, or cooperative may submit to the Secretary two nominations for each appointment to be made.

§ 1251.319 Selection.

From the nominations made pursuant to § 1251.318, the Secretary shall appoint the members of the Board, and an alternate for each such member, on the basis of representations provided for in § 1251.316 and § 1251.317.

§ 1251.320 Acceptance.

Any person appointed by the Secretary as a member, or as an alternate member, of the Board shall qualify by filing a written acceptance with the Secretary within a period of time prescribed by the Secretary.

§ 1251.321 Vacancies.

To fill any vacancy occasioned by the failure to qualify of any person appointed as a member, or as an alternate member, of the Board, or in the event of the death, removal, resignation, or disqualification of any member or alternate member of the Board, a successor for the unexpired term of such member or alternate member of the Board shall be nominated, qualified, and appointed in the manner specified in § 1251.316, § 1251.318, § 1251.319, and § 1251.320.

§ 1251.322 Alternate members.

An alternate member of the Board, during the absence of the member for whom he or she is the alternate, shall act in the place and stead of such member and perform such other duties as assigned. In the event of the death, removal, resignation, or disqualification of a member, his alternate shall act for him until a successor for such member is appointed and qualified.

§ 1251.323 Procedure.

(a) A majority of the members, including alternates acting for members of the Board, shall constitute a quorum, and any action of the Board shall require the concurring votes of at least a majority of those present and voting. At assembled meetings, all votes shall be cast in person.

(b) For routine and noncontroversial matters which do not require deliberation and exchange of views, and in matters of an emergency nature when there is not enough time to call an assembled meeting of the Board, the Board may also take action upon the concurring votes of a majority of its members by mail, telephone, or telegraph, but any such action by telephone shall be confirmed promptly in writing.

§ 1251.324 Compensation and reimbursement.

The members of the Board, and alternates when acting as members, shall serve without compensation but shall be reimbursed for necessary and reasonable expenses, as approved by the Board, incurred by them in the performance of their duties under this subpart.

§ 1251.325 Powers of the Board.

The Board shall have the following powers:

(a) To administer the provisions of this subpart in accordance with its terms and provisions;

(b) To make rules and regulations to effectuate the terms and provisions of this subpart;

(c) To receive, investigate, and report to the Secretary complaints of violations of the provisions of this subpart; and

(d) To recommend to the Secretary amendments to this subpart.

§ 1251.326 Duties.

The Board shall have the following duties:

(a) To meet and organize and to select from among its members a chairman and such other officers as may be necessary, to select committees and subcommittees of Board members, to adopt such rules for the conduct of its business as it may deem advisable, and it may establish advisory committees of persons other than Board members;

(b) To appoint or employ such persons as it may deem necessary and to define the duties and determine the compensation of each;

(c) To prepare and submit to the Secretary for this approval budgets on a fiscal-period basis of its anticipated expenses and disbursements in the administration of this subpart, including probable costs of plans and projects as estimated in the budget or budgets submitted to it by prospective contractors, with the Board's recommendations with respect thereto;

(d) With the approval of the Secretary, to enter into contracts or agreements with persons, including, but not limited to, State, regional, or national agencies or State, regional, or national egg organizations which administer research, education, or promotion programs, advertising agencies, public relations firms, public or private research organizations, advertising and promotion media, and egg producer organizations, for the development and submission to it of plans and projects authorized by § 1251.327 and for the carrying out of such plans or projects when approved by the Secretary, and for the payment of the cost thereof with funds collected pursuant to § 1251.329. Any such contracts or agreements shall provide that such contractors shall develop and submit to the Board a plan or project together with a budget or budgets which shall show estimated costs to be incurred for such projects, and that any such plan or projects shall become effective upon approval by the Secretary.

Any such contract or agreement shall also provide that the contractor shall keep accurate records of all of its transactions and make periodic reports to the Board of activities carried out and an accounting for funds received and expended, and such other reports as the Secretary may require;

(e) To review and submit to the Secretary any plans or projects which have been developed and submitted to it by the prospective contractor, together with its recommendations with respect to the approval thereof by the Secretary;

(f) To maintain such books and records and prepare and submit such reports from time to time to the Secretary as he may prescribe, and to make appropriate accounting with respect to the receipt and disbursement of all funds entrusted to it;

(g) To prepare and make public, at least annually, a report of activities carried out and an accounting for funds received and expended;

(h) To cause its books to be audited by a competent public accountant at least once each fiscal period and at such other times as the Secretary may request, and submit a copy of each such audit to the Secretary;

(i) To give the Secretary the same notice of meetings of the Board as is given to members in order that his representative may attend such meetings;

(j) To act as an intermediary between the Secretary and any producer or handler; and

(k) To submit to the Secretary such information pursuant to this subpart as he may request.

RESEARCH, EDUCATION, AND PROMOTION

§ 1251.327 Research, education, and promotion.

The Board shall develop and submit to the Secretary for approval any programs or projects authorized in this section. Such programs or projects shall provide for:

(a) The establishment, issuance, effectuation, and administration of appropriate plans or projects for advertising, sales promotion, and consumer education with respect to the use of eggs, egg products, spent fowl, and products of spent fowl: *Provided, however,* That any such program or project shall be directed towards increasing the general demand for eggs, egg products, spent fowl, or products of spent fowl;

(b) The establishment and carrying on of research, marketing, and development projects and studies with respect to sale, distribution, marketing, utilization, or production of eggs, egg products, spent fowl, and products of spent fowl, and the creation of new products thereof in accordance with section 7(b) of the act, to the end that the marketing and utilization of eggs, egg products, spent fowl, and products of spent fowl may be encouraged, expanded, improved, or made more acceptable, and the data collected by such activities may be disseminated;

(c) The development and expansion of foreign markets and uses for eggs, egg products, spent fowl, and products of spent fowl;

(d) Each program or project authorized under subparagraphs (a), (b), and (c) of this section shall be periodically reviewed by the Board to insure that each such program or project contributes to a coordinated national program of research, education, and promotion contributing to the maintenance of markets and for the development of new markets and of new products from eggs, egg products, spent fowl, and products of spent fowl. If it is found by the Board that any such program or project does not further the national purpose of the act, then the Board shall terminate such program or project; and

(e) No advertising or promotion programs shall use false or unwarranted claims or make any reference to private brand names of eggs, egg products, spent fowl, and products of spent fowl or use unfair or deceptive acts or practices with respect to quality, value, or use of any competing product.

EXPENSES AND ASSESSMENTS

§ 1251.328 Expenses.

The Board is authorized to incur such expenses as the Secretary finds are reasonable and likely to be incurred by the Board for its maintenance and functioning and to enable it to exercise its powers and perform its duties in accordance with the provisions of this subpart. The funds to cover such expenses shall be paid from assessments received pursuant to § 1251.329.

§ 1251.329 Assessments.

Each handler designated in § 1251.330 and pursuant to regulations issued by the Board shall collect from each producer, except those categories specified by section 12(a) or (b) of the act, and shall pay to the Board, at such times and in such manner as prescribed by regulations issued by the Board, an assessment at the rate of 5 cents per 30-dozen case of eggs or the equivalent thereof unless lowered by the Board and approved by the Secretary, for such expenses and expenditures, including provisions for a reasonable reserve and those administrative costs incurred by the Department of Agriculture after this subpart is effective, as the Secretary finds are reasonable and likely to be incurred by the Board under this subpart, except that no more than one such assessment shall be made on any case of eggs.

§ 1251.330 Collecting handlers and collection.

(a) Handlers responsible for collecting the assessment specified in § 1251.329 shall be any one of the following:

(1) The first person to whom eggs are sold, consigned, or delivered by producers and who grades, cartons, breaks, or otherwise performs a function of a handler under § 1251.309, (2) a producer who grades, cartons, breaks, or otherwise performs a function of a handler under § 1251.309 for eggs of his own production, (3) any person who handles eggs for a producer under oral or written agreement providing for the marketing thereof, (4) any person who purchases eggs from producers for the purpose of resale, or (5) such other persons as designated by the Board under rules and regulations issued pursuant to this subpart.

(b) Handlers defined in paragraph (a)(4) of this section who sell eggs on which the assessment has been collected by another handler shall also transfer to the purchaser the collected assessments and records of collection. Handlers defined in paragraph (a)(1) of this section who sell eggs, on which the assessment has been collected, to another handler shall certify that with respect to such eggs he has complied with this subpart and to the rules and regulations issued by the Board pursuant to this subpart.

(c) Handlers shall collect and remit to the Egg Board all assessments collected in the manner and in the time specified by the Board pursuant to rules and regulations issued by the Board.

(d) Handlers shall maintain such records as the Egg Board may prescribe pursuant to rules and regulations issued by the Board.

(e) The Board with the approval of the Secretary may authorize other organizations or agencies to collect assessments in its behalf.

§ 1251.331 Producer refunds.

Any egg producer against whose eggs any assessment is made under the authority of the act and collected from him and who is not in favor of supporting the programs as provided for in this subpart shall have the right to demand and receive from the Board a refund of such assessment upon submission of proof satisfactory to the Board that the producer paid the assessment for which refund is sought. Any such demand shall be made personally by such producer in accordance with regulations and on a form and within a time period prescribed by the Board and approved by the Secretary. Any such refund shall be made within 60 days after demand is received therefor.

§ 1251.332 Influencing governmental action.

No funds collected by the Board under this subpart shall in any manner be used for the purpose of influencing governmental policy or action except to recommend to the Secretary amendment to this subpart.

REPORTS, BOOKS, AND RECORDS

§ 1251.333 Reports.

Each handler subject to this subpart and other persons subject to section 7(c) of the act may be required to report to the Board periodically such information as is required by regulations and will effectuate the purposes of the act, which

information may include but not be limited to the following:

(a) Number of cases of eggs handled;

(b) Number of cases of eggs on which an assessment was collected;

(c) Name and address of person from whom any assessment is collected; and

(d) Date collection of assessment was made on each case of eggs handled.

§ 1251.334 Books and records.

Each handler subject to this subpart and persons subject to section 7(c) of the act shall maintain and make available for inspection by the Board and the Secretary such books and records as are necessary to carry out the provisions of the subpart and the regulations issued hereunder, including such records as are necessary to verify any reports required. Such records shall be retained for at least 2 years beyond the marketing year of their applicability.

§ 1251.335 Confidential treatment.

(a) All information obtained from such books, records, or reports shall be kept confidential by all officers and employees of the Department of Agriculture and the Board, and only such information so furnished or acquired as the Secretary deems relevant shall be disclosed by them, and then only in a suit or administrative hearing brought at the direction, or upon the request of the Secretary, or to which the Secretary or any officer of the United States is a party, and involving this subpart. Nothing in this subsection shall be deemed to prohibit (1) the issuance of general statements based upon the reports of the number of persons subject to this subpart or statistical data collected therefrom, which statements do not identify the information furnished by any person, (2) the publication, by direction of the Secretary, of general statements relating to refunds made by the Egg Board during any specific period of time, or (3) the publication, by direction of the Secretary, of the name of any person violating this subpart together with a statement of the particular provisions of this subpart violated by such person.

(b) All information with respect to refunds, except as provided in paragraph (a) (2) of this section made to individual producers shall be kept confidential by all officers and employees of the Department of Agriculture and the Board.

Certification of Organizations

§ 1251.336 Certification of organizations.

Any organization may request the Secretary for certification of eligibility to participate in nominating members and alternate members on the Board to represent the geographic area in which the organization represents egg producers. Such eligibility shall be based in addition to other available information upon a factual report submitted by the organization which shall contain information deemed relevant and specified by the Secretary for the making of such determination, including, but not limited to, the following:

(a) Geographic territory covered by the organization's active membership;

(b) Nature and size of the organization's active membership, proportion of total of such active membership accounted for by producers of commercial eggs, a chart showing the egg production by State in which the organization has members, and the volume of commercial eggs produced by the organization's active membership in such State(s);

(c) The extent to which the commercial egg producer membership of such organization is represented in setting the organization's policies;

(d) Evidence of stability and permanency of the organization;

(e) Sources from which the organization's operating funds are derived;

(f) Functions of the organization; and

(g) The organization's ability and willingness to further the aims and objectives of the act.

The primary consideration in determining the eligibility of an organization shall be whether its egg producer membership consists of a substantial number of egg producers who produce a substantial volume of the applicable geographic area's commercial eggs to reasonably warrant its participation in the nomination of members for the Board or to request the issuance of an order. The Secretary shall certify any organization which he finds to be eligible under this subsection and his determination as to eligibility shall be final.

Miscellaneous

§ 1251.337 Suspension and termination.

(a) The Secretary shall, whenever he finds that this subpart or any provision thereof obstructs or does not tend to effectuate the declared policy of the act, terminate or suspend the operation of this subpart or such provision.

(b) The Secretary may conduct a referendum at any time, and shall hold a referendum on request of 10 percent or more of the number of egg producers voting in the referendum approving this subpart, to determine whether egg producers favor the termination or suspension of this subpart, and the Secretary shall suspend or terminate such subpart at the end of 6 months after he determines that suspension or termination of the order is approved or favored by a majority of the egg producers voting in such referendum who, during a representative period determined by the Secretary, have been engaged in the production of commercial eggs, and who produced more than 50 percent of the volume of eggs produced by the egg producers voting in the referendum.

§ 1251.338 Proceedings after termination.

(a) Upon the termination of this subpart the Board shall recommend not more than six of its members to the Secretary to serve as trustees for the purpose of liquidating the affairs of the Board. Such persons, upon designation by the Secretary, shall become trustees of all the funds and property then in the possession or under control of the Board, including claims for any funds unpaid or property not delivered or any other claim existing at the time of such termination.

(b) The said trustees shall: (1) continue in such capacity until discharged by the Secretary, (2) carry out the obligations of the Board under any contracts or agreements entered into by it pursuant to § 1251.326, (3) from time to time account for all receipts and disbursements and deliver all property on hand, together with all books and records of the Board and of the trustees, to such person as the Secretary may direct, and (4) upon the request of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such person full title and right to all of the funds, property, and claims vested in the Board or the trustees pursuant to this subsection.

(c) Any person to whom funds, property, or claims have been transferred or delivered pursuant to this subsection shall be subject to the same obligation imposed upon the Board and upon the trustees.

(d) Any residual funds not required to defray the necessary expenses of liquidation shall be turned over to the Secretary to be disposed of, to the extent practicable, in the interest of continuing one or more of the research or promotion programs hitherto authorized.

§ 1251.339 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this subpart or of any regulation issued pursuant hereto, or the issuance of any amendment to either thereof, shall not:

(a) Affect or waive any right, duty, obligation, or liability which shall have arisen or which may hereafter arise in connection with any provision of this subpart or any regulation issued thereunder;

(b) Release or extinguish any violation of this subpart or any regulation issued hereunder; or

(c) Affect or impair any rights or remedies of the United States, or of the Secretary, or of any person, with respect to any such violation.

§ 1251.340 Personal liability.

No member or alternate member of the Board shall be held personally responsible, either individually or jointly with others, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts, either of commission or omission, as such member or alternate, except for acts of dishonesty, or wilful misconduct.

§ 1251.341 Separability.

If any provision of this subpart is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this subpart of the applicability thereof to other persons or circumstances shall not be affected thereby.

Single copies of this notice may be obtained from the Poultry Division, AMS, U.S. Department of Agriculture, Washington, D.C. 20250.

Signed at Washington, D.C. on March 21, 1975.

JOHN C. BLUM,
Associate Administrator.

[FR Doc.75-7690 Filed 3-26-75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 27]

CANNED PINEAPPLE JUICE

Proposal To Amend Standards of Identity and Quality

The Commissioner of Food and Drugs is issuing a proposal to amend the standards of identity and quality for canned pineapple juice (21 CFR 27.54 and 27.55) to provide for the use of concentrated pineapple juice and nutritive carbohydrate sweeteners; comments by May 27, 1975.

A. The Pineapple Growers Association of Hawaii, 1902 Financial Plaza of the Pacific, Honolulu, HI 96813, has filed a petition proposing that the standards of identity and quality for canned pineapple juice be amended to provide for optional use of concentrated pineapple juice in the preparation of the canned food. The Association also proposes that the standards be amended by adopting some recent changes made in other standards to reflect advances in food technology to meet consumers' demands without reducing their protection and by adopting some of the language set forth in an anticipated Codex Alimentarius International Standard for Pineapple Juice. Additionally, the Association proposes that the standards be amended (1) to provide for use of suitable dry nutritive carbohydrate sweeteners in lieu of naming each sweetener that may be used; (2) to provide for label declaration of all optional ingredients used and other labeling in accordance with the provisions of 21 CFR Part 1; and (3) to provide for, in the quality standard, a minimum pineapple juice soluble-solids requirement of 13.5° Brix for the product made from concentrate.

The grounds given by the petitioner in support of the proposed amendments are as follows:

1. Pineapple juice from concentrate can be produced as it is needed, rather than only during the harvest-canning season. Consequently, vitamin C loss due to aging will be minimized.

2. The new product will be more uniform than the standard canned pineapple juice since each can of the finished reconstituted product will be standardized to a minimum of 13.5° Brix.

3. Pineapple juice from concentrate has been successfully market tested for consumer acceptance in interstate commerce under temporary permits issued by the Food and Drug Administration.

4. The proposal to provide for suitable dry nutritive carbohydrate sweeteners will provide manufacturers with more flexibility in the use of sweetening agents and at the same time will benefit consumers economically.

The Pineapple Growers Association of Hawaii proposes that Part 27 be amended as follows:

1. Section 27.54 is revised to read as follows:

§ 27.54 Canned pineapple juice; identity; label statement of optional ingredients.

(a) Canned pineapple juice is the juice, intended for direct consumption, obtained by mechanical process, which may include centrifuging but not filtering, from the flesh or parts thereof, with or without core material, of sound, ripe pineapple (*Ananas comosus*). The juice may have been concentrated and later reconstituted with water suitable for the purpose of maintaining essential composition and quality factors of the juice. Canned pineapple juice contains finely divided insoluble solids, but it does not contain pieces of shell, seeds or other coarse or hard substances. It may be sweetened with any suitable dry nutritive carbohydrate sweetener. It may contain added vitamin C in a quantity such that the total vitamin C in each 4 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 60 milligrams. In the canning of pineapple juice, dimethylpolysiloxane complying with the requirements of § 121.1099 of this chapter may be employed as a defoaming agent in an amount not greater than 10 parts per million by weight of the finished food. Before or after sealing in the container, canned pineapple juice is so processed by heat as to prevent spoilage.

(b) The name of the food is "Pineapple Juice" if the juice from which it is prepared has not been concentrated and/or diluted with water. The name of the food is "Pineapple Juice from Concentrate" if the finished juice has been made from pineapple juice concentrate as specified in paragraph (a) of this section. If a nutritive sweetener is added, the label shall bear the statement "Sweetener added." If no sweetener is added, the word "Unsweetened" may immediately precede or follow the words "Pineapple Juice" or "Pineapple Juice from Concentrate."

(c) Each of the optional ingredients shall be declared on the label as required by the applicable sections of Part 1 of this chapter.

2. Section 27.55, paragraph (a) (1) is revised to read as follows:

§ 27.55 Canned pineapple juice; quality; label statement of substandard quality.

(a) The standard of quality for canned pineapple juice is as follows:

(1) The soluble solids content of pineapple juice (exclusive of added sugars) without added water shall not be less than 10.5° Brix as determined by refractometer at 20° C, uncorrected for acidity and read as °Brix on International Sucrose Scales. Where the juice has been obtained using concentrated juice with addition of water, the soluble pineapple juice solids content (exclusive of added sugars) shall be not less than 13.5° Brix, uncorrected for acidity and read as °Brix on the International Sucrose Scales.

* * * * * *

B. In regard to the petitioner's proposal to provide for the use of nutritive carbohydrate sweeteners that are "suitable" and "dry" and have the statement "Sweetener added" declared on the label of the food to which they are added, the Commissioner offers the following comments and proposes several changes:

1. Whereas the petitioner proposes to provide for only the "dry" form of sweeteners, the Commissioner recognizes that it may be more efficient and economical for a packer who wishes to sweeten a pineapple juice prepared from concentrate to use a liquid sweetener as a means of reconstituting the concentrate. Therefore, the Commissioner invites comments as to whether or not it would be reasonable and would promote consumers' interests to provide also for the optional use of liquid sweeteners in juice that is prepared from concentrate.

2. To avoid possible misinterpretation of the petitioner's proposal regarding the declaration of sweeteners by means of the label statement "Sweetener added," the Commissioner advises that, if adopted, this statement would be in addition to, and not in lieu of, a label declaration of the common or usual name of the sweetener used, as required by 21 CFR Part 1.

3. Questions have been raised as to whether sweeteners such as mannitol and sorbitol fall into the category of "safe and suitable" nutritive carbohydrate sweeteners. The Commissioner is aware that chemical books and scientific dictionaries may differ in the definition of the term "carbohydrate." For the purpose of clarification, he concludes that mannitol and sorbitol are sugar alcohols instead of carbohydrate sweeteners and, therefore, are not suitable for use in canned pineapple juice.

4. The Federal Food, Drug, and Cosmetic Act does not permit unsafe ingredients or unsafe quantities of ingredients to be used in foods. The Commissioner, however, is of the opinion that in "nonrecipe" type identity standards (in which the permitted ingredients are not always specifically identified but, instead, are provided for by "class" designations) the requirement that they be safe should be emphasized to serve as a reminder to those who must comply with the standards. Therefore, he proposes that the word "safe" also be used in the phrase "suitable dry nutritive carbohydrate sweeteners" proposed by the petitioner.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, as amended, 70 Stat. 919; (21 U.S.C. 341, 371(e))) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 27 be amended by revising § 27.54(a) to read as follows:

§ 27.54 Canned pineapple juice; identity; label statement of optional ingredients.

(a) Canned pineapple juice is the juice, intended for direct consumption, obtained by mechanical process, which may include centrifuging but not filtering, from the flesh or parts thereof, with or without core material of sound, ripe pineapple (*Ananas comosus*). The juice may have been concentrated and later reconstituted with water suitable for the purpose of maintaining essential composition and quality factors of the juice. Canned pineapple juice contains finely divided insoluble solids, but it does not contain pieces of shell, seeds, or other coarse or hard substances. It may be sweetened with any safe and suitable dry nutritive carbohydrate sweetener. It may contain added vitamin C in a quantity such that the total vitamin C in each 4 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 60 milligrams. In the canning of pineapple juice, dimethylpolysiloxane, complying with the requirements of § 121.1099 of this chapter, may be employed as a defoaming agent in an amount not greater than 10 parts per million by weight of the finished food. Before or after sealing in the container, canned pineapple juice is so processed by heat as to prevent spoilage.

* * * * *

Interested persons may on or before May 27, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding these proposals. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: March 18, 1975.

HOWARD R. ROBERTS,
Acting Director, Bureau of Foods.

[FR Doc.75–7956 Filed 3–26–75;8:45 am]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[33 CFR Part 117]

[CGD 75–062]

OKLAWAHA RIVER, FLORIDA

Proposed Drawbridge Operation Regulations

At the request of Marion County Board of County Commissioners, the Coast Guard is considering amending the regulations for the Sharpes Ferry drawbridge across the Oklawaha River to require that the draw open on signal from 7 a.m. to 7 p.m. Saturday and Sunday, and from 7 a.m. to 9 a.m., and 5 p.m. to 7 p.m. Monday through Friday. At all other times, at least 1 hour notice would be required. This change is being considered because of infrequent openings for vessels (4 from 24 June 1971 through 27 May 1974).

Interested persons may participate in this proposed rule making by submitting written data, views, or arguments to the Commander (oan), Seventh Coast Guard District, Room 1018, Federal Building, 51 SW 1st Avenue, Miami, Florida 33130. Each person submitting comments should include his name and address, identify the bridge, and give reasons for any recommended change in the proposal. Copies of all written communications received will be available for examination by interested persons at the office of the Commander, Seventh Coast Guard District.

The Commander, Seventh Coast Guard District, will forward any comments received before April 29, 1975, with his recommendations to the Chief, Office of Marine Environment and Systems, who will evaluate all communications received and take final action on this proposal. The proposed regulations may be changed in the light of comments received.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations, be amended by revising § 117.434 to read as follows:

§ 117.434 Oklawaha River, Florida.

(a) *Sharpes Ferry Bridge.* From 7 a.m. to 7 p.m. on Saturday and Sunday, and from 7 a.m. to 9 a.m. and 5 p.m. to 7 p.m., Monday through Friday, the draw shall open on signal. At all other times the draw shall open on signal if at least 1 hours notice is given.

(b) *Bridges over the Oklawaha River, north of State Road 464 at Mullan Farms, State Road 464 at Moss Bluff and State Road 42 at Starkes Ferry.* From 7 a.m. to 7 p.m. the draws shall open on signal. From 7 p.m. to 7 a.m. the draws shall open on signal if at least 3 hours notice is given.

(c) The owner of or agency controlling each bridge shall conspicuously post notices containing these regulations both upstream and downstream of each bridge, on the bridge or elsewhere, in such a manner that they can easily be read at all times from an approaching vessel. The notice shall state how the authorized representative may be reached.

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937; (33 U.S.C. 499, 49 U.S.C. 1655(g)(2)); 49 CFR 1.46(c)(5), 33 CFR 1.05–1(c)(4)).

Dated: March 19, 1975.

R. I. PRICE,
Rear Admiral, U.S. Coast Guard Chief, Office of Marine Environment and Systems.

[FR Doc.75–7982 Filed 3–26–75;8:45 am]

[33 CFR Part 117]

[CGD 75053]

MYSTIC RIVER, MASS.

Proposed Drawbridge Operation Regulations

At the request of the Massachusetts Bay Transit Authority (MBTA), the Coast Guard is considering amending the regulations for the MBTA drawbridge across the Mystic River, mile 1.4, to require at least 24 hours notice for openings of the draw at all times. Present regulations require that the draw open on signal. This change is being considered because of limited demands for openings of the draw.

Interested persons may participate in this proposed rule making by submitting written data, views, or arguments to the Commander (oan), First Coast Guard District, 150 Causeway Street, Boston, Mass. 02114. Each person submitting comments should include his name and address, identify the bridge, and give reasons for any recommended change in the proposal. Copies of all written communications received will be available for examination by interested persons at the office of the Commander, First Coast Guard District.

The Commander, First Coast Guard District, will forward any comments received before April 29, 1975, with his recommendations to the Chief, Office of Marine Environment and Systems, who will evaluate all communications received and take final action on this proposal. The proposed regulations may be changed in the light of comments received.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations, be amended by revising paragraph (g)(1) of § 117.75 and by adding a new paragraph (g)(1–a).

§ 117.75 Boston Harbor, Mass., and adjacent waters; bridges.

* * * * *

(g) *Mystic River* (1) *Malden Bridge, mile 1.4 and Boston and Maine Railroad Bridge, mile 1.8.* The draws shall open on signal. However from 7:45 to 9 a.m., 9:10 to 10 a.m., and 5 to 6 p.m., except Sundays and legal holidays, the draws need not open for the passage of a vessel whose draft is less than 18 feet.

(1–a) *Massachusetts Bay Transit Authority (MBTA)—Railroad bridge, mile 1.4.* The draw shall open on signal if at least 24 hours notice is given to the MBTA dispatcher.

* * * * *

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937; (33 U.S.C. 499, 49 U.S.C. 1655(g)(2)); 49 CFR 1.46(c)(5), 33 CFR 1.05–1(c)(4)).

Dated: March 19, 1975.

R. I. PRICE,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.

[FR Doc.75–7984 Filed 3–26–75;8:45 am]

[33 CFR Part 117]

[CGD 75–070]

WEST PALM BEACH CANAL, FLORIDA

Proposed Drawbridge Operation Regulations

At the request of the Florida Department of Transportation, the Coast Guard is considering revising the regulations for the U.S. 1 drawbridge across the West Palm Beach Canal to require that the draw open on signal if at least 24 hours

notice is given. Presently the draw is required to open on signal from 9 a.m. to 5 p.m. This change is being considered because of infrequent requests for openings from vessels. There were no openings in 1974.

Interested persons may participate in this proposed rule making by submitting written data, views, or arguments to the Commander (oan), Seventh Coast Guard District, Room 1018, Federal Building, 51 S.W. 1st Avenue, Miami, Florida 33130. Each person submitting comments should include his name and address, identify the bridge, and give reasons for any recommended change in the proposal. Copies of all written communications received will be available for examination by interested persons at the office of the Commander, Seventh Coast Guard District.

The Commander, Seventh Coast Guard District, will forward any comments received before April 29, 1975, with his recommendations to the Chief, Office of Marine Environment and Systems, who will evaluate all communications received and take final action on this proposal. The proposed regulations may be changed in the light of comments received.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations, be amended by revising § 117.441a to read as follows:

§ 117.441a West Palm Beach Canal, Florida; U.S. 1 bridge.

The draw shall open on signal if at least 24 hours notice is given.

(Sec. 5, 28 Stat. 362, as amended, sec. 6(g)(2), 80 Stat. 937 (33 U.S.C. 499, 49 U.S.C. 1655(g)(2)); 49 CFR 1.46(c)(5), 33 CFR 1.05-1(c)(4))

Dated: March 19, 1975.

R. I. PRICE,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.

[FR Doc.75-7983 Filed 3-26-75;8:45 am]

Federal Aviation Administration

[14 CFR Part 71]

[Airspace Docket No. 75-WE-2]

TRANSITION AREA

Proposed Alteration

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal aviation regulations that would alter the description of the Oxnard, California Transition Area.

Interested persons may participate in the proposed rule making by submitting such written data, views, or arguments as they may desire. Communications should be submitted in triplicate to the Chief, Airspace and Procedures Branch, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261. All communications received on or before April 28, 1975, will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Regional Air Traffic Division Chief. Any data, views, or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

A public document will be available for examination by interested persons in the Office of the Regional Counsel, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261.

Radar procedures have been established by Point Mugu Approach Control for Ventura County Airport and NAS Point Mugu. In addition, a new instrument approach procedure has been developed to serve RWY 21 at NAS Point Mugu. The proposed 700 foot transition area provides additional controlled airspace for the instrument approach procedure and for radar vectoring.

In consideration of the foregoing, the FAA proposes the following airspace action.

In § 71.181 (40 FR 441) the description of the Oxnard, California 700 foot transition area is amended to read as follows:

OXNARD, CALIFORNIA

That airspace extending upward from 700 feet above the surface beginning at latitude 34°01'50" N., longitude 119°03'00" W., to latitude 34°02'30" N., longitude 118°53'30" W., to latitude 34°19'30" N., longitude 118°53'00" W., to latitude 34°19'30" N., longitude 119°29'50" W., thence 3 nautical miles from and parallel to the shoreline to latitude 34°14'50" N., longitude 119°22'00" W., to latitude 34°14'45" N., longitude 119°23'30" W., to latitude 34°06'55" N., longitude 119°22'30" W., to latitude 34°07'45" N., longitude 119°15'00" W., thence via a 7-mile radius of the Point Mugu RBN to point of beginning.

This amendment is proposed under the authority of sec. 307(a) of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1348(a)), and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Los Angeles, California, on March 17, 1975.

LYNN L. HINK,
Acting Director, Western Region.

[FR Doc.75-7916 Filed 3-26-75;8:45 am]

[14 CFR PART 71]

[Airspace Docket No. 75-NE-10]

TRANSITION AREA

Proposed Designation

The Federal Aviation Administration is considering an amendment to § 71.181 of Part 71 of the Federal Aviation Regulations that would designate a 1200-foot transition area in the northwest section of the State of Maine and the northeast section of the State of New Hampshire, in the vicinity of the Sugarloaf Regional Airport. The designation of this transition area would provide additional air traffic control flexibility in routing aircraft via direct and radar vector routes in the enroute system.

Interested persons may submit such written data or views as they may desire. Communications should be submitted in triplicate to the Director, New England Region, Attention: Chief, Air Traffic Division, Department of Transportation, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803. All communications received on or before April 28, 1975, will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements may be made for informal conferences with Federal Aviation Administration officials by contracting the Chief, Operations, Procedures and Airspace Branch, New England Region.

Any data or views presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

The official docket will be available for examination by interested persons at the Office of the Regional Counsel, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts.

In consideration of the foregoing, the Federal Aviation Administration proposes to amend § 71.181 of Part 71 of the Federal Aviation Regulations by adding the following 1200-foot transition area:

SUGARLOAF, MAINE

That airspace extending upward from 1200-
That airspace extending upward from 1200-feet above the surface within an area bounded by a line beginning at latitude 45°04'20"N, longitude 71°27'00"W to latitude 45°17'00" N, longitude 71°20'10"W to latitude 45°20'40" N, longitude 70°39'30" W to latitude 45°21'40"N, longitude 70°39'-00"W to latitude 45°22'30"N, longitude 70°08'10"W to latitude 45°25'00"N, longitude 69°48'00"W to latitude 45°23'00"N, longitude 69°48'00"W to latitude 45°14'50" N, longitude 69°50'20"W to latitude 45°07'-50"N, longitude 69°50'20"W to latitude 45°07'50"N, longitude 69°28'00"W to latitude 44°50'00"N, longitude 69°47'10"W to latitude 44°39'00"N, longitude 69°47'10"W to latitude 44°16'10"N, longitude 70°14'00"W to latitude 44°13'50"N, longitude 70°12'00" W to latitude 44°02'10"N, longitude 70°37'50"W to latitude 44°04'00"N, longitude 70°40'10"W to latitude 44°06'00"N, longitude 70°37'00"W to latitude 44°06'10"N, longitude 70°59'10"W to latitude 44°14'30"N, longitude 70°52'30"W to latitude 44°21'00"N, longitude 70°57'10"W to latitude 44°29'30"N, longitude 71°01'10"W to latitude 44°31'00"N, longitude 70°55'00"W to latitude 44°39'00"N, longitude 71°00'00"W to latitude 44°54'50"N, longitude 71°01'50"W to latitude 44°53'00"N, longitude 71°18'00"W, to point of beginning, excluding Canadian airspace.

(Sec. 307(a) of the Federal Aviation Act of 1958 (72 Stat. 749; 49 U.S.C. 1348) and sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).)

Issued in Burlington, Massachusetts, on March 13, 1975.

QUENTIN S. TAYLOR,
Director, New England Region.

[FR Doc.75-8045 Filed 3-26-75;8:45 am]

[40 CFR Part 52]

[FRL 350-5]

IMPLEMENTATION PLANS

California: Approval of Compliance Schedules

On May 31, 1972 (37 FR 10842), September 22, 1972 (37 FR 19812), and May 14, 1973 (38 FR 12702), pursuant to Section 110 of the Clean Air Act, as amended (42 U.S.C. 1857c-5) and 40 CFR Part 51, the Administrator approved and promulgated portions of the California plan for the implementation of the national ambient air quality standards. On December 4, 1974 and on January 13, 1975, after notice and public hearings, the Governor of California through his designee submitted to the Environmental Protection Agency (EPA) revisions to the state compliance schedule portion of the approved plan. This publication proposes that these revisions be approved, with specific exceptions discussed below, pursuant to section 110 of the Clean Air Act and 40 CFR 51.8

Thirty-seven compliance schedules were submitted. The schedules have been found to satisfy the requirements of section 110 of the Clean Air Act and 40 CFR Part 51. However, 10 of the schedules have expired and the affected sources are now required to be in compliance with the applicable air pollution control regulations. Therefore, EPA will take no action with regard to the compliance schedules submitted for these sources. It is proposed that the remaining 27 schedules listed below be approved as revisions to the State plan. (The schedule for the U.S. Navy, San Diego, has 3 parts).

Each proposed compliance schedule revision establishes a new date by which the individual air pollution source must comply with an emission limitation specified by the implementation plan. This date is indicated in the table below, under the heading "Final Compliance Date." In some cases, the schedule includes incremental steps towards compliance with the specified regulations. While the table below does not include these interim dates, the actual compliance schedule does. The increments of progress, as well as the final compliance date, are legally enforceable by the Administrator pursuant to section 113 of the Clean Air Act, as amended.

The heading "Effective Date" in the table below refers to the date the compliance schedule becomes effective for purposes of federal enforcement. The entry "Immediately" under that heading indicates that the schedule will be federally enforceable when the final promulgation of the schedule becomes effective.

Proposed compliance schedule revisions listed below are available for public inspection at the California Air Resources Board, at the office of EPA, Region IX, and at EPA's Washington, D.C. office, at the addresses listed below. An evaluation report setting forth EPA's position on each of the 27 schedules is also available at the office of EPA, Region IX.

State of California Air Resources Board,
1709 11th Street,
Sacramento CA 95814.

Environmental Protection Agency, Region IX,
Enforcement Division,
100 California Street,
San Francisco CA 94111.

Environmental Protection Agency,
Division of Stationary Source Enforcement,
Room 3202 Waterside Mall,
401 M Street SW.,
Washington D.C. 20460.

Interested persons are encouraged to submit written comments on any proposed compliance schedule. All comments postmarked on or before April 28, 1975 will be considered by EPA prior to finalizing this proposed rulemaking. Comments should be addressed to: Director, Enforcement Division, EPA, Region IX, 100 California Street, San Francisco, California 94111. All comments will be available for public inspection during business hours at the above address.

This proposed rulemaking is issued under the authority of section 110(a) of the Clean Air Act, as amended (42 U.S.C. § 1857c-5(a)).

Dated: March 13, 1975.

FRANK M. COVINGTON,
Acting Regional Administrator.

It is proposed to amend Part 52 of Chapter I, Title 40 of the Code of Federal Regulations as follows:

Subpart F—California

1. In § 52.220, paragraph (c) is amended as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(8) Supplemental information (compliance schedules) was submitted by the California Air Resources Board on December 27, 1973; February 19, April 22, June 7 and 19, September 4 and 19, October 18, and December 4, 1974; and January 13, 1975.

2. In § 52.240, paragraph (f) is amended by adding the following schedules to the table in subparagraph (1):

§ 52.240 Compliance schedules.

* * * * *

(f) * * *

(1) * * *

Source	Location (County)	Rule or regulation involved	Date of adoption	Effective date	Final compliance date
* * *					
Heppner Iron and Metal Co.	Fresno	407.2	Oct. 16, 1974	Immediately	July 1, 1975
United Alfalfa Mills (Order No. 2B as revised).	Imperial	114, 121	Sept. 11, 1974	do	Apr. 11, 1975
Southern Pacific Pipelines, Imperial Terminal (Order No. 1 as revised).	do	125	do	do	Mar. 11, 1975
Gulf Oil Corp. (Order No. 1303-18 as revised).	Los Angeles	53.2	June 11, 1974	do	Feb. 15, 1975
Masonite Corp. (Order No. 74-8 as revised).	Mendocino	V-1	Sept. 30, 1974	do	July 1, 1975
Harwood Products, Willits and Branscomb (Order No. 74-7 as revised).	do	V-1	do	do	Mar. 30, 1975
Castle Air Force Base (Order No. 74-2 as revised).	Merced	410	Aug. 19, 1974	do	Aug. 1, 1975
Delta Cotton Co. (Order No. 74-3)	do	401	do	do	July 30, 1975
Blythe Milling Co. (Order No. 74-10)	Riverside	50	Sept. 23, 1974	do	Mar. 15, 1975
Libby, McNeil, and Libby (as revised).	Sacramento	25	Sept. 30, 1974	do	May 1, 1975
* * *					
U.S. Navy:					
III. Activity Service Stations	San Diego	61, 63	Aug. 22, 1974	do	Sept. 30, 1975
V.2 Navy Public Works Center, Naval Station—Sandblasting Area 218.	do	50	do	do	Mar. 31, 1975
V.3 Naval Amphibious Base, Coronado—Sandblasting Area.	do	50	do	do	Do.
Pinkerton Foundry, Inc. (Order No. 73-7 as revised).	San Joaquin	401, 404, 405, 406.	Sept. 19, 1974	do	Mar. 15, 1975
Teichert Construction (Order No. 74-21).	do	401	do	do	June 30, 1975
The Learner Co. (Order No. 74-22 as revised).	do	401, 404	do	do	July 15, 1975
Lone Star Industries (Order No. 74-23)	do	401	do	do	Mar. 1, 1975
Stockton Elevators (Order No. 74-27 as revised).	do	401	do	do	Apr. 15, 1975
Lorenz Lumber Co. (Order No. 71-V-16 as revised).	Shasta	3.1, 3.2	Oct. 30, 1974	do	July 1, 1975
* * *					
Kimberly Clark Corp. (Order No. 71-V-27 as revised).	do	3.1, 3.2	do	do	July 31, 1975
Pine Mountain Lumber Co. (Order No. 74-3 as revised).	Siskiyou	4.1	Oct. 7, 1974	do	Feb. 23, 1975
U.S. Plywood Corp. (Order No. 74-4 as revised).	do	4.1	do	do	Apr. 7, 1975
Bedford Aggregates Gravel Plant (Order No. PV-74-01).	Tuolumne	401 (A), (B)	Oct. 3, 1974	do	July 31, 1975
Architectural Aggregates (Order No. PV-74-02).	do	401 (A), (B)	do	do	Do.
Woods Creek Gravel Plant (Order No. PV-74-03).	do	401 (A), (B)	do	do	Do.
Cal-Turf, Inc. (Order No. 123)	Ventura	52, 53	Aug. 27, 1974	do	Feb. 20, 1975
Halaco Engineering Co. (Order No. 125-1 as revised).	do	50	Oct. 16, 1974	do	Feb. 15, 1975
* * *					
Adams, Schwab and Adams Elevator Co. (Order No. 74-13).	Yolo	2.19	Oct. 8, 1974	do	July 31, 1975
Burmah Terminals, Inc. (Order No. 74-15).	do	2.21	do	do	Mar. 15, 1975

[FR Doc.75-7871 Filed 3-26-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 351-6]

IMPLEMENTATION PLANS

Florida: Approval of Plan Revisions

On May 31, 1972 (37 FR 10842), the Administrator approved portions of the Florida plan to attain and maintain the national ambient air quality standards. The State recently adopted, after notice and public hearing, a number of plan revisions which were then submitted to the Agency's regional office on February 12, 1975. The purpose of this notice is to describe two of these revisions, and to offer them for public comment. The two revisions involve changes in the sulfur dioxide emission limits for existing sulfur recovery plants and sulfuric acid plants.

Under the Florida implementation plan's original regulations for sulfur recovery plants, existing facilities were allowed to emit no more than 0.004 pounds of SO_2 for each pound of sulfur recovered from an oil well; this limit, to be achieved by July 1, 1975, corresponded to a sulfur recovery efficiency of 99.8 percent. Under the newly adopted regulation, existing plants would be subject to an immediately effective limit of 0.08 pounds of sulfur dioxide per pound of sulfur recovered; this corresponds to a recovery efficiency of 96 percent. All of the sources affected by the revised regulation are now operating in the Jay oil field (Santa Rosa County).

Submitted with the revision were air quality data and dispersion modeling results intended by the State to show that approval of its relaxed limits on SO_2 emissions from the sulfur recovery process would not hinder the attainment and maintenance of the national standards for this pollutant in the vicinity of the sources in question. Also submitted was a control strategy analysis designed to support the proposed changes.

The second of these revisions resulted from a petition of the Occidental Chemical Company, which operates two sulfuric acid plants in White Springs (Hamilton County). Under the regulations of the approved Florida plan, existing H_2SO_4 plants are required to achieve, by July 1, 1975, an emission limit of 10 pounds of SO_2 per ton of 100 percent sulfuric acid produced. This limit was based on the degree of SO_2 emission reduction needed to attain standards in the model County used in developing the plan's original control strategy for sulfur dioxide, that is, in Hillsborough County, site of the highest measured concentrations of the pollutant. The State now takes the position that this degree of control is not needed in Hamilton County, where there is only one other significant source of SO_2 emissions, and where the original emission limit might produce only a negligible improvement in air quality if achieved. Accordingly, it is proposed that for sulfuric acid plants in the Florida portion of the Jacksonville, Florida-Brunswick, Georgia Interstate Air Quality Control Region the emission limit be relaxed to 29# SO_2/ton 100 percent H_2SO_4. (The plants of Occidental Chemical Company presently emit about 35#/ton, as opposed to 42#/ton emitted in January, 1972.)

With this revision the State submitted new control strategy information, including air quality data and dispersion modeling results, intended to show that approval of the relaxed limit for sulfuric acid plants in the Jacksonville-Brunswick AQCR will not hinder the attainment and maintenance of the national standards for sulfur dioxide.

Copies of all the materials submitted by the State in support of these two revisions may be examined during normal business hours at the following locations:

Air Programs Office
Environmental Protection Agency
Region IV
1421 Peachtree Street, NE.
Atlanta, Georgia 30309

Department of Pollution Control
2562 Executive Center Circle, East
Montgomery Building
Tallahassee, Florida 32301

Department of Pollution Control
Northeast Region
3426 Bills Road
Jacksonville, Florida 32207

Also, the material related to sulfur recovery plants may be examined at the office of the Department of Pollution Control's Northwest Region, 1389 Shoreline Drive, Gulf Breeze, Florida 32561, as well as at the other regional offices of the Department in Orlando, Fort Lauderdale, Saint Petersburg, and Fort Myers.

An evaluation of the revised SO_2 limits and their effect can be had by consulting personnel of the Agency's Region IV Air Programs Office at the Atlanta address given above (404/526-3043).

Interested persons are encouraged to submit written comments on these plan revisions, and all relevant comments will be weighed carefully by the Agency before it takes action on the Florida proposals. To be considered, comments must be received on or before April 28, 1975, and should be addressed to the Acting Director of the Agency's Region IV Air Programs Office at the Atlanta address given above. It is the Administrator's tentative judgment that these two revisions satisfy the requirements of section 110(a) of the Clean Air Act and the implementing regulations of 40 CFR Part 51, and that they are thus approvable.

(Sec. 110(a) of the Clean Air Act (42 U.S.C. 1857c-5(a)))

Dated: March 14, 1975.

JACK E. RAVAN,
Regional Administrator, Region IV.

[FR Doc.75-8017 Filed 3-26-75;8:45 am]

[40 CFR Part 52]

[FRL 351-7]

IMPLEMENTATION PLANS

Maryland: Proposed Revision

On April 24, 1974 and December 11, 1974, the Governor of the State of Maryland submitted proposed revisions to the approved Maryland State Implementation Plan. These proposed revision covered a wide variety of additions, changes and deletions to Maryland Regulations 10.03.35 through 10.03.41 inclusive.

APRIL 24, 1974 SUBMITTAL

The April 24, 1974 submittal covered the following topics:

(1) Numerous amendments and changes to the Transportation Control Plans for the Metropolitan Baltimore Intra-State and the National Capital Interstate Air Quality Control Regions. These included revisions to the regulations governing Gasoline Transfer Vapor Control, Control of Evaporative Losses from Vehicular Tanks, Control of Dry Cleaning Solvent Evaporation and Control and Prohibition of Photochemically Reactive Organic Solvents;

(2) A number of proposed revisions to Maryland Regulation 10.03.35 governing the control of air pollution in the State of Maryland. These revisions included additions to the "Definitions" section of the plan; changes to the Air Pollution Episode Criteria; deletion of the entire section dealing with Prior Registration of Proposed Installations; a revision to the requirements for the registration of existing facilities; delineation of testing procedures for new and existing stationary emission sources; and a variety of changes to the source permitting procedures;

(3) Revisions to Maryland Regulations 10.03.36, 10.03.37, 10.03.40 and 10.03.41 governing the control of air pollution in Maryland Areas I, II, V and VI. These proposals included changes to the particulate matter regulations dealing with pathological incinerators; a revision in the definition of "photochemical oxidants"; and additions and changes to the methods for measurement of ambient air quality;

(4) Revisions to Maryland Regulations 10.03.38 and 10.03.39 governing the control of air pollution in Maryland Areas III and IV (the Metropolitan Baltimore Intrastate and the Maryland portion of the National Capital Interstate Air Quality Control Regions). These revisions included renumbering of certain parts of 10.03.38.03 and 10.03.39.03, dealing with the control and prohibition of Particulate Matter Emissions; a major addition to Maryland Regulations 10.03.38.04B, dealing with Sulfur Oxides from the burning of fuel which revises that section by limiting the sulfur in process gases used as fuel in existing installations to 0.3 percent by weight; revisions to the pertinent regulations dealing with Nitrogen Oxides Emission from Nitric Acid Plants; changes to the sections dealing with the prohibition of certain incinerators to exempt pathological incinerators; and numerous changes to Tables 1 and 3 of the Maryland Regulations concerning Emission and Dust Collector Performance Standards.

On April 26, 1974, the State of Maryland provided certification to the Administrator that, after having given adequate notice to the public, hearings on these amendments took place on August 10, 1973 and November 30, 1973, in Baltimore, Maryland; August 9, 1973, in Greenbelt, Maryland; and November 30, 1973, in Bethesda, Maryland.

Those sections of the April 24, 1974 submittal dealing with changes to the Transportation Control Plans for the Metropolitan Baltimore and the Maryland portion of the National Capital AQCR's were proposed as revisions to the approved Maryland State Implementation Plan on August 29, 1975 (39 FR 31533), as corrected on October 1, 1974 (39 FR

35386). The portions of the proposal dealing with the control and prohibition of photochemically reactive solvents was subsequently withdrawn on January 13, 1975 (40 FR 2448) due to several objections, including lack of justification of the stated cutoff size between regulated and unregulated sources, the vagueness of the criteria upon which the definition of "average daily emissions" was based, and the lack of specificity of the time period over which the emissions would be measured to determine whether they are in violation or not.

DECEMBER 11, 1974 SUBMITTAL

The December 11, 1974 submittal covered the following topics:

1) Renumbering and additions to Maryland Regulations 10.03.35.01, "Definitions";

2) A number of changes to Maryland Regulations 10.03.36 through 10.03.41 inclusive. These revisions included a change to section 10.03B(2)c (1) and (2) of Maryland Regulations 10.03.36 through 10.03.41 inclusive which would require dust collecting devices on certain new fuel burning equipment; a deletion of the 0.5 percent Sulfur Control Requirements for Residual Fuel Oil Burning in all areas in the State of Maryland; and a change in section 10.03D (1), (2) and (3) of Maryland Regulations 10.03.36 through 10.03.41 inclusive to prohibit certain new fuel burning equipment including rotary cup burners.

3) Various changes to Maryland Regulations 10.03.38 and 10.03.39 dealing with the control of air pollution in the Baltimore and Washington AQCR's. These revisions include the proposed phaseout of existing rotary cup burner installations; changes to sections 10.03.38(1)a,b and 10.03.39(1)a,b to require dust collectors for certain fuel burning equipment; and additions to 10.03.38.03B(6) a,c and 10.03.39.03B(6)a,c to exempt interruptible gas area units and rotary cup burners with collectors from the phaseout requirements of subsection .03B; and changes to 10.03.38/10.03.39.06E (1), (3) to prohibit certain new residual fuel boilers.

On December 17, 1974, the State of Maryland submitted proof that hearings regarding these amendments, took place on August 6, 1974, in Takoma Park, Maryland, and on August 7, 1974, in Baltimore, Maryland, after appropriate 30-day notices.

On January 30, 1975 (40 FR 4447), the December 11, 1974 submittal was proposed as a revision to the approved Maryland State Implementation Plan, and the public was offered a 30-day period in which to comment. The first purpose of today's office is to make several clarifications and corrections to the January 30, 1975 notice, and to offer the public an opportunity to comment on these changes. The clarifications and corrections are summarized as follows:

It should first be clarified that sections of the December 11, 1974 submittal, as proposed on January 30, 1975, further revise certain parts of the April 24, 1974 submittal as proposed here today. Where this is the case, it is the Administrator's intent to review the April 24, 1974 and December 11, 1974 submittals as one comprehensive set of revisions to the Maryland Implementation Plan. This will avoid confusion in those cases where the same regulation was revised twice, once in the April 24, 1974 submittal and, again, in the December 11, 1974 submittal. This intention to review both submittals together is for administrative ease and should not be interpreted to mean that the Administrator cannot or will not approve or disapprove discrete portions of the two submittals where he deems it appropriate to do so.

Second, it was proposed in the January 30, 1975 (40 FR 4447) notice to postpone implementation of the 0.5 percent sulfur-in-fuel content requirement until 1980. This proposal was based on EPA's understanding that the State had submitted a postponement of the 0.5 percent sulfur-in-fuels requirement when, in fact the State's submittal and a letter dated February 20, 1975, from the Maryland BAQC indicated the State's intention to request a deletion of this requirement. This misunderstanding apparently arose from the fact that the State had intended to submit for public hearing a deletion of the 0.5 percent sulfur-in-fuel oil requirement from the Federal Implementation Plan on the ground that it was unnecessary for the attainment of federal air quality standards, and a postponement of the requirement in the State regulation on the ground that it might eventually be necessary to attain the more stringent state air quality standards. EPA has examined comments received at the public hearing and determined that deletion of the 0.5 percent sulfur-in-fuel oil requirement was discussed. However, because of any confusion which may have resulted from this distinction between the contents of the State's regulations and its Federal Implementation Plan, EPA is particularly interested in receiving comments on the deletion of the 0.5 percent sulfur-in-fuel oil requirement.

Third, it should be noted that the Maryland Implementation Plan presently contains a compliance schedule promulgated by the Administrator to assure compliance with the 0.5 percent sulfur-in-fuel regulation. If that regulation is deleted pursuant to this proposal the compliance schedule contained at 40 CFR 52.1080(b) will also be deleted since it will no longer be required. Such deletion of the compliance schedule is therefore proposed by this notice.

The second purpose of this notice is to give the public an opportunity to comment on those portions of the April 24, 1974 submittal not already proposed in the August 29, 1974 or October 1, 1974 notices.

Copies of these proposed revisions, corrections, changes, and all accompanying correspondence and data are available for public inspection during normal business hours at the offices of EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106; in the offices of the Maryland Bureau of Air Quality Control, 610 North Howard Street, Baltimore, Maryland 21201; and the Freedom of Information Center, EPA, 401 M Street, SW., Washington, D.C. 20460. All comments should be directed to the Director, Air and Hazardous Materials Division, Environmental Protection Agency, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106 (AH 001.Md). Only comments received on or before April 28, 1975 will be considered. The Administrator's decision to approve or disapprove the proposal will be based on whether it meets the requirements of section 110 of the Clean Air Act and 40 CFR Part 51, Requirements for the Preparation, Adoption and Submittal of State Implementation Plans.

(42 U.S.C. 1857 c-5)

Dated: March 14, 1975.

A. R. MORRIS,
Acting Regional Administrator.

[FR Doc.75-8016 Filed 3-26-75;8:45 am]

FEDERAL ENERGY ADMINISTRATION

[10 CFR Part 212]

MANDATORY PETROLEUM PRICE REGULATIONS

Proposed Rulemaking and Public Hearing

The Federal Energy Administration hereby gives notice of a proposal to amend Part 212 of Title 10 of the Code of Federal Regulations to revise the mandatory petroleum price regulations applicable to producers of crude petroleum. The FEA will receive written comments and hold a public hearing with respect to this proposal.

I. *Retroactive invoicing for domestic crude petroleum.* The purpose of this notice is to propose amendments to the regulations (effective today, if adopted) to limit the extent to which prices for or amounts of new and released domestic crude petroleum may be retroactively increased through retroactive invoices. In specific cases that have been brought to the attention of the FEA, such retroactive invoicing has covered periods of up to eighteen months and significant volumes of crude oil. Such retroactive invoicing takes place either through retroactive recertification of volumes of new and released crude petroleum included in previous transactions, or through a retroactive increase in price, above that which prevailed when the crude oil was sold.

Producers of domestic crude petroleum, in order to charge a price in excess of the ceiling price established by § 212.73, must certify pursuant to the provisions of § 212.131 that the volumes for which a higher price is charged are either stripper well, new, or released crude petroleum. When this volume certification requirement was first implemented, it represented a significant departure from industry practice and required various determinations to be made prior to certification. This fact may account for delays at the beginning of this program. However, this reason no longer obtains with the same degree of force.

Retroactive invoicing which simply increases the price of crude oil over that which prevailed on the date the crude

oil was first purchased sometimes takes the form of a final invoice for volumes that had been only provisionaly invoiced, or the additional amounts are sometimes simply added to the initial invoice.

Both forms of retroactive invoicing may tend to have an adverse effect on those refiners, especially small refiners, that rely in large measure upon domestic crude petroleum. Resellers of domestic crude petroleum may also be adversely affected. In either case, if the purchasers to whom refined petroleum products or crude oil have already been sold by refiners or resellers which receive retroactive price increases are unwilling, in turn, to increase retroactively the prices they have paid, the refiners or resellers which receive retroactive price increases are in the position of having increased costs for crude oil which can be recovered, if at all, only in prices charged in subsequent sales. In any event, the retroactively invoiced prices are costs incurred currently with respect to crude petroleum received and refined or resold in preceding months, which costs should more properly have been incurred in the months when the crude oil was purchased or landed and passed through in the following months.

II. *Proposed amendments.* The FEA therefore proposes to amend Subpart D of 10 CFR Part 212 to limit extent to which the retroactive invoices may be used, in order to alleviate the problems described above.

The FEA proposes, therefore, to amend the definitions of "new crude petroleum" and "released crude petroleum" in § 212.72 to exclude those volumes that are not certified as new and released crude petroleum within the two-month period immediately following the month in which the petroleum is produced and sold. Because "old crude petroleum" is defined in that same section as the total volume of crude petroleum produced and sold from a property in a specific month less the volumes of new and releasced crude petroleum, this means that all volumes not certified as new and released crude petroleum within the two-month period following the month in which they were produced and sold would therefore be old crude petroleum. This amendment should remove any incentive to unduly delay certification of volumes, as any volumes which became old crude petroleum by delay in certification, as provided by the proposed regulation, would then be subject to the ceiling price rule of § 212.73.

The FEA also proposes to amend § 212.74 to prohibit any producer from charging or accepting a retroactive increase in the price of new or released domestic crude petroleum. This amendment is intended to address both the situation where the producer initiates a retroactive increase in price and the situation where the retroactive posting is initiated by a purchaser.

These two proposed amendments, taken together, should operate to bring the incurrence of costs more closely into line with the time of purchase of domestic crude petroleum and should lead to increased price stability and reliability. They should also facilitate the smooth implementation of the program to allocate old oil, by providing a degree of certainty otherwise lacking with respect to volumes of new, released, and old crude petroleum.

III. *General*—A. *Effective date.* The regulation changes proposed today will, if adopted, be effective as of the date of this notice. This is necessary in order to avoid the circumvention of the regulations which might otherwise occur between this date and the date of the adoption of the final regulation. The FEA wishes to avoid providing an incentive for disruptive retroactive price increases during the period that this rulemaking is pending.

B. *Procedures for written comments and public hearing.* Interested persons are invited to participate in this rulemaking by submitting data, views, or arguments with respect to the proposed regulations set forth in this notice to Executive Communications, Room 3309, Federal Energy Administration, Box CN, Washington, D.C. 20461.

Comments should be identified on the outside of the envelope and on documents submitted to FEA Executive Communications with the designation "Retroactive Increases in the Price of Domestic Crude Petroleum." Fifteen copies should be submitted. All comments received by Thursday, April 10, 1975 before 4:30 p.m., e.d.t. and all relevant information, will be considered by the Federal Energy Administration before the final action is taken on the proposed regulations.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The FEA reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

The public hearing in this proceeding will be held at 9:30 a.m., e.d.t., on Tuesday, April 15, 1975 and will be continued, if necessary on Wednesday, April 16, 1975 at Room 2105, 2000 M Street, NW., Washington, D.C., in order to receive comments from interested persons on the matters set forth herein.

Any person who has an interest in the proposed amendments issued today, or who is a representative of a group or class of persons that has an interest in today's proposed amendments, may make a written request for an opportunity to make oral presentation. Such a request should be directed to Executive Communications, FEA, and must be received before 4:30 p.m., e.d.t., on Tuesday, April 8, 1975. Such a request may be hand delivered to Room 3309, Federal Building, 12th & Pennsylvania Avenue, NW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. The person making the request should be prepared to describe the interest concerned; if appropriate, to state why he is a proper representative of a group or class of persons that has such an interest; and to give a concise summary of the proposed oral presentation and a phone number where he may be contacted through Monday, April 14, 1975. Each person selected to be heard will be so notified by the FEA before 4:30 p.m., e.d.t., Thursday, April 10, 1975 and must submit 100 copies of his statement to Executive Communications, FEA, Room 2214, 2000 M Street, NW., Washington, D.C. 20461, before 4:30 p.m., e.d.t., on Monday, April 14, 1975.

The FEA reserves the right to select the persons to be heard at these hearings, to schedule their respective presentations and to establish the procedures governing the conduct of the hearings. The length of each presentation may be limited, based on the number of persons requesting to be heard.

An FEA official will be designated to preside at the hearings. These will not be judicial or evidentiary-type hearings. Questions may be asked only by those conducting the hearings, and there will be no cross-examination of person presenting statements. Any decision made by the FEA with respect to the subject matter of the hearings will be based on all information available to the FEA. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if he so desires, to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

Any interested person may submit questions, to be asked of any person making a statement at the hearings, to Executive Communications, FEA, before 4:30 p.m., e.d.t. Friday, April 11, 1975. Any person who wishes to ask a question at the hearings may submit the question, in writing, to the presiding officer. The FEA or the presiding officer, if the question is submitted at the hearings, will determine whether the question is relevant, and whether the time limitations permit it to be presented for answer.

Any further procedural rules needed for the proper conduct of the hearings will be announced by the presiding officer.

A transcript of the hearings will be made and the entire record of the hearings, including the transcript, will be retained by the FEA and made available for inspection at the Administrator's Reception Area, Room 3400, Federal Building, 12th & Pennsylvania Avenue, NW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

As required by section 7(c)(2) of the Federal Energy Administration Act of 1974, Pub. L. 93-275, a copy of this notice has been submitted to the Administrator of the Environmental Protection Agency for his comments concerning the impact of this proposal on the quality of the environment. The Administrator had no comments on this proposal.

(Emergency Petroleum Allocation Act of 1973 as amended, Pub. L. 93-159, as amended by Pub. L. 93-511; Federal Energy Administration Act of 1974, Pub. L. 93-275; E.O. 11790, 39 FR 23185).

In consideration of the foregoing, it is proposed to amend Part 212, Chapter II of Title 10 Code of Federal Regulations, as set forth below.

Issued in Washington, D.C., March 23, 1975.

ROBERT E. MONTGOMERY, Jr.,
General Counsel,
Federal Energy Administration.

1. Section 212.72 is amended by:

a. Adding a sentence at the end of the definition of "new crude petroleum" to read as set forth below.

b. By adding a sentence at the end of the definition of "released crude petroleum" to read as set forth below.

c. By adding, in the appropriate alphabetical order, a definition of "Retroactive increase in price" to read as set forth below.

§ 212.72 Definitions.

* * * * *

"New crude petroleum" shall not include any number of barrels not certified as such pursuant to the provisions of § 212.131(a) within the consecutive two-month period immediately succeeding the month in which the crude petroleum is produced and sold.

* * * * *

"Released crude petroleum" shall not include any number of barrels not certified as such pursuant to the provisions of § 212.131(a) within the consecutive two-month period immediately succeeding the month in which the crude petroleum is produced and sold.

* * * * *

"Retroactive increase in price" means any price charged or offered in excess of the highest posted price prevailing at 6 a.m., local time, on the date the domestic crude petroleum was sold, for that grade of crude petroleum at that field, or if there are no posted prices in that field, the related price for that grade of domestic crude petroleum which is most similar in kind and quality at the nearest field for which prices are posted.

* * * * *

2. Section 212.74 is revised to read as follows:

§ 212.74 New and released crude petroleum.

Notwithstanding the provisions of § 212.73(a), a producer of crude petroleum may sell in each month, without respect to the ceiling price, the new crude petroleum and the released crude petroleum produced and sold from a property in that month; *Provided,* That no producer may charge or accept a retroactive increase in price for new crude petroleum and released crude petroleum.

[FR Doc.75-8037 Filed 3-26-75;8:45 am]

[10 CFR Parts 212, 213]

PROGRAM TO REDUCE IMPORTS OF FOREIGN CRUDE OIL AND PETROLEUM PRODUCTS

Rescheduling of Public Hearing and Extension of Comment Period

On March 13, 1975 the Federal Energy Administration issued a notice proposing amendments to §§ 212.31, 212.83, and 213.35 (40 FR 12287, March 18, 1975). The closing date for comments was to be March 28, 1975, and a public hearing was scheduled for March 27 and 28, 1975.

As to the proposed amendments to §§ 212.31, 212.83, and the conforming amendments to § 213.35 (which relate to the pricing of residual fuel oil, to disproportionate allocation of costs to domestically refined gasoline, and to relatively higher fees for imported gasoline than for other imported products), in response to a number of requests, the comment period is hereby extended until April 14, 1975 and the hearing is hereby rescheduled for April 17 and 18, 1975. Requests for an opportunity to make an oral presentation must be received before 4:30 p.m., e.d.t., on April 9, 1975 and should include the telephone number through April 15, 1975 of the person making the request. Persons selected will be notified by FEA before 4:30 p.m., e.d.t., April 11, 1975.

Interested persons are invited to participate in this rulemaking by submitting data, views, or arguments with respect to the proposed regulations set forth in this notice to Executive Communications, room 3309, Federal Energy Administration, Box CO, Washington, D.C. 20461.

As to the proposed amendments to § 213.35 discussed in Section II of the March 13, 1975 notice, the comment period will close and hearings will be held as originally scheduled.

Issued in Washington, D.C., March 24, 1975.

ROBERT E. MONTGOMERY, Jr.,
General Counsel,
Federal Energy Administration.

[FR Doc.75-7971 Filed 3-24-75;1:49 pm]

FEDERAL RESERVE SYSTEM

[12 CFR Part 213]

FOREIGN ACTIVITIES OF NATIONAL BANKS

Proposed Rulemaking

In response to requests received from member banks, the Board of Governors of the Federal Reserve System is considering amending Part 213 (Regulation M) pursuant to section 25 of the Federal Reserve Act, 12 U.S.C. 604(a). That section allows the Board, by regulation, to authorize foreign branches of member banks, subject to certain limitations and conditions, to exercise, in addition to their charter powers, such further powers as may be usual in connection with the transaction of the business of banking in the places where such foreign branches transact business.

The first proposed amendment would increase from $50,000 to $100,000 the amount of credit which a foreign branch of a member bank may extend to an executive officer of the branch in order to finance the acquisition or construction of living quarters to be used as his residence abroad, provided each such credit extension is promptly reported to its home office. This proposal has the effect of relieving a restriction and it is not, therefore, necessary that it be published for comment, 5 U.S.C. 553(d). The Board feels, however, that in order to determine an appropriate figure it would be in the public interest to receive comments on this matter from interested persons.

The second proposed amendment would allow foreign branches of member banks to engage in insurance agency and brokerage activities where such activities are usual in connection with the transaction of the business of banking in the place where the foreign branch transacts its business.

To aid in the consideration of these matters by the Board, interested persons are invited to submit relevant data, views, or arguments. Any such material should be submitted in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. All material submitted on or before May 9, 1975, will be considered by the Board.

PART 213—FOREIGN ACTIVITIES OF NATIONAL BANKS

To implement its proposal, the Board would amend § 213.3(b) by substituting the figure $100,000 for the figure $50,000 in subparagraph (6), by substituting a semicolon for a period at the end of subparagraph (7), and by adding a new subparagraph (8).

As amended, § 213.3(b) would read as follows:

§ 213.3 Foreign branches.

* * * * *

(b) *Further powers of foreign branches.* In addition to its other powers, a foreign branch may, subject to §§ 213.3(c) and 213.6 and so far as usual in connection with the transaction of the business of banking in the places where it shall transact business:

* * * * *

(6) Extend credit to an executive officer of the branch in an amount not to exceed $100,000 or its equivalent in order to finance the acquisition or construction of living quarters to be used as his residence abroad, provided each such credit extension is promptly reported to its home office;

(7) Pay to any officer or employee of the branch a greater rate of interest on deposits than that paid to other depositors on similar deposits with the branch;

(8) Act as insurance agent or broker.

By order of the Board of Governors, March 21, 1975.

[SEAL] THEODORE E. ALLISON, *Secretary of the Board.*

[FR Doc.75-7989 Filed 3-26-75;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[17 CFR Part 249]

[Release No. 34-11308; File S7-558]

SECO BROKERS AND DEALERS REPORTS

Initial Fees and Annual Assessments

The Securities and Exchange Commission has announced a proposal to modify the fees and assessments payable to the Commission by registered broker-dealers who are not members of the National Association of Securities Dealers, Inc. ("nonmember" or "SECO" broker-dealers).

Sections 15(b)(8) and 15(b)(9) of the Securities Exchange Act of 1934 ("the Act") authorize the Commission to collect such reasonable fees and charges as may be necessary to defray the costs of additional regulatory duties required to be performed with respect to nonmember broker-dealers. Pursuant to these sections of the Act the Commission has adopted Rule 15b9-1 (17 CFR 249.15b9-1) to establish initial fees for firms and Rule 15b9-2 (17 CFR 249.15b 9-2) to provide for annual assessments. This proposal deals with the amendment of Form SECO-2 (17 CFR 249.502) under Rule 15b9-1, which sets initial fees paid by SECO broker-dealers on behalf of new associated persons, and the adoption of Form SECO-4-75 (17 CFR 249. 504i) under Rule 15b9-2, which would establish the levels for annual nonmember firm assessments for the current fiscal year. The form (Form SECO-5) (17 CFR 249.505) setting initial fees payable on behalf of new associated persons would not be changed.[1]

In general, Form SECO-2 now provides for an initial fee payable by SECO broker-dealers for new associated persons of $35. Form SECO-4-74, covering fiscal 1974, provided for an annual assessment payable by SECO broker-dealers comprised of: (1) a base fee of $250 applicable to all such brokers or dealers; and (2) a fee of $12 for each associated person engaged directly or indirectly in securities activities during the year on behalf of the broker-dealer.

[1] The initial fee required to be paid by SECO broker-dealers is $500.

PROPOSED INITIAL FEES FOR NONMEMBER BROKER-DEALERS

Rule 15b9-1 provides that every nonmember broker or dealer registered with the Commission shall file a Form SECO-2 on behalf of each associated person and pay to the Commission the fee prescribed by the form. This fee, to be set forth on the proposed revised Form SECO-2, would be $50.

PROPOSED ANNUAL ASSESSMENTS FOR FISCAL YEAR 1975

Each fiscal year the annual assessment is set forth on a Form SECO-4 for that particular year. This year's assessment, to be set forth on Form SECO-4-75, would include a base charge of $250 and an assessment of $15 for each associated person. The increases in the associated person assessment and the SECO-2 charge have been necessitated by the increased costs to the Commission in administering the SECO program.

TEXT OF PROPOSED RULE

The Securities and Exchange Commission, acting pursuant to the provisions of the Securities Exchange Act of 1934, and particularly sections 15(b) and 23(a) thereof, hereby proposes to amend Part 249 of Title 17 of the Code of Federal Regulations by adopting § 249.504i as follows:

§ 249.504i Form SECO-4-75, 1975 assessment and information form for registered brokers and dealers not members of a registered national securities association.

This form shall be filed on or before June 1, 1975, pursuant to § 240.15b9-2 of this chapter, accompanied by the annual assessment fee required thereunder, for the fiscal year ended June 30, 1975, by every registered broker and dealer not a member of a registered national securities association.

The Commission proposes the foregoing to be effective June 1, 1975. All interested persons may submit their comments to the Commission at its office in Washington, D.C. 20549 no later than April 16, 1975. All comments should refer to File No. S7-558. Copies of the proposed Form SECO-4 (17 CFR 249.504i) and Form SECO-2 (17 CFR 249.502) to be amended have been filed with the Office of the Federal Register, and additional copies are available on request from the Commission at the above address.

(Sec. 15(b), 48 Stat. 895, as amended, 78 Stat. 565, 15 U.S.C. 78o; Sec. 23(a) 48 Stat. 901, as amended, 49 Stat. 1379, sec. 8, 15 U.S.C. 78w.)

By the Commission.

Dated: March 21, 1975.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.75-8036 Filed 3-26-75;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1917]

[Docket No. FI-529]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the City of Lamesa, Dawson County, Texas

The Federal Insurance Administrator, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968, Pub. L. 90-448), (42 U.S.C. 4001-4128), and 24 CFR Part 1917 (§ 1917.4 (a)), hereby gives notice of his proposed determinations of flood elevations for the City of Lamesa, Texas.

Under these Acts, the Administrator, to whom the Secretary has delegated his statutory authority, must develop criteria for land management in flood-prone areas. In order to participate in the National Flood Insurance Program, the City of Lamesa must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at City Hall, 310 South Main Street, Lamesa, Texas.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Mayor Lloyd Cline, City Hall, 310 South Main Street, Lamesa, Texas 79331. The period for comment will be ninety days following the second publication of this notice in a newspaper of local circulation in the above-named community.

The proposed 100-year flood elevations are:

Source of flooding	Location	Elevation—feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)	
			Right	Left
Sulfur Springs draw	Avenue S	2948.7	180	50
	Hillside Dr	2948.4	220	180
	1st St	2947.8	280	100
	South 2d St	2942.8	325	200
	Avenue O	2941.0	320	110
	Avenue N	2940.6	320	120
	Avenue M	2940.4	310	125
	Avenue L	2940.0	300	140
	Avenue K	2939.8	220	210
	Byran Ave	2939.6	60	120
	South 9th St	2936.5	[1] 270	430
	Houston Ave	2935.0	110	320
Playa Lake (9th St.)	North 9th St	2977.0	[2] 930	[3] 10
	Houston Ave	2977.0	[4] 340	[5] 80
Playa Lake (Elgin and North 7th St.).	Elgin Ave	2980.0	[6] 250	[7] 220
	North 7th St	2986.0	[6] 400	[7] 440

[1] Measured along South 10th St.
[2] Measured east from Houston Ave.
[3] Measured west from Houston Ave.
[4] Measured south from center of 9th St.
[5] Measured north from center of 9th St.
[6] Measured north or east from center of North 7th St. and Elgin Ave. Intersection.
[7] Measured south or west from center of North 7th St. and Elgin Ave. intersection.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: March 14, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75-7820 Filed 3-26-75;8:45 am]

[24 CFR Part 1917]

[Docket No. FI-531]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the Borough of Sea Girt, Monmouth County, New Jersey

The Federal Insurance Administrator, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 Pub. L. 90-448), (42 U.S.C. 4001-4128), and 24 CFR Part 1917 (§ 1917.4 (a)), hereby gives notice of his proposed determinations of flood elevations for the Borough of Sea Girt, New Jersey.

Under these Acts, the Administrator, to whom the Secretary has delegated his statutory authority, must develop criteria for land management in flood-prone areas. In order to participate in the National Flood Insurance Program, the Borough of Sea Girt must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at Borough Hall, Sea Girt, New Jersey 08750.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Mayor Thomas Black, Borough Hall, Sea Girt, New Jersey 08750. The period for comment will be ninety days following the second publication of this notice in a newspaper of local circulation in the above-named community.

The proposed 100-year flood elevations are:

Source of flooding	Location	Elevation—Feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)
Atlantic Ocean and Wreck Pond.	The Terrace	10	Entire street.
	Ocean Ave	10	Entire street.
	5th Ave	10	To 100 ft southwest of the Terrace.
	4th Ave	10	Do.
	3d Ave	10	To 150 ft southwest of the Terrace.
	2d Ave	10	To 125 ft southwest of the Terrace.
	1st Ave	10	To 225 ft southwest of the Terrace.
	Beacon Blvd	10	To 175 ft northwest of Ocean Ave.
	Chicago Blvd	10	To 100 ft northwest of Ocean Ave.
	Brooklyn Blvd	10	To 150 ft northeast of Ocean Ave.
	New York Blvd	10	To 400 ft northwest of Ocean Ave.
	Baltimore Blvd	10	To 425 ft northwest of Ocean Ave.
	Manasquan Turnpike	10	To 525 ft southwest of corporate limits.
	New York & Long Branch R.R.	10	To 500 ft southwest of corporate limits.
	Philadelphia Blvd	10	To 400 ft northwest of Ocean Ave.
	Trenton Blvd	10	To 300 ft northwest of Ocean Ave.
	Stockton Blvd	10	To 200 ft northwest of 3d Ave.
	Neptune Pl	10	To 100 ft northwest of 2d Ave.
	Sea Side Pl	10	To 350 ft northwest of 1st Ave.
	3d Ave	10	From 125 ft southwest of Stockton Blvd. to 100 ft northeast of Stockton Blvd.
	2d Ave	10	From 75 ft southwest of Neptune Pl and ends 130 ft northeast of Stockton Blvd.
	1st Ave	10	To 200 ft northeast of Stockton Blvd.
	Morven Ter	10	Entire road.
	Sea Girt Ave	10	To 350 ft northeast of 1st Ave.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: March 14, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75–7821 Filed 3–26–75;8:45 am]

[24 CFR Part 1917]

[Docket No. FI–534]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the Town of Ponce Inlet, Volusia County, Florida

The Federal Insurance Administrator, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 Pub. L. 90–448), (42 U.S.C. 4001–4128), and 24 CFR Part 1917 (§ 1917.4 (a)), hereby gives notice of his proposed determinations of flood elevations for the Town of Ponce Inlet, Florida.

Under these Acts, the Administrator, to whom the Secretary has delegated his statutory authority, must develop criteria for land management in flood-prone areas. In order to participate in the National Flood Insurance Program, the Town of Ponce Inlet must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at 4747 S. Peninsula Drive, Ponce Inlet, Florida 32019.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Mayor Richard Dygert, 4747 S. Peninsula Drive, Ponce Inlet, Florida 32019.

The proposed 100-year flood elevations are:

Source of flooding	Location	Elevation—Feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)
Intracoastal Waterway (Atlantic Ocean).	Old Carriage Rd.	7	Entire road.
	Anchor Dr.	7	Do.
	South Peninsula Dr.	7	From northern corporate limits to 5,500 ft south of corporate limits.
	Inlet Harbor Dr. (west of South Peninsula Dr.).	7	Entire road west of intersection with South Peninsula Dr.
	Ponce de Leon Dr.	7	Do.
	Front St.	7	Entire road.
	Rains Dr.	7	Entire road west of intersection with South Peninsula Dr.
	Cedar St.	7	Entire road.
	Sailfish Ave.	7	Do.
	Ponce Blvd. (west of South Peninsula Dr.).	7	Entire road west of intersection with South Peninsula Dr.
	Riverside Dr.	7	Entire road.
	Cedar Ave.	7	Entire road west of intersection with Oak Ridge Ave.
	Laurel Ave. (south of Ponce Ave.).	7	Entire road between Ponce St. and Pine St.
	Holly Ave. (south of Ponce Ave.).	7	Do.
	Pine St. (west of Oak Ridge Ave.).	7	Entire road between Oak Ridge Ave. and Riverside Dr.
	Bay St. (south of Oak Ridge Ave.).	7	Entire road between Oak Ridge Ave. and Cedar Ave.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: March 5, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75–7822 Filed 3–26–75;8:45 am]

[Docket No. FI–530]

[24 CFR Part 1917]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the City of Absecon, Atlantic County, New Jersey

The Federal Insurance Administrator, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 Pub. L. 90–448), (42 U.S.C. 4001–4128), and 24 CFR Part 1917 (§ 1917.4 (a)), hereby gives notice of his proposed determinations of flood elevations for the City of Absecon, New Jersey.

Under these Acts, the Administrator, to whom the Secretary has delegated his statutory authority, must develop criteria for land management in flood-prone areas. In order to participate in the National Flood Insurance Program, the City of Absecon must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at City Hall, Absecon, New Jersey 08201.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Mayor David F. Hodgson, City Hall, Absecon, New Jersey 08201. The period for comment will be ninety days following the second publication of this notice in a newspaper of local circulation in the above-named community.

The proposed 100-year flood elevations are:

Source of flooding	Location	Elevation—Feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)
Ingersolls Branch, Absecon Creek, and Absecon Bay.	Pleasant Ave	10	From Madison Sq. to Mill Rd.
	Summit Ave	10	To 100 ft southwest of Mill Rd.
	Anina St	10	100 100
Ingersolls Branch and Absecon Bay.	Mill Rd	10	600 1,500
Absecon Creek and Absecon Bay	do	10	1,500 1,200
	Morton Ave	10	To 650 ft north of Mill Rd.
	Cannon Ave	10	---------- 575
	Leona St	10	From 550 ft southwest of Lincoln Ave. to 200 ft northeast of Lincoln Ave.
	Pershing St	10	From 575 ft Southwest of Lincoln Ave. to 550 ft northeast of Lincoln Ave.
	Coolidge St		From 250 ft Southwest of Lincoln Ave. to the intersection with McKinley Ave.
	Wilson St		From the intersection with Lincoln Ave. to 800 ft northeast of intersection with Lincoln Ave.
	Harding St	10	2,650.
	Lincoln Ave	10	Entire street.
	McKinley Ave	10	Do.
	Taft Ave	10	Do.
	Garfield St	10	Do.
	Dawes Ave	10	Do.
	Grant St	10	Do.
	St. James Pl	10	Do.
	Charlotte Pl	10	Do.
	Deland Pl	10	Do.
	Maple Ave	10	From 1,000 ft south of Ohio Ave. to 225 ft north of Ohio Ave.
	Keefer Ave	10	From 425 ft south of Orchard St. to 150 ft north of Orchard St.
	Orchard St	10	Entire street.
	Ohio Ave	10	Between Keefer Ave. and St. James Pl.
	New Rd	10	1,350 1,075
	Pennsylvania-Reading Seashore Lines.	10	1,100 425
	Shore Rd	10	1,500 200
	Absecon Blvd	10	1,600 250
	Church St	10	---------- 500
	Vassar Sq	10	Entire Street.
	Plaza Sq	10	Do.
	Tremont Ave	10	Do.
	Berkley Ave	10	Do.
	Shore Rd	10	From 150 ft Southwest of Berkley Ave. to 275 ft Northeast of Berkley Ave.
	Faunce Landing Rd	10	1,500 ft west of 4th Ave.
	Lisbon Ave	10	1,375 ft north of Faunce Landing Rd.
	4th Ave	10	1,400 ft north of Faunce Landing Rd.
	Reed Rd	10	325 ----------
Conover Creek and Absecon Bay	Iowa Ave	10	300 ----------
	Illinois Ave	10	Entire street.
Absecon Bay	Absecon Blvd	10	To 2 miles north of corporate limits.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator, 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: March 14, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75-7823 Filed 3-26-75;8:45 am]

[24 CFR Part 1917]

[Docket No. FI-532]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the City of Long Branch, Monmouth County, New Jersey

The Federal Insurance Administrator, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968, Pub. L. 90-448), (42 U.S.C. 4001-4128), and 24 CFR Part 1917 (§ 1917.4 (a)), hereby gives notice of his proposed determinations of flood elevations for the City of Long Branch, New Jersey.

Under these Acts, the Administrator, to whom the Secretary has delegated his statutory authority, must develop criteria for land management in flood-prone areas. In order to participate in the National Flood Insurance Program, the City of Long Branch must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-

prone areas and the proposed flood elevations are available for review at City Hall Annex, 344 Broadway, Long Branch, New Jersey.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Mayor Henry R. Cioffi, City Hall Annex, 344 Broadway, Long Branch, New Jersey 07740. The period for comment will be ninety days following the second publication of this notice in a newspaper of local circulation in the above-named community.

The proposed 100-year flood elevations are:

Source of flooding	Location	Elevation—Feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)
Cranberry Brook	Ocean Ave	15	From 175 ft south of Lake Takanassee to 300 ft north of Lake Takanassee.
	South Lake Dr	16	Entire street.
	North Lake Dr	16	Entire street to New York & Long Branch RR.
	New York & Long Branch RR.	17	From 400 ft south of Cranberry Brook to 450 ft north of Cranberry Brook.
	Hoey Ave	21	From 150 ft south of Cranberry Brook to 400 ft north of Cranberry Brook.
	Lake Ave	21	Between the intersection of Hoey Ave. and 125 ft north of Shrewsbury Ave.
	Woodgate Ave	21	From 175 ft south of Cranberry brook to 100 ft north of Cranberry Brook.
	Van Court Ave	21	From 200 ft south of Cranberry Brook to 350 ft north of Cranberry Brook.
	Elinore Ave	21	Entire street.
	Red Oaks Dr	21	To 150 ft south of Cranberry Brook.
Atlantic Ocean	Plaza Ct	10	To 125 ft west of Atlantic Ocean.
	Adams St	10	To 90 ft west of Atlantic Ocean.
	Ocean Ave	10	From 250 ft north of corporate limits.
	do	10	From 200 ft north of Chelsea Ave. to Madison Ave.
	do	10	From 425 ft south of Ocean Ter. to 100 ft north of Ocean Ter.
	Ocean Ter	10	To 225 ft west of Ocean Ave.
	View Ave	10	To 300 ft west of Ocean Ave.
	Joline Ave	10	To 225 ft west of Atlantic Ocean.
Branchport, Manahassett and Troutmans Creek.	Neptune Ave	9	To 800 ft south of corporate limits.
	Columbia Ave	9	Entire street.
	Church St	9	To 475 ft south of Columbia Ave.
	White St	9	To 350 ft east of West St.
	West St	9	To 100 ft south of White St.
	Jerome Ave	9	To 600 ft west of West St.
	Colina Dr	9	Entire street.
	Beach Ave	9	Do.
	Naderal Ave	9	Do.
	Long Branch Ave	9	To Airedale Ave.
	Naragansett	9	To 200 ft south of Naderal Ave.
	Biddle Ave	9	Entire street.
	Patten Ave	9	Do.
	Kingsley St	9	To 700 ft east of Patten Ave.
	Florence Ave	9	From MacArthur Ave. to 325 ft northwest of Avenel Blvd.
	Atlantic Ave	9	From Liberty St. to Florence Ave.
	Joline Ave	9	From 100 ft east of Liberty St. to Florence Ave.
	Sea View Ave	9	From 100 ft east of Liberty St. to 200 ft west of Witmer St.
	Long Branch Ave	9	From Samson Pl. to 100 ft north of Cooper Ave.
	Ellis Ave	9	Entire street.
	Pacific Ave	9	To 125 ft northeast of 6th Ave.
	6th Ave	9	To 400 ft southeast of Pacific Ave.
	Atlantic Ave	9	From 180 ft northeast of 6th Ave. to 325 ft southwest of 6th Ave.
	do	9	To Edwards Ave.
	Jay St	9	To 100 ft northeast of New York & Long Branch RR.
	Branchpool Ave	9	To 50 ft north of New York & Long Branch RR.
	New York & Long Branch RR.	9	To 450 ft southwest of corporate limits.
	New Jersey Southern RR	9	To 500 ft east of corporate limits.
	Myrtle Ave	9	To 200 ft south of corporate limits.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: March 14, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75-7824 Filed 3-26-75;8:45 am]

[24 CFR Part 1917]

[Docket No. FI-537]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the Town of Dennis, Barnstable County, Massachusetts

The Federal Insurance Administrator, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act

of 1968 Pub. L. 90-448), (42 U.S.C. 4001-4128), and 24 CFR Part 1917 (§ 1917.4 (a)), hereby gives notice of his proposed determinations of flood elevations for the Town of Dennis, Massachusetts.

Under these Acts, the Administrator, to whom the Secretary has delegated his statutory authority, must develop criteria for land management in flood-prone areas. In order to participate in the National Flood Insurance Program, the Town of Dennis must adopt flood plain management measures that are consistent with the flood elevations determined by the Secretary.

Proposed flood elevations (100-year flood) are listed below for selected locations. Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review of Town Hall, S. Dennis, Massachusetts 02660.

Any person having knowledge, information, or wishing to make a comment on these determinations should immediately notify Ms. Nora Creighton, Chief Town Clerk, Town Hall, S. Dennis, Massachusetts 02660.

The proposed 100-year flood elevations are:

Source of flooding	Location	Elevation—Feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)	
			Right	Left
Chase Garden Creek (backwater from Cape Cod Bay).	Squadrilli	10	Entire street.	
	Spadoni	10	Do.	
	Black Flats Dr.	10	600 ft south of intersection with Louis A. Allen.	
	Hope Lane	10	150	125
	Nobscusset Rd.	10	100	125
	Beach St.	10	100	300
	New Boston Rd.	10	250	500
Cape Cod Bay	Dunes Rd.	10	150	
	Bay View Rd.	10	125	
	Dr. Lords Rd.	10	125	
Sesuit Creek (backwater from Cape Code Bay).	State Highway Rt. 6A	10	900	150
	Bridge St.	10	300	550
	Cold Storage Rd.	10	550 ft east of intersection with North St.	
	Saltworks Rd.	10	500 ft south of intersection with Sea St.	
Bass River (backwater from Nantucket Sound).	Capt. Harding	10	(1)	100
	Route 28	10	(1)	825
	Highbank Rd.	10	(1)	100
Kelleys Bay (backwater from Nantucket Sound).	Route 6	10	(1)	150
	Hawthorne St.	10	150	
	Norsemans Dr.	10	225	
	Mayfair Rd.	10	From intersection with Fairmount to 150 ft south of intersection with Colonial.	
	Fairmount	10	325	
	Oyster	10	600	
Follins Pond (backwater from Nantucket Sound).	Quaker Beach	10	100	
	Norsemans Beach Rd.	10	500	
	Follins Pond Rd.	10	400	
Bass River (backwater from Nantucket Sound).	Goosebay Lane	10	Entire street.	
	Main St.	10	From intersection with Ilig Rd. to 100 ft south of intersection with Farm Lane.	
Grand Cove (backwater from Nantucket Sound).	Cove Lane	10	Entire street.	
	Cove Rd.	10	To intersection with Stephan Lane.	
	Main St.	10	From 250 ft east of intersection with Buccaneer to 600 ft west of intersection with Trotting Rd.	
Ware Creek (backwater from Nantucket Sound).	South Main St. (Lower County Rd.).	10	300	(2)
Swan Pond River (backwater from Nantucket Sound).	Lower County Rd.	10	(2)	550
	Mayflower	10	Entire street.	
	Honeysuckle	10	100 ft west of intersection with Beth Ann.	
	Myrtle	10	Do.	
	Bayberry	10	150 ft west of intersection with Beth Ann.	
	Whortleberry	10	200 ft west of intersection with Beth Ann.	
	Dexter Snow	10	Entire street.	
	Nipigion	10	100 ft west of intersection with Greeneldie.	
	Lone Tree Rd.	10	150 ft north of intersection with Michaels Ave.	
	Route 28	10	300	550
	Baxter St.	10	150 ft south of intersection with Ann's Place.	
	Upper County Rd.	10	300	3,100
	Aunt Debby's Rd.	10	From intersection with Center St. to intersection with Cedar Lane.	
	Treasure Bay	10	Entire street.	
	Crestwood Lane	10	Do.	
	Indian Ter.	10	Do.	

Source of flooding	Location	Elevation—Feet above mean sea level	Width—From shoreline or bank of stream (facing downstream) to 100-yr flood boundary (feet)
	Corn	10	Do.
	Mound	10	Do.
	Chief	10	Do.
	Knox Rd	10	Do.
	Stafford Circle	10	Do.
	Vester	10	Do.
Nantucket Sound	Southwest of Kelleys Pond	10	To intersection of Garfield Lane and Thirnas, intersection of Merchant and Santucket, and intersection of Santucket and Loring Ave.
	Loring Ave	10	To intersection with Fisk St.
	Between Ware Creek and Swan Pond River.	10	Entire area south of Lower County Rd. between Lighthouse Rd. and Rhyspah Ave.
	Oakleaf	10	Entire street.
	Colonial	10	Do.
	Gull	10	Do.
	South Village Rd	10	To 160 ft north of intersection with South Village Circle.
	South Village Dr	10	Entire street.
	Sumac	10	Do.
	Swan Pond River Rd	10	To intersection with Uncle Zeke's.
	Fletcher	10	Entire street.
	Old Wharf Rd	10	From 150 ft west of Uncle Rolf Rd. to 150 ft east of Oak St. extended.
	Huckleberry	10	Entire street.
	Chase Ave	10	From 120 ft east of intersection with Birch Hill Rd. to 200 ft east of intersection with Caleb St.

[1] To corporate limits.
[2] To intersection with Rhyspah Ave.
[3] 100 ft west of intersection with School St.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001–4128); and Secretary's delegation of authority to Federal Insurance Administrator 34 FR 2680, February 27, 1969, as amended by 39 FR 2787, January 24, 1974.)

Issued: March 10, 1975.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.

[FR Doc.75-7825 Filed 3-26-75;8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF THE TREASURY

Office of the Secretary

BUTADIENE ACRYLONITRILE RUBBER FROM JAPAN

Antidumping Proceeding Notice

On February 26, 1975, information was received in a proper form pursuant to §§ 153.26 and 153.27, Customs Regulations (19 CFR 153.26, 153.27), indicating a possibility that butadiene acrylonitrile rubber from Japan is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160 et seq.).

There is evidence on record concerning injury to or likelihood of injury to or prevention of establishment of an industry in the United States. Available information indicates that through 1973 and 1974 domestic production capacity has been at 95 percent utilization with imports from Japan during 1974 amounting to less than 1 percent of domestic production. U.S. production decreased in late 1974 and early 1975, but this would appear to be more attributable to the decline in domestic automobile production than to imports from Japan. On the basis of such evidence, there appears to be substantial doubt as to whether there is injury to, likelihood of injury to, or prevention of establishment of an industry in the United States by reason of such importations from Japan. Accordingly, the United States International Trade Commission is being advised of such doubt pursuant to sec. 201(c)(2) of the Act (19 U.S.C. 160(c)(2)).

Having conducted a summary investigation as required by § 153.29 of the Customs Regulations (19 CFR 153.29) and having determined as a result thereof that there are grounds for so doing, the U.S. Customs Service is instituting an inquiry to verify the information submitted and to obtain the facts necessary to enable the Secretary of the Treasury to reach a determination as to the fact or likelihood of sales at less than fair value. Should the International Trade Commission, within 30 days of receipt of the information cited in the preceding paragraph, advise the Secretary that there is no reasonable indication that an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States, the Department will publish promptly in the FEDERAL REGISTER a notice terminating the investigation. Otherwise the investigation will continue to conclusion.

A summary of price information received from all sources is as follows:

The information received tends to indicate that the prices of the merchandise sold for exportation to the United States are less than the prices for home consumption.

This notice is published pursuant to § 153.30 of the Customs Regulations (19 CFR 153.30).

Dated: March 24, 1975.

[SEAL] DAVID R. MACDONALD,
Assistant Secretary of the Treasury.

[FR Doc.75-8031 Filed 3-26-75;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

COLVILLE RESERVATION, WASHINGTON

Hunting and Fishing Ordinance

MARCH 21, 1975.

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Commissioner of Indian Affairs by 230 DM 2.

Notice is hereby given that the Colville Business Council of the Confederated Tribes of the Colville Reservation, Washington, duly enacted the North Half Colville Hunting and Fishing Ordinance on March 4, 1974 under authority contained in Article V, sec. 1(a) of the Constitution of the Confederated Tribes of the Colville Reservation which was ratified by the Colville Indians on February 26, 1938, and approved by the Commissioner of Indian Affairs on April 19, 1938. The North Half Colville Hunting and Fishing Ordinance reads as follows:

CHAPTER 1. GENERAL PROVISIONS

1.1 *Title.* This ordinance shall be known as the North Half Colville Hunting and Fishing Ordinance.

1.2 *Policies.* 1.2.1 Hunting and fishing rights of the Colville people on the "North Half" have existed since before the coming of the white man. These rights were further secured by the establishment of a Reservation by the Executive Order of July 2, 1872, and were reserved in the Cession Agreement of May 9, 1891.

1.2.2 It is the policy of the Colville Tribes to preserve, protect and perpetuate wildlife resources of the North Half. To the extent that such resources are to be hunted, such shall be primarily for the purpose of providing food for Indian families and only secondarily for the sport and recreation of non-Indians.

1.2.3 Many Colville families have inadequate income and below-average living standards. Hunting and fishing for wildlife on the North Half are essential to these families for maintenance of an adequate diet.

1.3 *Jurisdiction.* 1.3.1 This ordinance shall be applicable to all enrolled members of the Colville Tribe and reciprocating tribes.

1.3.2 Special regulations may be promulgated from time to time establishing special areas, seasons, gear and limits applicable to members of the Colville Tribes and members of reciprocating tribes.

1.3.3 No act prohibited by this ordinance or by any other tribal ordinance may be committed, even though such act would be lawful under laws of the State of Washington.

1.4 *Definitions.* 1.4.1 "Animals, birds and fish", as used herein, shall mean any animals, birds or fish which are not domesticated.

1.4.2 "Bag limit" means the maximum number of animals, birds or fish which may be taken, caught, killed, or possessed by any person, specified and fixed by regulation of the Council for any particular period of time, or so specified and fixed as to size, sex, or species.

1.4.3 "Closed area" means any place on the North Half described or designated by regulation of the Council wherein it shall be unlawful to hunt or trap for animals or birds.

1.4.4 "Closed season" means all of the time during the entire year excepting the "open season" as specified by regulation of the Council.

1.4.5 "Closed waters" means any lake, river, stream, body of water, or any part thereof within the North Half described or designated by regulation of the Council wherein it shall be unlawful to fish.

1.4.6 "Council" means the Colville Business Council of the Confederated Tribes of the Colville Reservation.

1.4.7 "Colville, Colvilles, Colville people" shall refer to enrolled members of the tribes.

1.4.8 "Fish" and its derivatives, "fishing," "fished," etc., means any effort made to kill, injure, disturb, capture, or catch fish in waters on the North Half.

1.4.9 "Hunt" and its derivatives, "hunting," "hunted," etc., and "trap" and its derivatives, "trapping," "trapped," etc., means any effort to kill, injure, capture, or disturb a wild animal or wild bird.

1.4.10 "Member" shall mean any person whose name appears on the records of the Colville Confederated Tribes as an enrolled member of the Tribes.

1.4.11 "Member of reciprocating tribes" means any person who is a member of any other Indian tribe which grants reciprocal hunting and fishing privileges to members of the Colville Confederated Tribes as determined by the Colville Business Council and who

secures from the Colville Tribal Office and has in his possession any appropriate identification as to his status which shall be provided by the Colville Confederated Tribes.

1.4.12 "North Half' means that portion of the original Colville Indian Reservation of 1872, described as follows:

Beginning at a point on the Eastern boundary line of the Colville Indian Resesrvation where the township line between township 34 and 35 North of Range 37 East of the Williamette Meridian if extended West would intersect the same, said point being in the middle of the Channel of the Columbia River, and running thence West parallel with the forty ninth (49th) parallel of latitude to the Western boundary line of the said Colville Indian Reservation in the Okanogan River, thence North following the said Western boundary line to the said forty ninth (49th) parallel of latitude to the Northeast corner of the said Colville Indian Reservation, thence South following the Eastern boundary of said Reservation to the place of beginning containing by estimation one million five hundred thousand acres, the same being a portion of the Colville Indian Reservation created by Executive Order dated April 9, 1872.

1.4.13 "Open season" means the time specified by rule and regulation of the Council when it shall be lawful to hunt, trap, or fish for any animals, birds or fish. Each period of time specified as an open season shal linclude the first and last days thereof.

1.4.14 "Regulation' means any rule, regulation, resolution or ordinance promulgated by the Colville Business Council.

1.4.15 "Reservation" shall mean the Colville Indian Reservation.

1.4.16 "Tribes" means Confederated Tribes of the Colville Indian Reservation.

CHAPTER 2. TRIBAL REGULATION

2.1 *Council Empowered to Regulate.* The Council shall promulgate such regulations as it deems proper and necessary to carry out the policy of the Colville Tribes with respect to hunting and fishing on the North Half. Such regulations may establish closed and open areas, closed and open seasons, bag limits, gear restrictions, and any other provisions which the Council deems necessary to carry out the policies and provisions of this ordinance.

2.2 *Notice of Regulations.* All regulations promulgated by the Council with respect to hunting and fishing shall be communicated to the public as widely as possible, including providing information with respect to such regulations to newspapers, magazines and any other publications which are likely to bring such news to the attention of members of the general public; posting notices as to such regulations wherever possible on the Reservation and in adjoining communities; and making copies of such regulations available to all persons.

CHAPTER 3. PERMITS

3.1 *permit Required.* It shall be unlawful for any member to hunt, trap or fish on the North Half without first having procured and having in force and in his personal possession and on his person while hunting, trapping or fishing, a permit so to do issued to him by the Council. The Council may issue appropriate permits to members of the Colville Tribes and members of other tribes granting reciprocal privileges to members of the Colville Tribes.

3.2 *Permit Nontransferable; Identification of Permit Holder.* Any permits issued by the Council shall be nontransferable. Any member hunting, trapping or fishing, shall, upon the demand of any game protector, or other tribal law enforcement officer, exhibit his permit and tribal identification card to such officer, and write his name for the purpose of comparison with the signature on the permit or tribal identification card and his failure or refusal to exhibit his permit or tribal identification card and write his name upon demand shall be prima facie evidence that such member has no permit or tribal identification card or is not the person named in the permit or tribal identification card in his possession.

CHAPTER 4. PROHIBITED ACTS

4.1 *Hunting and Fishing Unlawful: When.* It shall be unlawful for any member to hunt, trap, or fish during the respective closed seasons therefor. It shall also be unlawful for any person to kill, take, or catch any species of birds, animals, or fish in excess of the number fixed as the bag limit. It shall also be unlawful for any person to hunt or trap for any birds or animals within the boundaries of any closed area. It shall be unlawful for any person to fish within any closed waters.

4.2 *Closed Seasons.* It shall be unlawful for any member to have in his possession or under his control any bird, animal or fish during the closed season or in excess of the bag limit.

4.3 *Hunting While Intoxicated.* It shall be unlawful for any person to hunt with firearms while under the influence of intoxicating liquor.

4.4 *Wasting Wildlife.* It shall be unlawful for any person to permit any animal, bird or fish needlessly to go to waste after killing the same.

4.5 *Obstructing Law Enforcement Officers.* It shall be unlawful for any member to resist or obstruct any game protector or other duly authorized tribal law enforcement officer or other peace officer in the discharge of his duty while enforcing the provisions of this ordinance or other tribal regulations pertaining to hunting and fishing.

4.6 *Interference with Game Control Signs.* It shall be unlawful for any person to destroy, tear down, shoot at, deface or erase any printed matter or signs placed or posted by or under the instructions of the Council to assist in the enforcement of tribal hunting and fishing regulations.

4.7 *Shooting Persons or Livestock.* It shall be unlawful to shoot any other person or any domestic livestock while hunting. Violation of this section shall subject the violator to revocation of the tribal hunting permit in addition to any other penalties imposed by the Colville Law and Order Code.

4.8 *Violation of Other Regulations.* It shall be unlawful and it shall constitute a violation of this ordinance for any person to violate any regulation or resolution of the Council now in effect or hereafter promulgated pertaining to hunting and fishing.

CHAPTER 5. ENFORCEMENT

5.1 *General Powers of Officers.* It shall be the duty of every tribal game protector or other law enforcement officer to enforce this ordinance and all regulations adopted by the Council governing hunting and fishing on the North Half, and such officer may issue citations and/or make arrests of any persons violating this ordinance or any regulations of the Council pertaining to hunting and fishing.

5.2 *Arrest Without Warrant.* Any game protector or tribal law enforcement officer may, without warrant, arrest any person found violating this ordinance or any regulation of the Council pertaining to hunting and fishing pursuant to section 2.2.04 (Criminal Actions) of the Colville Law and Order Code.

5.3 *Search Without Warrant.* Any tribal game protector or other tribal law enforcement officer may search without warrant any conveyance, vehicle, game bag, game basket, game coat or other receptacle for game animals, birds or fish, or any package, box, tent, camp or other similar place which he has reason to believe contains evidence of violations of this ordinance or regulations of the Council pertaining to hunting and fishing.

5.4 *Search Warrants.* The Tribal Court may also issue a search warrant and direct a search to be made in any place wherein it is alleged that any bird, animals or fish taken or in possession contrary to this ordinance or regulations of the Colville Tribes is concealed or illegally kept. Such warrant shall issue pursuant to the provisions of Section 2.2.05 of the Colville Law and Order Code.

5.5 *Seizure.* Any game protector or other tribal law enforcement officer may seize without warrant all birds, animals, fish or parts thereof taken, killed, transported, or possessed contrary to this ordinance or any regulation of the Council pertaining to hunting and fishing, and any dog, gun, trap, net seine, decoy, bait, boat, light, fishing tackle, motor vehicle, or other device unlawfully used in hunting, fishing or trapping, or held with intent to use unlawfully in hunting, fishing or trapping.

5.6 *Forfeiture—Procedures.* Any contraband game or fish seized shall be subject to forfeiture at theo rder of the Tribal Court of the Colville Confederated Tribes after notice and opportunity for hearing or trial as hereafter set forth. In case it appears upon the sworn complaint of the officer making the seizures

that any articles seized were not in the possession of any person and that the owner thereof is unknown, the court shall have power and jurisdiction to forfeit such articles so seized upon a hearing duly had after service of summons on the unknown owner by publishing such summons in any newspaper of general circulation in Ferry or Okanogan County, or the *Colville Tribal Tribune* for a period of 4 successive issues. The summons shall describe the articles seized and shall give the owner 15 days from the date of last publication to appear before the Tribal Court and contest the forfeiture.

5.7 *Forfeiture—Disposition of Property.* In the event the Tribal Court orders forfeiture of any articles seized, such articles shall be turned over to the Council for the use and benefit of the Colville Tribes. If any articles are not declared forfeited by order of the Tribal Court, they shall be returned to the person from whom seized, after the completion of the case and the fines, if any, have been paid.

CHAPTER 6. ARRESTS: CITATIONS: TRIALS: PENALTIES

6.1 *Arrests: Citations and Trials: Generally.* Arrests may be made and citations issued for violations of this ordinance pursuant to the provisions of Title 2 of the Colville Law and Order Code. Hearings and trials for violations shall be held pursuant to the provisions of Titles 1, 2 and 4 of that Code.

6.2 *Penalties.* In the event a defendant pleads guilty or is found guilty, the court may impose all or any of the following penalties:

6.2.1 A fine of not less than $10 nor more than $250.

6.2.2 A jail term of not less than 1 day nor more than 30 days.

6.2.3 Forfeiture of any articles seized by reason of use of illegal activities.

6.2.4 Suspension or revocation of tribal hunting and fishing license or permit.

CHAPTER 7. MISCELLANEOUS PROVISIONS

7.1 *Permits—Standards—Revocation.* In issuing permits the Council shall seek to meet the needs of Colville people for food consistent with conservation of the resource. The Council may adopt any reasonable method of permitting designed to achieve an equitable distribution of the resource, including lotteries, drawings, and the like. Nothing herein shall bar suspension or revocation of outstanding permits for any reason.

7.2 *Severability.* If any provisions of this ordinance or the application thereof to any person or circumstance is held invalid, this ordinance can be given effect without the invalid provision or application; and to this end the provisions of this ordinance are declared to be severable.

MORRIS THOMPSON,
Commissioner of Indian Affairs.

[FR Doc.75-7986 Filed 3-26-75;8:45 am]

Bureau of Land Management

[N-11030]

NEVADA

Airport Lease Application

MARCH 20, 1975.

1. Notice is hereby given that pursuant to the act of May 24, 1928 (49 U.S.C. 211–214) The Anaconda Company has applied for an airport lease for the following land:

MOUNT DIABLO MERIDIAN, NEVADA

T. 28 N., R. 67 E.,
Sec. 22, S½, S½NE¼;
Sec. 23, W½W½;
Sec. 27, NE¼, N½SE¼.

2. The purpose of this notice is to inform the public that the filing of this application segregates the described land from all other forms of appropriation under the public land laws.

3. Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, 2002 Idaho Street, Elko, Nevada 89801.

WILLIAM J. MALENCIK,
Chief,
Division of Technical Services.

[FR Doc.75-7999 Filed 3-26-75;8:45 am]

[NM 23949]

NEW MEXICO

Application

MARCH 20, 1975,

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), City of Socorro has applied for a 4 inch natural gas pipeline right-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 1 S., R. 1 W.
Sec. 15, Lot 1, E½SE¼;
Sec. 27, SW¼NE¼;
Sec. 34, W½NE¼.
T. 2 S., R. 1 W.
Sec. 3, Lot 2, S½NE¼, E½SE¼;
Sec. 14, W½W½;
Sec. 15 NE¼NE¼;
Sec. 23, W½NW¼, SE¼NW¼, N½SW¼, SE¼SW¼;
Sec. 26, E½NW¼.

This pipeline will convey natural gas across 5.014 miles of natural resource lands in Socorro County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, PO Box 1456, 200 Neel Avenue, NW, Socorro, NM 87801.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc.75-8000 Filed 3-26-75;8:45 am]

[NM 24740]

NEW MEXICO

Application

MARCH 20, 1975.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), Continental Oil Company has applied for a 4 inch natural gas pipeline right-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 19 S., R. 31 E.,
Sec. 15, SW¼SW¼;
Sec. 22, SW¼NE¼, N½NW¼, SE¼NW¼, N½SE¼, and SE¼SE¼.

This pipeline will convey natural gas across 1.313 miles of national resource lands in Eddy County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, NM 88201.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc.75-8001 Filed 3-26-75;8:45 am]

[NM 24828]

NEW MEXICO

Application

MARCH 19, 1975.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), K. B. Kennedy Engineering Co., Inc., has applied for 3-inch, 6-inch, and 10-inch natural gas pipelines rights-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 14 S., R. 29 E.,
Sec. 23, SW¼NE¼, W½SE¼.
T. 13 S., R. 30 E.,
Sec. 1, lots 1, 2, SW¼NE¼, E½SW¼, NW¼ SE¼;
Sec. 11, SE¼SE¼;
Sec. 12, N½NW¼, SW¼NW¼, W½SW¼;
Sec. 13, NE¼NE¼, W½NE¼, E½NW¼, SW¼NW¼;
Sec. 14, E½NE¼, SW¼NE¼, SW¼, N½ SE¼, SW¼SE¼;
Sec. 15, S½SE¼;
Sec. 22, SE¼SE¼;
Sec. 23, E½NW¼, SW¼NW¼, W½SW¼;
Sec. 27, E½NE¼, SW¼NE¼, SE¼SW¼, W½SE¼;
Sec. 34, E½NW¼, SW¼NW¼, W½SW¼ and NE¼SW¼.
T. 14 S., R. 30 E.,
Sec. 3, lot 4;
Sec. 4, lot 1, SE¼NE¼, N½SE¼, SW¼ SE¼;
Sec. 9, NW¼NE¼, E½NW¼, N½SW¼, SW¼SW¼;
Sec. 16, W½W½;
Sec. 21, W½W½;
Sec. 28, W½W½;
Sec. 33, W½W½.

T. 15 S., R. 30 E.,
Sec. 4, lot 4, SW¼NW¼, W½SW¼;
Sec. 5, lot 1, SE¼SW¼;
Sec. 8, E½NW¼, NE¼SW¼, E½SE¼;
Sec. 17, NE¼NE¼.
T. 12 S., R. 31 E.,
Sec. 17, SW¼NE¼, SE¼NW¼, E½SW¼, SW¼SW¼;
Sec. 20, N½NW¼, SW¼NW¼, NW¼SW¼;
Sec. 30, W½NE¼, NE¼SW¼, NW¼SE¼;
Sec. 31, lots 1, 2, 3, and NE¼NW¼.
T. 13 S., R. 31 E.,
Sec. 7, lot 4, SE¼SW¼, SE¼;
Sec. 8, NW¼SW¼;
Sec. 18, lot 1.

These pipelines will convey natural gas across 22.526 miles of national resource lands in Chaves County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, NM 88201.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc.75-8002 Filed 3-26-75;8:45 am]

Bureau of Reclamation

TWIN BUTTES RESERVOIR, SAN ANGELO, TEXAS

Public Hearing for Designating Certain Areas for Off-Road Vehicle Use

Pursuant to Title 43, subtitle B, part 420, of the Code of Federal Regulations and Executive Order No. 11644, dated February 8, 1972, a public hearing will be held in San Angelo, Texas, at San Angelo City Hall, City Commission Chamber, April 16, 1975, 9 a.m., to receive views and comments from interested individuals and organizations on designating lands for off-road vehicle areas and trails in the Twin Buttes Reservoir area near San Angelo, Texas. The area is further described as being located on a portion of section 101 of the David Lloyd Survey, Tom Green County, Texas.

Each oral statement made at the hearing will be limited to a period of 10 minutes. Speakers will not trade their time to obtain a longer oral presentation; however, the person authorized to conduct the hearing may allow any speaker to provide additional oral comments after all persons wishing to comment have been heard. Speakers will be scheduled according to the time preference mentioned in their requests, whenever possible. Any scheduled speaker not present when called will lose his privilege in the scheduled order and his name will be recalled at the end of the scheduled speakers. Requests for scheduled presentations will be accepted up to 4:30 p.m., April 10, 1975. All subsequent requests will be handled on a first-come-first-served basis following the scheduled presentations.

Organizations or individuals desiring to present their statements at the hearing should contact the Regional Director, Bureau of Reclamation, Southwest Region, Room 1418, Herring Plaza, Box H-4377, Amarillo, Texas 79101, telephone number (806) 376-2401, and announce their intentions to participate. Written comments from those unable to attend and from those wishing to supplement their oral presentation at the hearing should be received by April 24, 1975, for inclusion in the records of the hearing.

Dated: March 21, 1975.

E. F. SULLIVAN,
Acting Commissioner, Bureau of Reclamation.

[FR Doc.75-7921 Filed 3-26-75;8:45 am]

Office of the Secretary

[Int Des 75-14]

BELLE AYR SOUTH MINE, CAMPBELL COUNTY, WYOMING

Availability of Draft Environmental Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a draft environmental impact statement on a proposed expansion of coal mining operations at Amax Coal Company's Belle Ayr South Mine, Campbell County, Wyoming. The draft statement assesses the environmental impacts of the lessee's plan for the strip mining of federally owned coal and the concurrent reclamation and revegetation of surface lands. The proposed action is an extension and expansion of present mining operations in the Belle Ayr South Mine, including a further extension thereof onto Federal coal lease Wyoming 0317682, Ts. 47 and 48 N., R. 71 W., 6th Prin. Mer.

The draft environmental statement is available for public review in the U.S. Geological Survey Public Inquiries Office, Room 1012, Federal Building, Denver, Colorado 80202; the U.S. Geological Survey Library, Building 25, Denver Federal Center, Denver, Colorado 80225; the U.S. Geological Survey Library, Room 4A100, USGS National Center, Reston, Virginia; the Converse County Library, 300 Walnut Street, Douglas, Wyoming 82633; the George Amos Memorial Library, 412 South Gillette Avenue, Gillette, Wyoming 82716; the Library of Natrona County, 307 East Second, Casper, Wyoming 82601; and the State Library, State of Wyoming, Supreme Court Building, Cheyenne, Wyoming 82002.

Limited numbers of copies of the statement are available from the U.S. Geological Survey Public Inquiries Office, Room 1012, Federal Building, Denver, Colorado 80202 and the United States Geological Survey, National Center, Mailstop 108, Reston, Virginia 22092.

The Department will accept written comments on the draft environmental impact statement on the Belle Ayr South Mine for a period of 45 days subsequent to the date of this notice, and will consider any comments received in preparing the final environmental statement on this proposal. Written comments should be addressed to Director, United States Geological Survey, National Center, Mailstop 108, Reston, Virginia 22092.

The proposed mining and reclamation plan assessed in this statement was one of the mining proposals identified in the preparation of the regional analysis (Part I) of the Department's final environmental statement, FES 74-55, entitled "Proposed Development of Coal Resources in the Eastern Powder River Coal Basin of Wyoming," which was filed with the Council on Environmental Quality on October 18, 1974. Public hearings on the draft of that statement were held as follows: June 24-25, 1974 at Cheyenne, Wyoming; June 26, 1974 at Casper, Wyoming; and June 27-28, 1974 at Gillette, Wyoming.

The Department has deferred a decision on the need for public hearings on the draft environmental statement at this time. If sufficient interest in holding such hearings becomes evident, the Department will consider the matter further.

Dated: March 24, 1975.

ROYSTON C. HUGHES,
Assistant Secretary of the Interior.

[FR Doc.75-7987 Filed 3-26-75;8:45 am]

CHARLES A. CAMPBELL

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b)(6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of February 4, 1975.

Dated: February 4, 1975.

CHARLES A. CAMPBELL.

[FR Doc.75-8003 Filed 3-26-75;8:45 am]

DAVID G. JETER

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b)(6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 1, 1975.

Dated: January 30, 1975.

DAVID G. JETER.

[FR Doc.75-8004 Filed 3-26-75;8:45 am]

J. W. KEPNER

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 28, 1974.

Dated: January 28, 1975.

J. W. KEPNER.

[FR Doc.75-8005 Filed 3-26-75;8:45 am]

ROBERT E. KERGER

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of February 7, 1975.

Dated: February 7, 1975.

ROBERT E. KERGER.

[FR Doc.75-8006 Filed 3-26-75;8:45 am]

OWEN A. LENTZ

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 30, 1975.

Dated: January 30, 1975.

O. A. LENTZ.

[FR Doc.75-8007 Filed 3-26-75;8:45 am]

ROBERT R. McLAGAN

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 28, 1975.

Dated: January 28, 1975.

R. R. McLAGAN.

[FR Doc.75-8008 Filed 3-26-75;8:45 am]

HARRY H. MOCHON, JR.

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) Tiger Intl (delete).
(3) No change
(4) No change.

This statement is made as of January 27, 1975.

Dated: January 27, 1975.

H. H. MOCHON, Jr.

[FR Doc.75-8009 Filed 3-26-75;8:45 am]

JULIO A. NEGRONI

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 30, 1975.

Dated: January 30, 1975.

JULIO NEGRONI.

[FR Doc. 75-8010 Filed 3-26-75;8:45 am]

WILLIAM K. PENCE

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) None.
(2) None.
(3) None.
(4) None.

This statement is made as of January 28, 1975.

Dated: January 28, 1975.

WILLIAM K. PENCE.

[FR Doc.75-8011 Filed 3-26-75;8:45 am]

LEROY J. SCHULTZ

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 27, 1975.

Dated: January 27, 1975.

L. J. SCHULTZ.

[FR Doc.75-8012 Filed 3-26-75;8:45 am]

CHARLES W. WATSON

Statement of Changes in Financial Interests

In accordance with the requirements of section 710(b) (6) of the Defense Production Act of 1950, as amended, and Executive Order 10647 of November 28, 1955, the following changes have taken place in my financial interests during the past six months:

(1) No change.
(2) No change.
(3) No change.
(4) No change.

This statement is made as of January 27, 1975.

Dated: January 27, 1975.

CHARLES W. WATSON.

[FR Doc.75-8013 Filed 3-26-75;8:45 am]

DEPARTMENT OF COMMERCE

Domestic and International Business Administration

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.)

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 73-00424-00-66700. Applicant: Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, Mass. 02139. Article: Spare parts for prevost projector consisting of 18 condenser lenses and 18 flat pieces. Manufacturer: Officine Prevost, Italy. Intended use of article: The articles are spare parts to an existing prevost projector used in conjunction with AEC basic research for scanning and measuring spark chamber and bubble chamber film.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The application relates to compatible components for an instrument that had been previously imported for the use of the applicant institution. The article is being furnished by the manufacturer which produced the instrument with which the article is intended to be used and is pertinent to the applicant's purposes.

The Department of Commerce knows of no similar components being manufactured in the United States, which is interchangeable with or can be readily adapted to the instrument with which the foreign article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director, Special Import Programs Division.

[FR Doc.75-7972 Filed 3-26-75;8:45 am]

UNIVERSITY OF MIAMI, ET AL.

Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Special Import Programs Division, Office of Import Programs, Washington, D.C. 20230, on or before April 16, 1975.

Amended regulations issued under cited Act, as published in the February 24, 1972 issue of the FEDERAL REGISTER, prescribe the requirements applicable to comments.

A copy of each application is on file, and may be examined during ordinary Commerce Department business hours at the Special Import Programs Division, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00375-00-17500. Applicant: University of Miami, Rosenstiel School of Marine & Atmospheric Science, 4600 Rickenbacker Causeway, Miami, Florida 33149. Article: Replacement Parts for Recording Current Meter. Manufacturer: Ivar Aanderaa, Norway. Intended use of article: The articles are replacement parts to an existing recording current meter which is being used in an experiment to distinguish between motions of the density surface due to internal waves and apparent motions of a temperature surface. This study has a significant bearing on the usual method of measuring internal waves by measuring the temperature field. Application received by Commissioner of Customs: February 12, 1975.

Docket number: 75-00395-33-46040. Applicant: City of Hope National Medical Center, Department of Pathology, 1500 East Duarte Road, Duarte, California 91010. Article: Electron Microscope, Model EM 301 with Anticontamination System. Manufacturer: Philips Electronic Instruments NVD, The Netherlands. Intended use of article: The article is intended to be used for (1) ultrastructural identification of intramitochondrial virus-like particles in human mammary carcinoma, (2) continued studies into the determination of possible diagnostic criteria for a wide variety of soft tissue sarcomas and other solid malignant tumors and associated morphologic characterization and localization of virus-like particles, (3) elucidation of ultrastructural characteristics of Reed-Sternberg cells in Hodgkin's Disease and so-called Reed-Sternberg-like cells which have been described in non-neoplastic disorders, with a careful search for E.B. viral particles in cases of Hodgkin's disease, (4) combined study of their ultrastructure, histochemistry and membrane receptor sites, with special emphasis on "histiocytic" lymphoma, and (5) a combined study of the transmission and scanning electron microscopy with ultrahistochemistry of Hodgkin's disease and non-Hodgkin's lymphomas and studies of membrane receptor sites. The objectives pursued in the course of these investigations is to determine the morphologic diagnostic criteria for a wide variety of pathologic malignant disorders and to determine the morphologic characterization and location of associated virus particles. The article will also be used in teaching post-doctorate fellows in Pathology and Surgical Pathology residents the basic information in reference to techniques in tissue preparation, sectioning, and basic electron microscopy operation via rotation through the electron microscopy laboratory. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00396-33-46040. Applicant: Columbia University, College of Physicians and Surgeons, Dept. of Physiology, 630 West 168th Street, New York, New York 10032. Article: Electron Microscope, Model EM 301 and Accessories. Manufacturer: Philips Electronic Instruments NVD, The Netherlands. Intended use of article:

The article is intended to be used for the following studies:

(1) The ultrastructure of identified synapses in Aplysia nervous system.

(2) The study of axoplasmic transport in single identified neurons of Aplysia.

(3) The morphology of individual macromolecular protein complexes. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00397-33-90000. Applicant: Santa Rosa Medical Center, 519 W. Houston, San Antonio, Texas 78285. Article: EMI Scanner with Magnetic Tape Storage System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used to scan patients' heads in series of either 0.8 cm or 1.3 cm wide slices, and thereby yield information on brain tissue for presentation in the most useful form for evaluation by neurologists and neurosurgeons. The article will also be used for the teaching of residents from the University of Texas at San Antonio. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00398-33-83600. Applicant: Cornell University, Department of Physics, Ithaca, New York 14850. Article: PLM-3 Pulsed Platinum NMR Thermometer with Plug in Cards. Manufacturer: Instruments for Technology Ltd., Finland. Intended use of article: The article is intended to be used to measure the nuclear magnetic susceptibility of platinum and the nuclear magnetic spin lattice relaxation time of the platinum powder. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00399-01-77040. Applicant: Grand Forks Energy Research Center, Energy Research and Development Administration, Box 8213, University Station, Grand Forks, N.D. 58202. Article: Mass Spectrometer, Model MS 3074 and Data System, DS-50. Manufacturer: AEI Scientific Apparatus Inc., United Kingdom. Intended use of article: The article is intended to be used for studies of organic products resulting from the liquefaction and gasification of lignite. The phenomena to be studied include the kinetics of the liquefaction of lignite during both batch and continuous processing studies. The article will enable the obtaining of specific information concerning the type of organic compounds present in the product. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00400-00-80050. Applicant: National Radio Astronomy Observatory, Associated Universities, Inc., Edgemont Road, Charlottesville, Virginia 22901. Article: Coupling Sleeves for 60 mm Helical Circular Waveguide. Manufacturer: Furukawa Electric Co. Ltd., Japan. Intended

use of article: The articles are accessories to an existing helical circular waveguide which is intended to be used as part of the Very large Array radio telescope to transmit radio wavelength radiation received from extraterrestrial objects to recording apparatus. The study of this radiation enables astronomers to study the sources of energy, origin, and evolution of the universe. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00401-85-40600. Applicant: University of Georgia, Department of Geology, Athens, Georgia 30602. Article: Double Collecting Mass Spectrometer-V.G. Micromass 602C with Digital Printer, Small Sample Adapter. Manufacturer: V.G. Micromass, United Kingdom. Intended use of article: The article is intended to be used for examination of the influence of surface meteoric waters upon subsurface volcanic processes through the study of variations in $^{18}O/^{16}O$ in rocks and minerals. Special emphasis will be placed upon the study of samples obtained from various localities in Antarctica. The article will also be used for isotope geochemistry studies.

The article will serve as an education tool for student research in many fields of geology. In addition the article will be used in a course titled: "Isotope geology and geochronology" serving to educate students in the general aspects of this subject area. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00402-75-49400. Applicant: Brookhaven National Laboratory, Associated Universities, Inc., Upton, Long Island, New York 11973. Article: Neutron Guide Tube. Manufacturer: Universitat Munchen Geschaftsfuhrer, West Germany. Intended use of article: The article is intended to be used in a program of investigating the properties of atomic nuclei. In particular, nuclei in high states of excitation are produced at charged particle accelerators and at the Brookhaven High Flux Research Reactor and the various properties of their excited energy levels are determined and compared with the predictions of nuclear models. Application received by Commissioner of Customs: March 4, 1975..

Docket number: 75-00403-33-46040. Applicant: University of California, San Diego, P.O. Box 109, La Jolla, California 92037. Article: Electron Microscope, Model EM 9S-2. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used in studies of structural adaptations in marine organisms by staff and students in Scripps Institution of Oceanography. The course entitled "Cell Physiology of Marine Organisms" is being offered and deals with (1) how methods of cell biology can solve problems peculiar to marine animals and (2) how marine animals provide favorable systems for elucidation of general problem cell biology (sic). Students being trained in electron microscopy will be familiarized with principles, construction, and operation of the electron microscope. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00404-00-46040. Applicant: Arizona State University, Tempe, Arizona 85281. Article: Heating Specimen Stage for JEM 100B Electron Microscope. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for studies of small crystals and thin films of inorganic compounds (mostly oxides) and alloys as a function of temperature. High resolution electron microscopy of the specimens will allow the study of the changes in the arrangements of atoms related to structural transformation. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00405-33-90000. Applicant: Tucson Medical Center, 5301 E. Grant Road, Tucson, Arizona 85712. Article: EMI Scanner with Magnetic Tape Storage System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used in the examination of the patient's head through the use of a narrow beam of x-rays. This unit will make it possible to analyze the brain visually far more accurately than has been heretofore possible. The article will be used in conjunction with the present neurological and neurosurgical and radiological training programs as an educational tool to assist in properly training residents in the diagnosis of certain medical problems such as headaches, seizure activity, brain tumor suspects, head injuries, stroke and intracerebral bleeding. Application received by Commissioner of Customs: March 4, 1975.

Docket number: 75-00406-44-01100. Applicant: Tulane University School of Medicine, 1430 Tulane Avenue, New Orleans, Louisiana 70112. Article: Morgan Transfertest Model B with Associated Gas Analyzers. Manufacturer: P. K. Morgan, Ltd., United Kingdom. Intended use of article: The article is intended to be used for the measurement of lung volume and capacities and for the determination of single-breath diffusing capacity. The purpose of this measurement is to assess damage of the alveolar capillary interspace which is experimentally detected by decrease in the transfer of gas from the air to the blood. The article will also be used to teach National Institutes of Health trainees the technique of measuring pulmonary diffusing capacity, which will enable them to set up and supervise their own pulmonary function laboratory when they complete training. Application received by Commissioner of Customs: March 4, 1975.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director,
Special Import Programs Division.

[FR Doc.75-7973 Filed 3-26-75;8:45 am]

NEW YORK UNIVERSITY MEDICAL CENTER ET AL.

Consolidated Decision on Applications for Duty Free Entry of Scientific Articles

The following is a consolidated decision on applications for duty-free entry of EMI Scanner Systems pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq). (See especially section 701.11(e).)

A copy of the record pertaining to each of the applications in this consolidated decision is available for public review during ordinary business hours of the Department of Commerce, at the Special Import Programs Division, Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket Number: 75-00211-33-90000. Applicant: New York University Medical Center, 550 First Avenue, New York, N.Y. 10016. Article: EMI Scanner System. Manufacturer: EMI Limited, United Kingdom. Intended Use of Article: The article is intended to be used for the investigation of cerebral diseases such as tumors, cysts and hemorrhages which overcome the limitations of conventional X-ray techniques in brain tissue investigations. The article will provide the diagnostician with accurate information on the nature and location of diseased or damage tissue and eliminate the principal physical and psychological discomforts to patients which have been unavoidable with some other techniques. Application Received By Commissioner of Customs: November 19, 1974. Advice Submitted by the Department of Health, Education, and Welfare on: February 21, 1975. Article Ordered: June 25, 1973.

Docket Number: 75-00221-33-90000. Applicant: Delaware Valley Neurosurgical Association—Episcopal Hospital, C-111 Episcopal Hospital, Front Street and Lehigh Avenue, Philadelphia, Pa. 19125. Article: EMI Scanner System. Manufacturer: EMI Limited, United Kingdom. Intended Use Of Article: The article will be used to study the brain by computerized transaxial tomography (CTT). Examples of planned projects are the study of traumatic and/or spontaneous intracranial hemorrhage, management of cerebral edema, the effect of immunotherapy on the growth of brain tumors, dementia, isotope brain scan versus CTT and ultrasound versus CTT. The article will also be used to train neurological, neurosurgical and radiological residents, as well as medical students and physicians in the use of CTT. Application Received By Commissioner Of Customs: November 20, 1974. Advice Submitted By The Department Of Health, Education, And Welfare on: February 21, 1975. Article Ordered: November 19, 1973.

Docket number: 75-00247-33-90000. Applicant: Children's Hospital of Pittsburgh, 125 DeSota Street, Pittsburgh, Pa. 15213. Article: EMI Scanner System with

Magnetic Tape System and High Density Display Unit. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used, in addition to performing clinical studies on patients, in the postgraduate medical training programs of Children's Hospital of Pittsburgh and Presbyterian-University Hospitals. It will be used primarily in the training of neuroradiology fellows, neurosurgery residents, neurology residents and neuropathology fellows. Application received by Commissioner of Customs: December 4, 1974. Advice submitted by the Department of Health, Education, and Welfare on: February 21, 1975. Article ordered: September 12, 1974.

Docket number: 75-00249-33-90000. Applicant: The Swedish Hospital Medical Center, 747 Summit, Seattle, Washington 98104. Article: EMI Scanner System with Magnetic Tape Storage Option. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used to investigate lesions of the orbit, multiple sclerosis, migraine headaches, tumors of the sella and acoustic neuromas. The article will also be used to train technologists in the operation of the article. Application received by Commissioner of Customs: December 4, 1974. Advice submitted by the Department of Health, Education, and Welfare on: February 21, 1975. Article ordered: October 16, 1974.

Comments: No comments have been received with respect to any of the foregoing applications. Decision: Applications approved. No instrumuent or apparatus of equivalent scientific value to the foreign articles, for such purposes as these articles are intended to be used, were being manufactured in the United States at the time the articles were ordered. Reasons: Each foreign article is a newly developed system which is designed to provide precise transverse axial X-ray tomography. The Department of Health, Education, and Welfare (HEW) advises in its respectively cited memoranda that the sensitivity and the noninvasive methodology of each article are pertinent to the purposes for which each foreign article is intended to be used. HEW also advises that it knows of no domestic instrument of equivalent scientific value to any of the articles to which the foregoing applications relate for such purposes as these articles are intended to be used which was being manufactured in the United States at the time the articles were ordered.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to any of the foreign articles to which the foregoing applications relate, for such purposes as these articles are intended to be used, which were being manufactured in the United States at the time the articles were ordered.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director,
Special Import Programs Division.

[FR Doc.75-7978 Filed 3-26-75;8:45 am]

UNIVERSITY OF CALIFORNIA AND IOWA STATE UNIVERSITY

Consolidated Decision on Applications for Duty Free Entry of Scientific Articles

The following is a consolidated decision on applications for duty-free entry of ^{3}HE Neutron Spectrometers pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.). (See especially Section 701.11(e).)

A copy of the record pertaining to each of the applications in this consolidated decision is available for public review during ordinary business hours of the Department of Commerce, at the Special Import Programs Division, Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 74-00050-75-77025. Applicant: University of California, Purchasing Department, P.O. Box 1500, Berkeley, California 94701. Article: ^{3}He Fast Neutron Spectrometer. Manufacturer: Seforad-Applied Radiation Ltd., Israel. Intended use of article: The foreign article will be used in research studies of delayed neutron spectra from decay of short-lived fission products. It is intended the studies will include as many spectra as are accessible under the available experimental conditions. Application received by Commissioner of Customs: July 30, 1973. Advice submitted by the National Bureau of Standards on: May 10, 1974.

Docket Number: 74-00292-75-77025. Applicant: Iowa State University, Ames Laboratory, Ames, Iowa 50010. Article: Neutron Spectrometer. Manufacturer: Technion Research Foundation, Israel. Intended use of article: The article is intended to be used to study the neutron energy spectrum of various mass-separated fission products nuclides. Application received by Commissioner of Customs: January 14, 1974. Advice submitted by the National Bureau of Standards on: May 13, 1974.

Comments: No comments have been received with respect to either of the foregoing applications. Decision: Applications approved. No instrument or apparatus of equivalent scientific value to the foreign articles, for such purposes as these articles are intended to be used, is being manufactured in the United States. Reasons: Each foreign article provides the highest resolution available which is significantly superior to the resolution capability provided by neutron spectrometers of the proportional counter type (i.e., each foreign article provides an energy resolution of better than 20 keV (kiloelectronvolts) for thermal neutrons). The National Bureau of Standards (NBS) advised in the respectively cited memoranda that the capabilities described above are pertinent to the purposes for which each of the foreign articles cited above is intended to be used. NBS also advised that it knows of no domestically manufactured instrument which is scientifically equivalent to any of the foreign articles to which the foregoing applications relate for such purposes as these articles are intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director, Special Import Programs Division.

[FR Doc.75-7975 Filed 3-26-75;8:45 am]

UNIVERSITY OF CALIFORNIA—LOS ALAMOS

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket Number: 75-00231-75-68495. Applicant: University of California, Los Alamos Scientific Laboratory, P.O. Box 990, Los Alamos, New Mexico 87544. Article: Pump: Electric Drive. Manufacturer: Stansted Eng. Co. Ltd., United Kingdom. Intended use of article: The article is intended to be used to extend P-V-T data on the molecular hydrogens up to 40 kbar to better understand the processes leading to laser fusion and the creation of metallic hydrogen.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: This application is a resubmission of Docket Number 74-00493-01-68495 which was denied without prejudice to resubmission on September 17, 1974 for informational deficiencies. The foreign article, a hydraulic pump, provides the specification of constant pressure characteristics. The National Bureau of Standards (NBS) advises in its memorandum dated February 27, 1975 that the specification described above is pertinent to the applicant's intended purpose. NBS also advises that it knows of no domestic constant pressure pump of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director, Special Import Programs Division.

[FR Doc.75-7974 Filed 3-26-75;8:45 am]

UNIVERSITY OF ILLINOIS

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00188-00-46040. Applicant: University of Illinois, Urbana-Champaign Campus, Purchasing Division, 223 Admin. Bldg., Urbana, Illinois 61801. Article: Low Temperature Specimen Stage, Type KH-4BM (Modified). Manufacturer: Hitachi Perkin-Elmer, Japan. Intended use of article: The article is an accessory device for an existing electron microscope which will allow the general observation of specimens at low temperatures (in addition to room temperature) for the study of nucleation and growth of martensitic phases at low temperatures; pre-transformation lattice instabilities as observed at room temperatures and below.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The application relates to a compatible accessory for an instrument that had been previously imported for the use of the applicant institution. The article is being furnished by the manufacturer which produced the instrument with which the article is intended to be used and is pertinent to the applicant's purposes.

The Department of Commerce knows of no similar accessory being manufactured in the United States, which is interchangeable with or can be readily adapted to the instrument with which the foreign article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director, Special Import Programs Division.

[FR Doc.75-7976 Filed 3-26-75;8:45 am]

YALE UNIVERSITY

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00241-00-46040. Applicant: Yale University, Purchasing Department, 20 Ashmun Street, New Haven, Conn. 06520. Article: 35mm Roll Film Camera. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is an accessory to an existing electron microscope being used to examine the ultrastructural characteristics of a variety of transporting epithelia. The article will allow for 45 additional exposures of specimens on 35mm film thus allowing for better utilization of stereo-pair photography of the intra-cellular contacts which are to be studied and also allowing for better recording of serial reconstructions of the transporting epithelia studied by both standard transmission and freeze etch electron microscopy.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The application relates to a compatible accessory for an instrument that had been previously imported for the use of the applicant institution. The article is being furnished by the manufacturer which produced the instrument with which the article is intended to be used and is pertinent to the applicant's purposes.

The Department of Commerce knows of no similar accessory being manufactured in the United States, which is interchangeable with or can be readily adapted to the instrument with which the foreign article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

A. H. STUART,
Director, Special Import Programs Division.

[FR Doc.75-7977 Filed 3-26-75;8:45 am]

SEMICONDUCTOR TECHNICAL ADVISORY COMMITTEE

Partially Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. III, 1973), notice is hereby given that a meeting of the Semiconductor Technical Advisory Committee will be held on Wednesday, April 30, 1975, at 9:30 a.m. in Room 3708, Main Commerce Building, 14th and Constitution Avenue NW., Washington, D.C.

The Semiconductor Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, the Acting Assistant Secretary for Administration, approved the recharter and extension of the Committee for two additional years, pursuant to section 5 (c) (1) of the Export Administration Act of 1969, as amended, (50 U.S.C. App. 2404 (c) (1)) (Supp. III, 1973) and the Federal Advisory Committee Act.

The Committee advises the Office of Export Administration, Bureau of East-West Trade with respect to questions involving technical matters, world-wide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to semiconductor products, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls.

The Committee meeting agenda has four parts:

GENERAL SESSION

(1) Opening remarks by the Chairman.

(2) Presentation of papers or comments by the public.

(3) Discussion of integrated circuits.

EXECUTIVE SESSION

(4) Discussion of matters properly classified under Executive Order 11652 dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The public will be permitted to attend the General Session, at which a limited number of seats will be available to the public. To the extent time permits members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (4), the Assistant Secretary of Commerce for Administration, with the concurrence of the delegate of the General Counsel, formally determined on December 16, 1974, pursuant to section 10(d) of the Federal Advisory Committee Act that the matters to be discussed in the Executive Session should be exempt from the provisions of the Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552(b)(1), i.e., it is specifically required by Executive Order 11652 that they be kept confidential in the interest of the national security. All matters have been properly classified under the Executive Order. All Committee members have appropriate security clearances.

Minutes of the open portion of the meeting will be available upon written request addressed to the Central Reference and Records Inspection Facility, Room 7043, U.S. Department of Commerce.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Domestic and International Business Administration, Room 1620, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202–967–4196.

In accordance with paragraph (4) of the Order of the United States District Court for the District of Columbia in *Aviation Consumer Action Project, et al., v. C. Langhorne Washburn, et al.*, September 10, 1974, as amended, September 23, 1974 (Civil Action No. 1838–73), the Complete Notice of Determination to close portions of the series of meetings of the Semiconductor Technical Advisory Committee and of any subcommittees thereof, was published in the FEDERAL REGISTER (40 FR 18, appearing in the issue of January 2, 1975).

Dated: March 21, 1975.

RAUER H. MEYER,
Director, Office of Export Administration, Bureau of East-West Trade.

[FR Doc.75–7961 Filed 3–26–75;8:45 am]

National Bureau of Standards

FEDERAL INFORMATION PROCESSING STANDARDS TASK GROUP 15 COMPUTER SYSTEMS SECURITY

Meeting

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. III, 1973), notice is hereby given that the Federal Information Processing Standards Task Group 15 (FIPS TG–15), Computer Systems Security, will hold a meeting from 9 a.m. to 4 p.m. on Tuesday, May 6, 1975 and Wednesday, May 7, 1975, in Room B–163, Building 222, of the National Bureau of Standards at Gaithersburg, Maryland.

The purpose of this meeting is to continue drafting guidelines in four areas of computer systems security: information management; internal controls; teleprocessing and network control; and requirements.

The public will be permitted to attend, to file written statements, and, to the extent that time permits, to present oral statements. Persons planning to attend should notify Dr. Dennis K. Branstad, Institute for Computer Sciences and Technology, National Bureau of Standards, Washington, D.C. 20234 (Phone 301–921–3861).

Dated: March 21, 1975.

RICHARD W. ROBERTS,
Director.

[FR Doc.75–7920 Filed 3–26–75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control

SAFETY AND OCCUPATIONAL HEALTH STUDY SECTION

Meeting

Pursuant to Pub. L. 92–463, the Director, Center for Disease Control announces the meeting dates and other required information for the following National Advisory body of the National Institute for Occupational Safety and Health which is scheduled to assemble during the month of April 1975.

Committee name	Date/time/place	Type of meeting and/or contact person
Safety and Occupational Health Study Section.	Apr. 9–11, 1975, 9 a.m., Bldg. 1, Room 207, Center for Disease Control, 1600 Clifton Rd. NE., Atlanta, Ga. 30333.	Open 9 a.m. to 12 noon on Apr. 9, closed remainder of meeting, contact: Dr. John F. Bester, NIOSH, Room 3–44 Park Bldg., 5600 Fishers Lane, Rockville, Md. 20852, Code: 301–443–4123.

Purpose: The committee is charged with the initial review of research, training, demonstration, and fellowship grant applications for Federal assistance in program areas administered by the National Institute for Occupational Safety and Health, and with advising the Institute staff on training and research needs.

Agenda: From 9 a.m. to 12 noon on April 9, the Study Section meeting will be open to reading of minutes of previous meeting; administrative and staff reports; presentation of certificates to retiring members and presentations by staff of the Center for Disease Control. From 12 noon until the end of the meeting, the Study Section will review research, demonstration, and training grant applications and will not be open to the public, in accordance with the determination by the Director, Center for Disease Control, pursuant to the provisions of Public Law 92–463, section 10(d).

Agenda items are subject to change as priorities dictate.

A roster of members and other relevant information regarding the meeting may be obtained from the contact person listed above.

Dated: March 19, 1975.

DAVID N. SENCE,
Director,
Center for Disease Control.

[FR Doc.75–7913 Filed 3–26–75;8:45 am]

Food and Drug Administration

[FAP 5B3078]

BORG-WARNER CORP.

Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409 (b)(5), 72 Stat. 1786; (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B3078) has been filed by Carr, Bonner, O'Connell, Kaplan and Thompson, 900 Seventeenth St. NW., Washington, DC 20006, on behalf of Borg-Warner Corp. proposing that § 121.2627 Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer (21 CFR 121.2627) be amended to provide for additional safe uses of the copolymer. Use of the copolymer, currently restricted to low moisture fats and oils, would be expanded to include contact with all types of food, except that it could not be used in fabricating bottles intended to hold carbonated beverages or beer.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Assistant Commissioner for Public Affairs, Rm. 15B–42 or the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, during working hours, Monday through Friday.

Dated: March 18, 1975.

HOWARD R. ROBERTS,
Acting Director, Bureau of Foods.

[FR Doc.75–7955 Filed 3–26–75;8:45 am]

PANEL ON REVIEW OF TOPICAL ANALGESICS

Meeting Place

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463, 86 Stat. 770–776; (5 U.S.C. App. D), the Food and Drug Administration announced in a notice published in the FEDERAL REGISTER of March 17, 1975 (40 FR 12142), public advisory committee meetings and other required information, in accordance with provisions set forth in section 10(a) (1) and (2) of the act.

Notice is hereby given that the Panel on Review of Topical Analgesics scheduled for April 17 and 18, 1975, will be held in Conference Rm. M, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20852, at 9 a.m.

Dated: March 21, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75–7954 Filed 3–26–75;8:45 am]

PANEL ON REVIEW OF VIRAL VACCINES AND RICKETTSIAL VACCINES

Meeting Change

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463, 86 Stat. 770–776; (5 U.S.C. App. D), the Food and Drug Administration announced in a notice published in the FEDERAL REGISTER of March 17, 1975 (40 FR 12142), public advisory committee meetings and other required information, in accordance with provisions set forth in section 10(a) (1) and (2) of the act.

Notice is hereby given that the Panel on Review of Viral Vaccines and Rickettsial Vaccines scheduled for April 11 and 12, 1975, is rescheduled for April 10, 11, and 12; the open session is on April 10, 1975.

Dated: March 21, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-7953 Filed 3-26-75;8:45 am]

Food and Drug Administration

ADVISORY COMMITTEES

Meeting

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776; 5 U.S.C. App. I), the Food and Drug Administration announces the following public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a) (1) and (2) of the act:

Committee name	Date, time, place	Type of meeting and contact person
1. Panel on Review of Miscellaneous External Drug Products.	April 20 and 21, 9 a.m., Conference Room A, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Closed April 20, open April 21, 9 a.m. to 10 a.m., closed April 21 after 10 a.m., Thomas D. DeCillis (HFD-510), 5600 Fishers Lane, Rockville, Md. 20852, 301-443-4960.

Purpose. Reviews and evaluates available data on the safety and effectiveness of active ingredients of currently marketed nonprescription drug products containing miscellaneous external drug products.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continuing review of over-the-counter miscellaneous external drug products under investigation.

Committee name	Date, time, place	Type of meeting and contact person
2. Pediatric Advisory Panel of the Psychopharmacological Agents Advisory Committee.	April 25, 9 a.m., Hospitality House, Motor Inn, 2000 Jefferson Davis Hwy., Arlington, Va.	Open—Julius Cinque (HFD-120), 5600 Fishers Lane, Rockville, Md. 20852, 301-443-3300.

Purpose. Reviews and evaluates all available data concerning the safety and effectiveness of presently marketed and new prescription drug products proposed for marketing for use in the practice of psychiatry and related fields.

Agenda. Subpanel reports on phenothiazines and the mentally retarded; the development of long term protocols; and the pediatric guidelines.

Agenda items are subject to change as priorities dictate.

During the open sessions shown above, interested persons may present relevant information or views orally to any committee for its consideration. Information or views submitted to any committee in writing before or during a meeting shall also be considered by the committee.

A list of committee members and summary minutes of meetings may be obtained from the contact person for the committee both for meetings open to the public and those meetings closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act.

Most Food and Drug Administration advisory committees are created to advise the Commissioner of Food and Drugs on pending regulatory matters. Recommendations made by the committees on these matters are intended to result in action under the Federal Food, Drug, and Cosmetic Act, and these committees thus necessarily participate with the Commissioner in exercising his law enforcement responsibilities.

The Freedom of Information Act recognized that the premature disclosure of regulatory plans, or indeed internal discussions of alternative regulatory approaches to a specific problem, could have adverse effects upon both public and private interests. Congress recognized that such plans, even when finalized, may not be made fully available in advance of the effective date without damage to such interests, and therefore provided for this type of discussion to remain confidential. Thus, law enforcement activities have long been recognized as a legitimate subject for confidential consideration.

These committees often must consider trade secrets and other confidential information submitted by particular manufacturers which the Food and Drug Administration by law may not disclose, and which Congress has included within the exemptions from the Freedom of Information Act. Such information includes safety and effectiveness information, product formulation, and manufacturing methods and procedures, all of which are of substantial competitive importance.

In addition, to operate most effectively, the evaluation of specific drug or device products requires that members of committees considering such regulatory matters be free to engage in full and frank discussion. Members of committees have frequently agreed to serve and to provide their most candid advice on the understanding that the discussion would be private in nature. Many experts would be unwilling to engage in candid public discussion advocating regulatory action against a specific product. If the committees were not to engage in the deliberative portions of their work on a confidential basis, the consequent loss of frank and full discussion among committee members would severely hamper the value of these committees.

The Food and Drug Administration is relying heavily on the use of outside experts to assist in regulatory decisions. The Agency's regulatory actions uniquely affect the health and safety of every citizen, and it is imperative that the best advice be made available to it on a continuing basis in order that it may most effectively carry out its mission.

A determination to close part of an advisory committee meeting does not mean that the public should not have ready access to these advisory committees considering regulatory issues. A determination to close the meeting is subject to the following conditions: First, any interested person may submit written data or information to any committee, for its consideration. This information will be accepted and will be considered by the committee. Second, a portion of every committee meeting will be open to the public, so that interested persons may present any relevant information or views orally to the committee. The period for open discussion will be designated in any announcement of a committee meeting. Third, only the deliberative portion of a committee meeting, and the portion dealing with trade secret and confidential information, will be closed to the public. The portion of any meeting during which nonconfidential information is made available to the committee will be open for public participation. Fourth, after the committee makes its recommendations and the Commissioner either accepts or rejects them, the public and the individuals affected by the regulatory decision involved will have an opportunity to express their views on the decision. If the decision results in promulgation of a regulation, for example, the proposed regulation will be published for public comment. Closing a committee meeting for deliberations on regulatory matters will therefore in no way preclude public access to the committee itself or full public comment with respect to the decisions made based upon the committee's recommendation.

The Commissioner has been delegated the authority under section 10(d) of the Federal Advisory Committee Act to issue a determination in writing, containing the reasons therefor, that any advisory committee meeting is concerned with matters listed in 5 U.S.C. 552(b), which contains the exemptions from the public disclosure requirements of the Freedom of Information Act. Pursuant to this authority, the Commissioner hereby determines, for the reasons set out above, that the portions of the advisory committee meetings designated in this notice as closed to the public involve discussion of existing documents falling within one of the exemptions set forth in 5 U.S.C. 552(b), or matters that, if in writing, would fall within 5 U.S.C. 552(b), and that it is essential to close such portions of such meetings to protect the free exchange of internal views and to avoid undue interference with Agency and committee operations. This determination shall apply only to the designated portions of such meetings which relate

to trade secrets and confidential information or to committee deliberations.

Dated: March 24, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-8070 Filed 3-26-75;8:45 am]

TOXICOLOGY ADVISORY COMMITTEE

Request for Nominations for Members

A notice was published in the FEDERAL REGISTER of December 24, 1974 (39 FR 44473), announcing establishment of the Food and Drug Administration's Toxicology Advisory Committee. This notice requests nominations for members of that advisory committee, to be submitted to the Commissioner of Food and Drugs by April 28, 1975. The charter of the Toxicology Advisory Committee is on public display in the office of the Hearing Clerk and is available upon request from the Associate Commissioner for Science.

The purpose of the Toxicology Advisory Committee is to advise the Commissioner in discharging his responsibilities under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act as they relate to safety evaluation of the potential toxicity of chemicals present in food, drugs, medical devices, and cosmetics. The committee will review and evaluate all available data relating to evaluation of the safety of such chemicals, advise the Commissioner on matters concerning the safety of specific chemicals, and recommend the development of standardized methodology for the toxicity testing of such materials.

Whenever the Commissioner concludes that it is appropriate to obtain an independent review of any scientific issue involving application of the anticancer clauses in the Federal Food, Drug, and Cosmetic Act, he will ordinarily refer such matter to the Toxicology Advisory Committee for advice and recommendations except as specifically required by section 706(b)(5)(C) of the act.

The advisory committee will consist of the Associate Commissioner for Science, as chairman, and 12 members who are expert in one or more of the following disciplines:

Toxicology
Pharmacology
Oncology (carcinogenesis)
Mutagenesis
Teratogenesis
Pathology
Metabolism
Biochemistry
Biostatistics
Immunology
Medicine
Laboratory Animal Science

The Commissioner hereby invites the submission of nominations for members for this advisory committee. Any interested person may nominate one or more qualified persons. A complete curriculum vitae of the nominee shall be enclosed with the nomination. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest which would preclude membership on the advisory committee. Nominations should state the particular field of expertise, listed above, for which the nominee is qualified.

Members of the advisory committee will be invited to serve for overlapping terms of four years, with initial appointments terminating at different times to permit orderly rotation of members. All members who are not already full-time or part-time Federal employees will be special government employees for this purpose. Members who are not full-time Federal employees will be paid $128.80 per day for time spent at meetings, plus travel and per diem expenses, in accordance with pertinent government regulations.

Nominations are invited from individuals and from consumer, industry, government, and professional organizations. To be considered, nominations shall be mailed no later than April 28, 1975 to: Associate Commissioner for Science (HFS-1), Food and Drug Administration, Rm. 14-57, 5600 Fishers Lane, Rockville, MD 20852.

Dated: March 24, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-8069 Filed 3-26-75;8:45 am]

Office of the Secretary

THE PRESIDENT'S COMMITTEE ON MENTAL RETARDATION

Meeting

The President's Committee on Mental Retardation was established to provide advice and assistance in the area of mental retardation to the President including evaluation of the adequacy of the national effort to combat mental retardation; coordination of activities of Federal agencies; provision of adequate liaison between Federal activities and related activities of state and local governments, foundations and private organizations; and develop information designed for dissemination to the general public. The Committee will meet on Thursday, May 8, 1975, 9 a.m. to 5 p.m. and on May 9, 1975, 9 a.m. to 3 p.m., at the Crystal City Marriott Hotel, 1999 Jefferson-Davis Highway, Arlington, Virginia 22202. This meeting will be the quarterly meeting of the Committee. They will discuss full citizenship, minimum occurrence, humane services, and public awareness as they relate to the mentally retarded. These meetings are open to the public.

Dated: March 19, 1975.

FRED J. KRAUSE,
Executive Director, President's Committee on Mental Retardation.

[FR Doc.75-7948 Filed 3-26-75;8:45 am]

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Meeting

Notice is hereby given that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will meet on April 11 and 12, 1975, and, if an additional meeting day is required, on April 13, 1975, in Conference Room 6, C Wing, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. The meeting will convene at 9 a.m. each day and will be open to the public, subject to the limitations of available space.

The agenda will include further discussion of research on the fetus and, time permitting, discussion of other issues identified in the legislative mandate to the Commission under Pub. L. 93-348.

Requests for information should be directed to Ms. Anne Ballard (301-496-7776), Room 125, Westwood Building, 9000 Rockville Pike, Bethesda, Maryland 20014.

Dated: March 20, 1975.

CHARLES U. LOWE,
Executive Director, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

[FR Doc.75-7949 Filed 3-26-75;8:45 am]

CENTER FOR DISEASE CONTROL

Statement of Organization, Functions, and Delegations of Authority

Part 9 (Center for Disease Control) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health, Education, and Welfare (39 FR 1461, January 9, 1974) is hereby amended to reflect the transfer of the Center's facilities planning functions from the Office of the Center Director (9A01) to the Engineering Services Office (9A1904) as indicated in the following changes to Section 9-B, *Organization and Functions,* under the heading entitled "Office of the Director (9A00)":

1. Revise the mission statement of the Office of the Center Director (9A01) by deleting item (8) and renumbering items (9) and (10) to items (8) and (9), respectively.

2. Revise the mission statement of the Engineering Services Office (9A1904) by deleting items (5), (6), and (7) and inserting new items (5) and (6). The revised statement reads as follows:

Engineering Services Office (9A1904). (1) Operates, maintains, repairs, and modifies the Center's Atlanta area plant facilities; and conducts a maintenance and repair program for the Center's program support equipment; (2) develops services for new, improved, and modified

equipment to meet program needs; (3) maintains physical security for the Chamblee and Lawrenceville facilities; (4) provides technical assistance for and reviews maintenance and operation programs of field installations and recommends appropriate action; (5) carries out facilities planning functions of the Center, including new or expanded facilities, and a major repair and improvement program; (6) maintains liaison with the Division of Health Facilities Planning of the Office of the Assistant Secretary for Health, and the Office of Facilities Engineering and Property Management, Office of the Secretary.

Dated: March 20, 1975.

THOMAS S. MCFEE,
Acting Assistant Secretary for Administration and Management.

[FR Doc.75-7947 Filed 3-26-75;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

BOSTON AIR TRAFFIC CONTROL ADIVSORY COMMITTEE

Establishment

Notice is hereby given of the establishment of the Boston Air Traffic Control Advisory Committee. The Air Traffic Division of the FAA, New England Region, is the sponsor of the committee. The committee is composed of representatives of the military services, the Federal Aviation Administration, and civil users of the air traffic control system. The committee provides a forum for discussion and solution of air traffic control service problems arising within the FAA, New England Region. The chairman of the committee is designated by the Chief, Air Traffic Division, FAA, New England Regional Office.

The Secretary of Transportation has determined that the formation and use of this Advisory Committee are necessary in the public interest in connection with the performance of duties imposed on the Federal Aviation Administration by law. Meetings of the committee will be open to the public.

Issued in Burlington, Massachusetts, on March 5, 1975.

QUENTIN S. TAYLOR,
Director.

[FR Doc.75-7918 Filed 3-26-75;8:45 am]

CIVIL AERONAUTICS BOARD

[Dockets 27548, 27551; Order 75-3-84]

DELTA AIR LINES, INC.

Order Dismissing Complaints

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 24th day of March, 1975.

By tariff revisions[1] marked to become effective April 1, 1975, Delta Air Lines, Inc. (Delta) proposes to establish 7–30 day excursion fares in midwest/east coast-Florida markets of 750 miles or more during the period April 1–December 18, 1975. Similar fares are currently in effect in Delta's remaining markets of 750 miles or more.[2] The discount is a uniform 25 percent during the entire off-peak season; the fares would apply on all days of the week; require ticketing and reservations 7 days in advance; and provide a 50 percent reduction from regular coach fares for children under 12. Eastern Air Lines, Inc., (Eastern) has filed to match Delta, except that it would require a 3-day minimum stay (or the following Monday, whichever is later) rather than 7 days.

In proposing to extend its 7–30 day excursion fares to the Florida market, Delta alludes to the need for generating additional off-season north-south traffic and the necessity of competing with National's midweek proposal, and a midweek tour-basing fare earlier proposed but since withdrawn by Eastern. Delta concedes the more restrictive application of its competitors' proposals, but argues that the more proper approach would be simply to extend to Florida the same discount fare available in most other domestic markets.

Eastern and National Airlines, Inc. (National) have filed complaints which essentially rest on the argument that the discount should not be available every day of the week as Delta proposes. The complainants allege that fares restricted to midweek application are preferable because they serve to smooth out day-of-week traffic fluctuations, whereas fares available on all days of the week have the counter effect of accentuating weekend peaks. Since Delta's proposal goes beyond that required to meet those of National and Eastern, it is contended that Delta should have submitted a profit-impact estimate which it has not done and that the existence of the 7–30 day excursion fares in other domestic markets does not justify the same fare in the Florida market, which has traditionally been treated and considered separately by the Board.

Delta answers that its proposal is consistent with recent Board precedent, and that there is no valid basis for discriminating against one of the forty-eight contiguous states on the ground that its so-called uniqueness warrants its ostracism from an industrywide and virtually nationwide program of excursion fares. Delta alleges that neither complainant has advanced facts to show that the fares should be confined to midweek days; rather, they simply assert that tradition requires this. Delta alleges that reality demands a break with tradition; that with the advent of excursion fares of general nationwide applicability, limiting the excursion fare to Florida to midweek days would create unnecessary complexity and confusion; and that uniformity, simplicity, consistency, and reduction of consumer uncertainty far outweigh vague assertions concerning Florida's unique status. Finally, Delta contends that a profit impact is unnecessary to support its proposal since similar excursion fares have previously been justified and permitted in all but the few remaining north-south Florida markets.

Upon consideration of the proposal, the complaints and answer thereto, and all relevant matters, the Board finds that the complaints do not set forth sufficient facts to warrant investigation and the requests therefor, and consequently the requests for suspension will be denied and the complaints dismissed.

As indicated, Delta's proposal is an extension to its north-south Florida markets of fares which all carriers have been permitted to establish in markets of 750 miles in distance and, in our opinion, the complainants have not made a persuasive case for restricting the fares to midweek periods. It is true that available evidence has rather consistently shown a significant day-of-week traffic imbalance in the Florida market. However, it is also true that carriers have generally had a significant amount of unused space on peak as well as off-peak days of the week during the off-season. We have no reason to suspect otherwise this year in view of the generally slack domestic traffic. As for liberalization of the minimum-stay requirement to 3 days (or the following Monday), Eastern has consistently claimed that its past weekend excursion fares have had good generative results and we see no reason to suspend on this count, particularly since the complaints are silent on the question.

Accordingly, pursuant to the Federal Aviation Act of 1958, as amended, and particularly sections 204(a), 403, 404, and 1002 thereof,

It is ordered, That: 1. The complaints of Eastern Air Lines, Inc., and National Airlines, Inc. in Dockets 27548 and 27551 are dismissed; and

2. Copies of this order be served on Delta Air Lines, Inc., Eastern Air Lines, Inc., and National Airlines, Inc.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.75-8020 Filed 3-26-75;8:45 am]

[1] Revisions to Airline Tariff Publishers Company, Agent, C.A.B. No. 202.

[2] Order 75-2-124.

[Docket No. 27613]

POMPANO BEACH SURF RIDER, INC., d/b/a ALTAIR VACATIONS LTD.

Prehearing Conference and Hearing

Notice is hereby given that a prehearing conference in this proceeding is assigned to be held on April 14, 1975, at 10 a.m. (local time), in Room 503, Universal Building, 1825 Connecticut Avenue, NW., Washington, D.C., before Administrative Law Judge Greer M. Murphy. Notice is also given that the hearing may be held immediately following conclusion of the prehearing conference unless a person objects or shows reason for postponement on or before April 7, 1975.

Ordinary transcript will be adequate for the proper conduct of this proceeding.

Dated at Washington, D.C., March 24, 1975.

[SEAL] ROBERT L. PARK,
Chief Administrative Law Judge.

[FR Doc.75-7685 Filed 3-26-75;8:45 am]

[Dockets 26057 and 26075; Agreement CAB 24929; Order 75-3-67]

TRANS WORLD AIRLINES, INC., AND SWISSAIR

Order Approving Agreement

Issued under delegated authority March 21, 1975.

Joint application of Trans World Airlines, Inc., and Swissair for prior approval of a fuel-saving capacity-limitation agreement concerning U.S.-Switzerland markets.

By application dated January 29, 1975, Trans World Airlines, Inc. (TWA), and Swissair request prior Board approval pursuant to section 412 of the Federal Aviation Act of 1958, as amended (the Act), and Subpart P of the Board's rules of practice, 14 CFR 302.1601, of an agreement (Agreement CAB 24929) between them which would establish maximum scheduled weekly frequency levels in the New York-Switzerland and Chicago/Boston-Switzerland markets. The discussions which led to the adoption of the agreement were held pursuant to the authority granted by the Board in order 73-11-34, dated November 8, 1973, as extended and expanded by order 74-4-29, dated April 4, 1974, order 74-7-33, dated July 8, 1974, and order 74-11-132, dated November 25, 1974.[1]

The agreement will be implemented, subject to prior Board approval, on April 1, 1975, and will continue in effect until October 31, 1975. The agreement establishes maximum weekly scheduled frequencies in the New York-Switzerland and Chicago/Boston-Switzerland markets as follows:

[1] A report of these discussions has been filed with the Board.

	April 1 to mid-June	Mid-June to mid-September	Mid-September to October 31
New York-Switzerland:			
Swissair	10 round trips with B-747 aircraft.	11 round trips with B-747 aircraft.	10 round trips with B-747 aircraft.
TWA	10 round trips with B-707 aircraft.	14 round trips with B-707 aircraft.	12 round trips with B-707 aircraft.
Chicago/Boston-Switzerland:			
Swissair	5 round trips with DC-10 aircraft for 11 weeks.		6 round trips with DC-10 aircraft for 20 weeks.

Provision is made for the temporary suspension of the above frequency limitations during a period of cessation or curtailment of service by either party resulting from a labor dispute or other cause beyond the control of the affected party. Additionally, allowance is made for the use of unpublished extra sections for operational reasons or to meet periods of unusual demand. Either party may terminate the agreement on 30 days' notice.

In support of the application the applicants assert that the agreement will result in fuel savings of 2,300,000 gallons. The applicants also note that the Board, in order 74-7-33, broadened the basis for international capacity discussions to include the radical price increase in, as well as the availability of, international aviation fuel.[2] In this connection, TWA and Swissair have provided data which show that their per-gallon fuel costs in these markets have tripled in the past year and which indicate that the aforementioned fuel savings will be translated into a fuel-cost savings amounting to $900,000 during the term of the agreement.

However, the applicants emphasize that achieving these fuel and fuel-cost savings will not unwarrantedly reduce the level of services offered to the public in these markets, and state that the frequency of flights will still be high with an estimated average load factor for the markets involved of 58 percent.

The city of Chicago, Ill. (Chicago), has filed an answer to the application requesting the Board to disapprove the agreement absent the submission of additional information. Specifically, Chicago requests that the applicants provide a specific load-factor estimate for the Chicago/Boston-Switzerland market. Chicago also requests that the carriers explicitly delineate which weeks the city will be provided with five DC-10 round trips and which weeks it will be provided with six.

TWA has filed a reply to Chicago's answer. TWA estimates that the load factor in the Chicago/Boston-Switzerland market will be 61.3 percent assuming no drop in traffic from 1974. TWA also asserts that Swissair will operate responsibly in this market and arrange its schedules so as to provide reasonable service throughout the term of the agreement.

No other comments relative to the application have been received.

In consideration of the foregoing the Board notes that to the extent that the applicants have justified the proposed capacity-limitation agreement on both a fuel and fuel-cost savings basis, the application appears to raise issues which are currently being considered in the *Capacity Reduction Agreements Case*, docket 22908. However, the agreements relate to international markets and in each of these markets the proposed service appears adequate to meet the needs of the traveling public. Therefore, recognizing the special circumstances applicable with respect to both excess capacity and the financial losses of the U.S.-flag carriers in the transatlantic markets, and the responsibility of the Board, in accordance with the national program for fuel conservation, to consider measures which will avoid superfluous or extravagant utilization of fuel supplies, we have decided to approve the subject capacity agreement.[3] Our decision herein, however, should not be construed as prejudging in any manner the Board's final decision with respect to any of the issues currently being considered in the *Capacity Reduction Agreements Case*.[4]

With respect to Chicago's answer, it appears that most of the desired information has been provided. Further, we do not believe that it is essential for the carriers to specifically identify which weeks the city will receive six round trips and which weeks only five. Generally, of course, we would anticipate that the 20 weeks with six round trips will run consecutively during the peak season with the 11 weeks of only five frequencies being divided between the spring and fall shoulder periods. The fact that the actual weeks of each service are not specifically designated appears to be an effort to provide flexibility with respect to the operations of Swissair. In any event, the proposed service appears adequate, and we shall retain jurisdiction for the purpose of further amending or revoking the approval granted herein[5] at any future date should a showing be made that the public interest so requires.[6] Therefore, we will deny Chicago's request for disapproval of the agreement to the extent that said request still remains in light of the absence of all the additional information asked for.

Pursuant to authority duly delegated by the Board in the Board's Regulations, 14 CFR 385.3 and 385.13, it is found that

[2] See order 74-7-33, dated July 8, 1974; second full paragraph on p. 3 therein and ordering paragraph 1. The applicants also cite the Board's language on p. 5 of order 74-4-149, dated Apr. 26, 1974, wherein the Board, in approving certain capacity-limitation agreements, stated that such conservation measures take on added significance in light of the financial crisis threatening both TWA and Pan American World Airways, Inc.

[3] See order 74-4-149, dated Apr. 26, 1974, order 74-7-33, dated July 8, 1974, and order 75-1-140, dated Jan. 31, 1975.

[4] As noted, the term of this agreement extends through Oct. 31, 1975. In this connection, the Board wishes to make it as clear as possible that the decision herein is based on the circumstances of the current situation and that any change in those circumstances, such as a final decision in the Capacity Reduction Agreements Case, may be a cause for review of this agreement and the approval granted herein.

[5] Section 412(b) of the Act (49 U.S.C. 1382) requires the Board to disapprove any agreement, whether or not previously approved by it, which it finds to be adverse to the public interest or in violation of the Act.

[6] We have also considered the impact of the agreement on the employees of TWA. Based on the limited amount of information currently before us, we are unable to conclude that the public interest requires the imposition of any labor protective conditions. As noted, however, jurisdiction shall be retained for the purpose of, *inter alia*, imposing such a condition should a showing be made that the public interest so requires.

the capacity-reduction agreement discussed herein is neither adverse to the public interest nor in violation of the Act and should be approved subject to appropriate terms and conditions, and that to the extent still extant, Chicago's request for disapproval of said agreement should be denied.

Accordingly, It Is Ordered That:

1. Agreement CAB 24929 be and it hereby is approved pursuant to section 412 of the Act, subject to the following terms and conditions:

(a) Jurisdiction shall be retained to modify or revoke the approval granted herein at any time, or to take whatever action as may be appropriate in the public interest;

(b) Schedule deletions resulting from the agreement considered herein, which occur at any of the controlled, high-density airports [7] and which result in the vacating of slots allocated by the Airline Scheduling Committees of the respective airports pursuant to authority granted in order 72-11-72, shall not be refilled by the air carrier applicants, nor be reallocated to other carriers by the respective Airline Scheduling Committee; *Provided, however,* That slots originally vacated may be reinstated by the vacating carrier to the extent such carrier vacates another flight at the same airport which operates plus or minus 3 hours of the flight to be reinstated; [8]

(c) All schedule changes resulting from this agreement shall be reported to the Board within 15 days of the end of each month, in accordance with the format of Appendix A [9] hereto, and copies of such reports shall be provided to all carriers requesting them;

(d) Within 28 days of the date of service of this order, the air carrier applicants shall file with the Board's Docket Section a report containing the following additional data for the subject markets:

a. Seats operated in 1974 (April through September).

b. Passengers carried in 1974 (April through September).

c. Forecast passengers in 1975 (April through September).

d. Projected seats in 1975 (April through September).

e. Fuel use by month for the system of each carrier in 1974 (April through September).

f. Fuel use by month in the subject agreement markets in 1974 (April through September);

2. Copies of this order shall be served upon the United States Departments of Defense, Justice, and Transportation; the United States Postal Service; the Port Authority of New York and New Jersey; the Massachusetts Port Authority; the City of Chicago, Department of Aviation; and all certificated route and supplemental air carriers; and

3. To the extent still extant, Chicago's request for disapproval of Agreement CAB 24929, be and it hereby is denied.

Persons entitled to petition the Board for review of this order may file such petitions within 5 days of the date of service of this order.

This order shall be effective and become the action of the Civil Aeronautics Board upon expiration of the above period unless within such period a petition for review thereof is filed or the Board gives notice that it will review this order on its own motion.

This order shall be published in the FEDERAL REGISTER.

WILLIAM B. CALDWELL, Jr.,
Director, Bureau of Operating Rights.

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.75-8021 Filed 3-26-75;8:45 am]

[7] Airport scheduling agreements affect John F. Kennedy International Airport, O'Hare International Airport, Washington National Airport, and La Guardia Airport. See order 72-11-72, dated Nov. 16, 1972.

[8] Compare order 73-12-32, Dec. 7, 1973, at p. 7.

[9] Appendix A filed as part of the original document.

CIVIL SERVICE COMMISSION

DEPARTMENT OF AGRICULTURE

Grant of Authority To Make Noncareer Executive Assignment

Under authority of section 9.20 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission authorizes the Department of Agriculture to fill by noncareer executive assignment in the excepted service the position of Assistant Administrator, Pub. L. 480 Programs, Foreign Agricultural Service.

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7963 Filed 3-26-75;8:45 am]

DEPARTMENT OF AGRICULTURE

Grant of Authority To Make Noncareer Executive Assignment

Under authority of § 920 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission authorizes the Department of Agriculture to fill by noncareer executive assignment in the excepted service the position of Assistant Administrator, Foreign Market Development, Foreign Agricultural Service.

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7964 Filed 3-26-75;8:45 am]

DEPARTMENT OF AGRICULTURE

Revocation of Authority To Make Noncareer Executive Assignment

Under authority of § 9.20 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission revokes the authority of the Department of Agriculture to fill by noncareer executive assignment in the excepted service the position of Associate General Sales Manager, Export Marketing Service.

UNITED STATES CIVIL SERVICE COMMISSION.
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7968 Filed 3-26-75;8:45 am]

FEDERAL ENERGY ADMINISTRATION

Grant of Authority To Make Noncareer Executive Assignment

Under authority of § 9.20 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission authorizes the Federal Energy Administration to fill by noncareer executive assignment in the excepted service the position of Associate Assistant Administrator for International Energy Production and Logistics, Office of the Assistant Administrator for International Energy Affairs.

UNITED STATES CIVIL SERVICE COMMISSION.
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7966 Filed 3-26-75;8:45 am]

GENERAL SERVICES ADMINISTRATION

Grant of Authority To Make Noncareer Executive Assignment

Under authority of § 9.20 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission authorizes the General Services Administration to fill by noncareer executive assignment in the excepted service the position of Director of Congressional Affairs, Office of Congressional Affairs, Office of the Assistant Administrator, Office of the Administrator.

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7965 Filed 3-26-75;8:45 am]

GENERAL SERVICES ADMINISTRATION

Revocation of Authority To Make Noncareer Executive Assignment

Under authority of § 9.20 of Civil Service Rule IX (5 CFR 9.20), the Civil Service Commission revokes the authority of the General Services Administration to fill by noncareer executive assignment in the excepted service the position of Director of Communications, Office of the Administrator.

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7967 Filed 3-26-75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Title Change in Noncareer Executive Assignment

By notice of June 5, 1973, FR Doc. 73-11183, the Civil Service Commission authorized the Department of Health, Education, and Welfare to fill by noncareer executive assignment the position of Director of Policy Services, Office of the Secretary. This is notice that the title of this position is now being changed to Director, Editorial Operations Division, Office of the Assistant Secretary for Public Affairs, Office of the Secretary.

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7969 Filed 3-26-75;8:45 am]

FEDERAL EMPLOYEES PAY COUNCIL

Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, Pub. L. 92-463, notice is hereby given that the Federal Employees Pay Council will meet at 2 p.m. on Wednesday, April 30, 1975. This meeting will be held in room 5323 of the U.S. Civil Service Commission Building, 1900 E Street, NW., and will consist of continued discussions on the fiscal year 1976 comparability adjustment for the statutory pay systems of the Federal Government.

The Chairman of the U.S. Civil Service Commission is responsible for the making of determinations under section 10(d) of the Federal Advisory Committee Act as to whether or not meetings of the Federal Employees Pay Council shall be open to the public. He has determined that this meeting will consist of exchanges of opinions and information which, if written, would fall within exemptions (2) or (5) of 5 U.S.C. 552(b). Therefore, this meeting will not be open to the public.

For the President's Agent.

RICHARD H. HALL,
Advisory Committee Management Officer for the President's Agent.

[FR Doc.75-7970 Filed 3-26-75;8:45 am]

CONSUMER PRODUCT SAFETY COMMISSION

CHILDREN'S SLEEPWEAR

Sizes 7 Through 14 (FF5-74); Affirmative Labeling

Correction

In FR Doc. 75-7455, appearing at page 12811, in the issue for Friday, March 21, 1975 should have appeared in the Notices section. Also, in the last paragraph, the second line was omitted and should read as follows: "in sizes 7 through 14 complying with this".

DEFENSE MANPOWER COMMISSION

MEETING

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the Commissioners of the Defense Manpower Commission will meet on April 18, 1975, at 2 p.m. in the New Executive Office Building, Room 2010, 726 Jackson Place, NW., Washington, D.C. 20036.

The purpose of the meeting will be to conduct an in-progress review of issues in the Requirements Functional Area and such other business as may be presented by the members.

The meeting will be open to the public. Since meeting space is limited, interested persons wishing to attend should telephone 202/254-7803 before close of business April 16, 1975.

Dated: March 18, 1975.

BRUCE PALMER, Jr.,
General, USA (Ret.),
Executive Director.

[FR Doc.75-7884 Filed 3-26-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 353-2]

EFFLUENT STANDARDS AND WATER QUALITY INFORMATION ADVISORY COMMITTEE

Meeting

The Effluent Standards and Water Quality Information Advisory Committee is undertaking the development of an information base to establish feasible technical and economic applications of Best Available Technology (BAT) under Pub. L. 92-500 for U.S. Industry.

A series of workshops will be scheduled on selected industries in order to develop the inputs.

Task Forces will be established at these workshops consisting of ES&WQIAC and industry representatives for the purposes of assembling available data and establishing needs for additional data. A range of data formats have been developed by ES&WQIAC and will be mailed to interested parties on request. Comments on the utility and availability of the data prescribed on these forms should be directed to the ES&WQIAC headquarters. Call A.C. 703-557-7390 or write to Dr. Martha Sager, Chairman, ES&WQIAC or Mr. Martin Brossman, Executive Secretary, ES&WQIAC, EPA, Room 821, Crystal Mall, Bldg. #2, Washington, D.C. 20460.

The Planning Meeting for the workshops will be held on April 24, 1975 at 9 a.m. in Room 1112, Crystal Mall, Bldg. #2, 1921 Jefferson Davis Highway, Arlington, Virginia. The agenda for the meeting includes: a presentation by the Industrial Pollution Control Division of the Office of Research & Development (EPA) on its programs directed toward Best Available Technology (BAT); a discussion of proposed topics for BAT workshops received by ES&WQIAC; a review of comments on the data formats suggested by ES&WQIAC; and the establishment of task forces and industry workshops for future meetings on Best Available Technology.

The meeting will be open to the public and under the overall direction of the Committee Chairman. Since space is limited, call or write to Dr. Martha Sager, Chairman, or Mr. Martin Brossman, Executive Secretary, ES&WQIAC, EPA, Room 821, Crystal Mall, Bldg. #2, Washington, D.C. 20460 Telephone: A.C. 703-557-7390.

MARTHA SAGER,
Chairman, ES&WQIAC.

[FR Doc.75-8125 Filed 3-26-75;8:45 am]

RECEIPT OF APPLICATIONS FOR PESTICIDE REGISTRATION

Data To Be Considered in Support of Applications

On November 19, 1973, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (38 FR 31862) its interim policy with respect to the administration of section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This policy provides that EPA will, upon receipt of every application for registration, publish in the FEDERAL REGISTER a notice containing the information shown below. The labeling furnished by the applicant will be available for examination at the Environmental Protection Agency, Room EB-31, East Tower, 401 M Street SW, Washington D.C. 20460.

On or before May 27, 1975, any person who (a) is or has been an applicant, (b) believes that data he developed and submitted to EPA on or after October 21, 1972, is being used to support an application described in this notice, (c) desires to assert a claim for compensation under section 3(c)(1)(D) for such use of his data, and (d) wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data, must notify the Administrator and the applicant named in the notice in the FEDERAL REGISTER of his claim by certified mail. Notification to the Administrator should be addressed to the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, 401 M Street SW., Washington D.C. 20460. Every such claimant must include, at a minimum, the information listed in the interim policy of November 19, 1973.

Applications submitted under 2(a) or 2(b) of the interim policy will be processed to completion in accordance with existing procedures. Applications submitted under 2(c) of the interim policy cannot be made final until the 60 day period has expired. If no claims are received within the 60 day period, the 2(c) application will be processed according to normal procedure. However,

if claims are received within the 60 day period, the applicants against whom the claims are asserted will be advised of the alternatives available under the Act. No claims will be accepted for possible EPA adjudication which are received after May 27, 1975.

Dated: March 21, 1975.

JOHN B. RITCH, Jr.,
Director, Registration Division.

APPLICATIONS RECEIVED (OPP-32000/214)

EPA File Symbol 2749-URG. Aceto Chemical Co., Inc., Agri. Chemicals Div., 126-02 Northern Blvd., Flushing NY 11368. FENTHION SPRAY CONCENTRATE INSECTICIDE. Active Ingredients: Fenthion (0,0-Dimethyl 0-[4-methylthio)-m-tolyl]phosphorothioate 45%; Xylene 47%. Method of Support: Application proceeds under 2(c) of interim policy. PM14
126-021-

EPA Reg. No 14651-4. Agricultural Enterprises, Inc., 933 West 6th, Fremont NB 68025. AGRI-BON LIVESTOCK SHAKER DUSTER. Active Ingredients: 2-chloro-1-(2,4,5 - trichlorophenyl)vinyl dimethyl phosphate 3.00%. Method of Support: Application proceeds under 2(c) of interim policy. PM14

EPA File Symbol 12016-RR. Anderson-Stolz Corp., 1733 Walnut St., Kansas City, MO 64108. SOL-VET 302. Active Ingredients: Sodium pentachlorophenate 79%; Sodium salts of other chlorophenols and related compounds 11%. Method of Support: Application proceeds under 2(c) of interim policy. PM32

EPA File Symbol 5667-A. Barrett Chemical Co., H & Luzerne Sts., Philadelphia, PA 19124. BARRETT'S DISINFECTANT CLEANER NO. 11. Active Ingredients: Didecyl dimethyl ammonium chloride 4.5%; Tetrasodium ethylenediamine tetraacetate 2.0%; Sodium carbonate 1.0%; Sodium metasilicate, anhydrous 0.5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 5667-L. Barrett Chemical Co. BARRETT'S DISINFECTANT CLEANER NO. 14. Active Ingredients: Didecyl dimethyl ammonium chloride 2.5%; Tetrasodium - ethylenediamine tetraacetate 2.0%; Sodium carbonate 1.5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 5667-T. Barret Chemical Co. BARRETT'S DISINFECTANT CLEANER NO. 12. Active Ingredients: Didecyl dimethyl ammonium chloride 4.25%; Tetrasodium ethylenediamine tetraacetate 1.60%; Sodium carbonate 2.00%; Sodium metasilicate, anhydrous 0.50%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 4313-LR. Carroll Co., 2900 W. Kingsley Rd., Garland TX 75041. OCIDE HOSPITAL CLEANER-DISINFECTANT. Active Ingredients: Isopropyl alcohol 15.5%; Disodium dodecyloxydibenzene disulfonate 8.4%; Tetrasodium ethylenediamine tetraacetate dodecyl benzene sulfonate 5.0%; Ortho-phenylphenol 4.5%; Ortho - benzyl - para-chlorophenol 2.2%; Para-tertiary-pentylphenol 1.0%; Tetrasodium ethylenediamine tetraacetate 0.6%; Essential oils 0.1%. Method of Support: Application proceeds under 2(c) of interim policy. PM32

EPA Reg. No. 5736-40. DuBois Chemicals, Div. of Chemed Corp., DuBois Tower, Cincinnati OH 45202. WATER BASE TROUNCE SYNTHETIC INSECT KILLER. Active Ingredients: (5-Benzyl-3-furyl) methyl 2,2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate 0.200%; Related compounds 0.028%; d-trans Allethrin (allyl homolog of Cinerin I) 0.150%; Related compounds 0.012%; Aromatic petroleum hydrocarbons 0.272%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 9444-UN. Cline-Buckner, Inc., 16317 Piuma Ave., Cerritos CA 90701. PURGE-REPELL CONCENTRATED AEROSOL INSECT KILLER. Active Ingredients: Pyrethrins 0.75%; Piperonyl Butoxide Technical 1.50%; N-Octyl bicycloheptene dicarboximide 2.50%; Di-n-propyl isocinchomeronate 1.00%; Petroleum Hydrocarbons 10.25%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA Reg. No. 1927-43. Terminix/Div. of Cook Industries, Inc., PO Box 16902, Memphis TN 38112. TERMINIX MFG CONCENTRATE. Active Ingredients: Deodorized Kerosene 81.5%; Technical Piperonyl Butoxide 5.0%; Pyrethrins 1.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 6900-RLR. J. J. Dill Co., PO Box 788, Kalamazoo MI 49005. MALATHION 1-D MALATHION PREMIUM GRADE 1% DUST. Active Ingredients: Malathion (O,O-dimethyl phosphorodithioate of diethyl-mercaptosuccinate) 1.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM16

EPA File Symbol 9232-RA. Federal International Chemicals, 1191 S. Wheeling Rd., Wheeling IL 60090. CONQUEST.256 NEUTRAL FRAGRANCE CLEANER-DISINFECTANT-DEODORANT. Active Ingredients: N-Alkyl (Myristyl 60%, Palmitoyl 30%, Lauryl 5%, Stearyl 5%) Dimethyl Benzyl Ammonium Chlorides 6.25%; N-Alkyl (Lauryl 68%, Myristyl 32%) Dimethyl Ethylbenzyl Ammonium Chlorides 6.25%, Tetrasodium Ethylenediamine Tetraacetate 3.60%; Ethanol 3.12%. Method of Support: Application proceeds under 2 (b) of interim policy. PM31

EPA File Symbol 11932-R. Good Housekeeper Maintenance Supplies, 906 Jacob St., Thomasville NC 27360. GHK DISINFECTANT CLEANER (19-a). Active Ingredients: Didecyl dimethyl ammonium chloride 4.5%; Tetrasodium ethylenediamine tetraacetate 2.0%; Sodium carbonate 1.0%; Sodium metasilicate, anhydrous 0.5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 1021-RGGL. McLaughlin Gormley King Co., 8810 Tenth Ave., N, Minneapolis MN 55427. D-TRANS INTERMEDIATE 2047. Active Ingredients: d-trans Allethrin (allyl homolog of Cinerin I) 7.2%; Piperonyl butoxide, technical [Equivalent to 25.92% (butylcarbityl) (6-propylpiperonyl) ether and 6.48% other related compounds] 32.4%; N-octyl bicycloheptene dicarboximide 18.0%; Petroleum distillate 2.4%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 1021-RGUI. McLaughlin Gormley King Co., 8810 Tenth Ave., N, Minneapolis MN 55427. PYROCIDE INTERMEDIATE 7246. Active Ingredients: Pyrethrins 6.20%; Piperonyl butoxide, technical [Equivalent to 24.96% (butylcarbityl)(6-propylpiperonyl) ether and 6.24% related compounds] 31.20%; Petroleum distillate 62.60%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 3298-EI. Murd Co., 2155 N. American St., Philadelphia PA 19122. ZURD CRAWLING INSECT KILLER. Active Ingredients: o-Isopropoxyphenyl methylcarbamate. 1.0%; Petroleum distillate 84.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM12

EPA File Symbol 4029-EG. Oil Specialties & Refining Co., Inc., 18 Bridge St., Brooklyn NY 11201. DAIRY & LIVESTOCK SPRAY. Active Ingredients: Pyrethrins 0.15%; Piperonyl Butoxide, Technical 1.50%; Petroleum Distillate 98.35%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 4029-ET. Oil Specialties & Refining Co., Inc. COMPACTOR AND KITCHEN INSECTICIDE SPRAY. Active Ingredients: Pyrethrins 0.12%; Piperonyl Butoxide, Technical 1.20%; Petroleum Distillate 0.48%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 4029-EU. Oil Specialties & Refining Co., Inc. INDUSTRIAL WATER COOLING TOWER ALGAECIDE. Active Ingredients: n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 5%; n-Alkyl (60% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 5%. Method of Support: Application proceeds under 2(c) of interim policy. PM31

EPA File Symbol 491-EEN. Selig Chemical Industries, PO Box 43106, Atlanta GA 30336. ULVP. Active Ingredients: (5-Benzyl-3-furyl)methyl 2,2 - dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate 4.22%; Related compounds 0.57%; Aromatic petroleum hydrocarbons 5.59%; Refined petroleum distillate 89.45%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 499-RIA. Whitmire Research Laboratories, Inc., 3568 Tree Court Industrial Blvd., St. Louis, MO 63122. WHITMIRE PRESCRIPTION TREATMENT NO. 583. Active Ingredients: Pyrethrins 1.20%; Piperonyl butoxide, technical 2.40%; N-Octyl bicycloheptene dicarboximide 3.96%; Petroleum distillate 87.44%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

APPLICATIONS RECEIVED (OPP-32000/215)

EPA File Symbol 34149-A. Beaumont Chem. Co., PO Box 509, Beaumont TX 77704. BUGHOUSE ROACH & ANT SPRAY. Active Ingredients: Pyrethrins 0.052%; Piperonyl Butoxide, Technical 0.260%; Chlorpyrifos (0,0-diethyl 0-(3,5,6-trichloro-2-pyridyl) Phosphorothioate 0.500%; Petroleum Distillate 98.736%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA Reg. No. 106-44. Brulin & Co., Inc., PO Box 270-B, Indianapolis IN 46206. BRULIN CDQ. Active Ingredients: n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 1.6%; n-Alkyl (50% C12, 30% C14, 17% C16, 3% C18) dimethyl ethylbenzyl ammonium chlorides 1.6%; Essential Oils 0.6%; Monoethanolamine 3.5%. Method of Support: Application proceeds under 2(a) of interim policy. PM31

EPA File Symbol 14794-G. Consolidated Water Treatment Corp., 5500 Government Blvd., Mobile AL 36609. FORMULA 400. Active Ingredients: Disodium cyanodithioimidocarbonate 4.90%; Potassium N-methyldithiocarbamate 6.76%. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA Reg. No. 8446-3. McInnis Lab., 1300 B St., Meridan MS 39301. SUPER ANTI-FLY BLOCK. Active Ingredients: Phenothiazine 2.000%. Method of Support: Application proceeds under 2(c) of interim policy. PM14

EPA Reg. No. 2139-99. Nor Am Agricultural Products, Inc., Research & Development Center, 11710 Lake Ave., Woodstock IL 60098. CARZOL SP. Active Ingredients: Formetanate Hydrochloride 92%. Method of Support: Application proceeds under 2(a) of interim policy. PM12

EPA File Symbol 2217-AGE. PBI Gordon Corp., 300 S. 3rd St., Kansas City KS 66118. A U S 90 WET TECHNICAL 2,4-DICHLOROPHENOXYACETIC ACID. Active Ingredients: 2,4-Dichlorophenoxyacetic Acid 90%. Method of Support: Application proceeds under 2(c) of interim policy. PM23

EPA File Symbol 773-LU. Pitman-Moore, Inc., PO Box 344, Washington Crossing NJ 08560. TELMIN B EQUINE WORMER. Active Ingredients: Trichlorfon [O,O-Dimethyl(2,2,2-trichloro-1-hydroxy ethyl)phosphonate] 37.50%; Mebendazole [Methyl 5-benzoylbenzimidazole-2-carbamate] 8.33%. Method of Support: Application proceeds under 2(c) of interim policy. PM14

EPA Reg. No. 904-153. B. G. Pratt Div., Gabriel Chem. Ltd., 204 21st Ave., Paterson NJ 07509. EC 5 MALATHION SPRAY. Active Ingredients: Malathion 57%; Aromatic Petroleum Derivative Solvent 36%. Method of Support: Application proceeds under 2(c) of interim policy. PM16

EPA File Symbol 10742-A. Prinova Co., Inc., 982 Terminal Way, San Carlos CA 94070. LADRIN MILDEW PREVENTATIVE. Active Ingredients: Didecyl Dimethyl Ammonium Chloride 25%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 842-RRU. G. S. Robins & Co., 126 Chouteau Ave., St. Louis MO 63102. ROBINS 57% EMULSIFIABLE MALATHION. Active Ingredients: Malathion 57%; Aromatic Petroleum Derivate Solvent 34%. Method of Support: Application proceeds under 2(c) of interim policy. PM16

[FR Doc.75-7897 Filed 3-26-75;8:45 am]

[FRL 351-3; OPP-32000/216 & 217]

RECEIPT OF APPLICATIONS FOR PESTICIDE REGISTRATION

Data To Be Considered in Support of Applications

On November 19, 1973, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (38 FR 31862) its interim policy with respect to the administration of section 3(c) (1) (D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This policy provides that EPA will, upon receipt of every application for registration, publish in the FEDERAL REGISTER a notice containing the information shown below. The labeling furnished by the applicant will be available for examination at the Environmental Protection Agency, Room EB-31, East Tower, 401 M Street SW., Washington, D.C. 20460.

On or before May 27, 1975, any person who (a) is or has been an applicant, (b) believes that data he developed and submitted to EPA on or after October 21, 1972, is being used to support an application described in this notice, (c) desires to assert a claim for compensation under section 3(c) (1) (D) for such use of his data, and (d) wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data, must notify the Administrator and the applicant named in the notice in the FEDERAL REGISTER of his claim by certified mail. Notification to the Administrator should be addressed to the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, 401 M Street SW., Washington, D.C. 20460. Every such claimant must include, at a minimum, the information listed in the interim policy of November 19, 1973.

Applications submitted under 2(a) or 2(b) of the interim policy will be processed to completion in accordance with existing procedures. Applications submitted under 2(c) of the interim policy cannot be made final until the 60 day period has expired. If no claims are received within the 60 day period, the 2(c) application will be processed according to normal procedure. However, if claims are received within the 60 day period, the applicants against whom the claims are asserted will be advised of the alternatives available under the Act. No claims will be accepted for possible EPA adjudication which are received after May 27, 1975.

Dated: March 21, 1975.

JOHN B. RITCH, Jr.,
Director,
Registration Division.

APPLICATIONS RECEIVED (OPP-32000/216)

EPA File Symbol 4-EUE. Bonide Chem. Co., Inc., 2 Wurz Ave., Yorkville NY 13495. SLUG & SNAIL KILLER W/MESUROL. Active Ingredients: 3,5-Dimethyl-4-(methylthio)phenol methylcarbamate 2.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM12

EPA File Symbol 6959-UE. Cessco, Inc., PO Box 12452, Charlotte NC 28205. ACCUDOSE SPECIFIC DOSAGE AEROSOL FOR LARGE SCALE TREATMENT. Active Ingredients: Malathion (O,O-dimethyl dithiosphosphate of diethyl mercaptosuccinate) 22.6000%; Betabutoxy beta-thiocyano diethyl ether 8.2680%; Petroleum Distillate 8.5320%; Pine Oil 0.4000%. Method of Support: Application proceeds under 2(c) of interim policy. PM16

EPA File Symbol 7478-UG. Chem Pak Co., PO Box 757, S. Miami FL 33143. SPRINGHILL ROSE FUNGICIDE SPRAY. Active Ingredients: Tetrachloroisophthalonitrile 50.0%; Dinitro (1-methylheptyl phenyl crotonate) 0.9%; Other nitro phenols and derivatives chiefly dinitro (1-methylheptyl) phenol 0.1%. Method of Support: Application proceeds under 2(c) of interim policy. PM13

EPA File Symbol 7478-UR. Chem Pak Co. FLORIDA CITRUS SPRAY. Active Ingredients: Copper Salts of Rosin and Fatty Acid (Copper as metallic 2%) 24.0%; 1,1-bis (chlorophenyl) 2,2,2-trichloroethanol 4.0%; Malathion (0,0-dimethyl dithiophosphate of diethyl mercaptosuccinate) 12.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM13

EPA File Symbol 7478-UU. Chem Pak Co. SPRINGHILL ROSE SPRAY. Active Ingredients: Tetrachloroisophthalonitrile 15.00%; 1,1, Bis (Chlorophenyl) 2,2,2 Trichloroethanol 3.60%; Lindane (Gamma Isomer of Benzene Hexachloride) 5.00%; Toxaphene 10.00%; Dintro (1-methylheptyl) phenyl crotonate and Dintro (1-methylhepthyl) phenol and related compounds 1.25%; Sulphur 10.00%. Method of Support: Application proceeds under 2(c) of interim policy. PM15

EPA Reg. No. 239-2211. Chevron Chem. Co., Ortho Div., 940 Hensley St., Richmond CA 94804. ORTHO DIFOLATAN 4 FLOWABLE. Active Ingredients: Captafol (cis-N-[(1,1,2,2-tetrachloroethyl) thio]-4-cyclohexene-1,2-dicarboximide) 39%. Method of Support: Application proceeds under 2(c) of interim policy. PM21

EPA File Symbol 6754-AA. Dettelbach Pesticide Corp., PO Box 9386, 4103 Peachtree Rd., N.E., Atlanta GA 30319. PROFESSIONAL ORKINCIDE PREPARED ANTICOAGULANT RODENT BAIT #5. Active Ingredients: 3-(alpha-acetonylfurfuryl)-4-hydroxycoumarin 0.025%. Method of Support: Application proceeds under 2(c) of interim policy. PM11

EPA File Symbol 6754-AT. Dettelbach Pesticide Corp., PO Box 9386, 4111 Peachtree Rd., N.E., Atlanta GA 30319. PROFESSIONAL ORKIN MICE BAIT. Active Ingredients: 2-Pivalyl-1, 3-Indandione 0.025%. Method of Support: Application proceeds under 2(c) of interim policy. PM11

EPA File Symbol 5305-UUG. Helena Chem. Co., Clark Tower, 5100 Poplar Ave., Memphis TN 38137. HELENA MALATHION 8. Active Ingredients: Malathion (O,O-Dimethyl dithiophosphate of diethyl mercaptosuccinate) 80.4%. Method of Support: Application proceeds under 2(c) of interim policy. PM16

EPA File Symbol 20375-RN. Nutmeg Chem. Co., 125 Market St., New Haven CT 06513. NUTMEG NC-151. Active Ingredients: Sodium, 2,4,5-Trichlorophenate 85%. Method of Support: Application proceeds under 2(c) of interim policy. PM32

EPA File Symbol 3333-RL. Park-Hill Chem. Corp., 29 Bertel Ave., Mount Vernon NY 10550. PARKO RAT-BAN KILLS RATS AND MICE. Active Ingredients: Warfarin 3 - (a - acetonylbenzyl) -4-hydroxycoumarin 0.025%. Method of Support: Application proceeds under 2(c) of interim policy. PM11

EPA File Symbol 904-EGI. B. G. Pratt Div. Gabriel Chem. Ltd., 204 21st Ave., Paterson NJ 07509. PRATT RESMETHRIN MOSQUITO CONCENTRATE 40. Active Ingredients: (5-Benzyl-3-furyl)methyl 2,2-dimethyl - 3 - (2-methylpropenyl) cyclopropane carboxylate 40.00%; Related compounds 5.45%; Aromatic Petroleum Hydrocarbons 52.95%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 4931-LU. Redwood Chem. Co., PO Box 45916, Houston TX 77045. REDWOOD CMTA ANT AND ROACH RESIDUAL AND CONTACT SPRAY. Active Ingredients: (5 - Benzyl - 3 - furyl) methyl 2, 2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate 0.100%; Related compounds 0.014%; 0,0-diethyl-0-(2-isopropyl-4-methyl - 6 - pyrimidinyl) phosphorothioate 0.500%; Aromatic petroleum hydrocarbons 0.132%; Petroleum distillate 98.750%. Method of Support: Application proceeds under 2(c) of interim policy. PM14

EPA File Symbol 36483-R. Reuter Labs., 7555 Gary Rd., Manassas VA 22110. MILKY SPORE. Active Ingredients: A mixed culture of not less than 100 million viable spores of resistant stages of either or both Bacillus popilliae or Bacillus lentimorbus per gram of inert powder. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 707-REA. Rohm and Haas, Independence Mall W., Philadelphia PA 19105. Active Ingredients: 5-chloro-2-methyl-4-isothiazolin-3-one calcium chloride 55.0%; 2-methyl-4-isothiazolin-3-one calcium chloride 15.0%. Method of Support: Application proceeds under 2(b) of interim policy. PM22

APPLICATIONS RECEIVED (OPP-32000/217)

EPA File Symbol 36532-R. Better Water Corp., 500 C Allied Dr., Nashville TN 37211. BIO-209. Active Ingredients: Disodium cyanodithioimidocarbonate 3.68%; Potassium N-methyldithiocarbamate 5.07%. Method of Support: Application proceeds under 2(b) of interim policy. PM22

EPA File Symbol 30948-RT. Bionomical Chem. and Services, Inc., 1003 Pineville Rd., Chattanooga TN 37405. PB-101 READY-TO-USE LIQUID WEED KILLER. Active Ingredients: Pentachlorophenol 1.76%; 2,3,4,6-Tetrachlorophenol 0.24%; Aromatic Petroleum Derivative 23.00%; Petroleum Distillate 75.00%. Method of Support: Application proceeds under 2(c) of interim policy. PM24

EPA File Symbol 7478-UE. Chem-Pak Co., PO Box 757, S. Miami FL 33143. KOPPER KOTE EMULSIFIABLE LIQUID COPPER FUNGICIDE. Active Ingredients: Copper Salts of Rosin and Fatty Acids (Copper as Metallic 4%) 48.00%. Method of Support: Application proceeds under 2(c) of interim policy. PM22

EPA File Symbol 7478-GO. Chem-Pak Co., PO Box 757, S. Miami FL 33143. LAWN KEEPER TURF FUNGICIDE. Active Indients: Tetrachloroisophthalonitrile 50.0%; Thiram (Tetra Methyl Thiuram Disulfide) 7.0%; Captan (N-trichloromethylmercapto-4-cyclohexene-1,-2-bicarboximide) 10.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM21

EPA Reg. No. 1109-20. Cities Service Co., Copperhill Operations, PO Drawer 50360, Atlanta GA 30302. COPPER SULFATE GRANULAR CRYSTALS. Active Ingredients: Copper Sulfate (Pentahydrate) 99%. Method of Support: Application proceeds under 2(c) of interim policy. PM24

EPA File Symbol 9444-UE. Cline-Buckner, Inc., 16317 Pluma Ave., Cerritos CA 90701. PURGE INSPECT REPELLENT LOTION. Active Ingredients: N,N-Diethyl-m-toluamide 8.31%; Other Isomers 0.44%; N-Octyl bicycloheptene dicarboximide 2.50%; 2,3:4,5-Bis (2-butelene) tetrahydro-2-furaldehyde 0.62%; Di-n-propyl isocinchomeronate 0.62%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 9444-UG. Cline-Buckner, Inc., 16317 Pluma Ave., Cerritos CA 90701. NEW PURGE IV ONCE-A-DAY CONCENTRATED AEROSOL INSECT KILLER. Active Ingredients: Pyrethrins 1.00%; Piperonyl Butoxide Technical 2.00%; N-octyl bicycloheptene dicarboximide 3.34%; Petroleum Hydrocarbons 13.66%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 35911-R. Richard Conn, Inc., 17200 W. 10 Mile Rd., Southfield MI 48075. R-C ADSAN HEAVY-DUTY GERMICIDE. Active Ingredients: Octyl Decyl Dimethyl Ammonium Chloride 4.50%; Dioctyl Dimethyl Ammonium Chloride 2.25%; Didecyl Dimethyl Ammonium Chloride 2.25%; Tetrasodium Ethylenediamine Tetraacetate 2.40%; Isopropyl Alcohol 3.60%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 2496-EN. The General Pest Control Co., 3561 W. 105th St., Cleveland OH 44111. MYSTIC GENERAL PURPOSE INSECT SPRAY AQUEOUS. Active Ingredients: Pyrethrins 0.1%; Piperonyl Butoxide, Technical 1.0%; Petroleum Distillate 0.4%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 6993-LL. Germain's Inc., 4820 E., 50th St., Los Angeles CA 90058. GERMAIN'S INSECT SPRAY FOR TENDER FOLIAGE PLANTS. Active ingredients: Tetramethrin 0.250%; Related compounds 0.034%; (5-Benzyl-3-furyl) methyl 2,2-dimethyl-3-(2-methylpropenyl cyclopropanecarboxylate 0.106%; Related compounds 0.014%; Petroleum Distillate 9.000%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA Reg. No. 5905-217., Helena Chem. Co., Suite 2900 Clark Tower, 5100 Poplar Ave., Memphis TN 38137. HELENA HEL-FIRE. Active Ingredients: Dinoseb (2-sec-butyl-4,6-dinitrophenol) 24.00%. Method of Support: Application proceeds under 2(c) of interim policy. PM23

EPA File Symbol 5905-UUU. Helena Chem. Co., Suite 2900 Clark Tower, 5100 Poplar Ave., Memphis TN 38137. HELENA DIAZINON 40W INSECTICIDE. Active Ingredients: 0,0-diethyl 0-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate 40%. Method of Support: Application proceeds under 2(c) of interim policy. PM14

EPA File Symbol 34774-R. Hertz Pools, 7206 N. Western Ave., Oklahoma City OK 73116. ALGI-RID CONCENTRATE. Active Ingredients: Poly[oxyethylene(dimethyliminio) ethylene(dimethyliminio)-ethylene dichloride] 60.0%. Method of Support: Application proceeds under 2(b) of interim policy. PM34

EPA File Symbol 9369-R. D. L. Johnson Co., Route 9 Box 268, Pensacola FL 32503. JOHNSON'S MANGE MAGIC FOR DOGS. Active Ingredients: Linseed Oil 92.00%; Sulfur 4.00%; Gum Thus 2.00%; Oil of Pine 1.00%; Iodine 0.125%; Creosote 0.50%; Phenol 0.25%; Camphone 0.125%. Method of Support: Application proceeds under 2(c) of interim policy. PM14

EPA File Symbol 8220-EU. Lambert Kay Div. of Carter-Wallace, Inc., PO Box 11523, Santa Ana CA 92711. CONCENTRATED TICK & FLEA POWDER FOR DOGS. Active Ingredients: Pyrethrins 0.10%; Piperonyl Butoxide, Technical 1.00%; Carbaryl (1-Naphthyl N-methylcarbamate) 5.00%; Silica Gel 40.00%; Base Oil 4.90%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 8220-EL. Lambert Kay Div. of Carter-Wallace, Inc., PO Box 11523, Santa Ana CA 92711. CONCENTRATED FLEA & TICK POWDER FOR CATS AND DOGS. Active Ingredients: Pyrethrins 0.10%; Piperonyl Butoxide, Technical 1.00%; Carbaryl (1-Naphthyl N-methylcarbamate) 5.00%; Silica Gel 40.00%; Base Oil 4.90%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 995-UT. The Mackwin Co., 25 McConnon Dr., Winona MN 55987. C-RIO PELLETED BAIT. Active Ingredients: Warfarin (3-Alpha-Acetonylbenzyl)-4-Hydroxycoumarin) 0.025%. Method of Support: Application proceeds under 2(c) of interim policy. PM11

EPA File Symbol 4476-TU. Morton Pharmaceuticals, Inc., 1625-39 N. Highland, Memphis TN 38108. INSECT SPRAY. Active Ingredients: (5-Benzyl-3-furyl) methyl 2,2-dimethyl - 3 - (2 - methylpropenyl) cyclopropanecarboxylate 0.200%; Related compounds 0.028%; d-trans Allethrin (allyl homolog of Cinerin I) 0.150%; Related compounds 0.012%; Aromatic petroleum hydrocarbons 0.272%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 4476-TG. Morton Pharmaceuticals, Inc. PET SPRAY. Active Ingredients: (5-Benzyl-3-furyl) methyl 2,2-dimethyl - 3 - (2 - methylproponyl) cyclopropanecarboxylate 0.200%; Related compounds 0.028%; d-trans Allethrin (allyl homolog of Cinerin I) 0.150%; Related compounds 0.012%; Aromatic Petroleum hydrocarbons 0.272%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 4476-TE. Morton Pharmaceuticals, Inc. HOUSE & GARDEN SPRAY. Active Ingredients: (5-Benzyl-3-furyl) methyl 2,2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate 0.200%; Related compounds 0.028%; d-trans Allethrin (allyl homolog of Cinerin I) 0.150%; Related compounds 0.012%; Aromatic petroleum hydrocarbons 0.272%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 1706-RUL. Nalco Chem. Co., 6216 W. 66th Place, Chicago IL 60638. NALCO 4SW-375. Active Ingredients: n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides 5%; n-alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 5%. Method of Support: Application proceeds under 2(c) of interim policy. PM31

EPA File Symbol 1769-EAA. National Chemsearch, Div. of USACHEM, Inc., 2727 Chemsearch Blvd., Irving TX 75062. NATIONAL CHEMSEARCH AL-CHEK WATER TREATMENT MICROBIOCIDE. Active Ingredients: Didecyl dimethyl ammonium chloride 5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 904-EUN. B. G. Pratt Div. Gabriel Chem. Ltd., 204 21st Ave., Paterson NJ 07509. DURSBAN 2 EC. Active Ingredients: Chlorpyrifos [O,O-diethyl O-(3,5,6-trichloro - 2 - pyridyl) phosphorothioate] 24.9%; Aromatic petroleum derivative solvent 53.7%. Method of Support: Application proceeds under 2(c) of interim policy. PM12

EPA File Symbol 904-EGO. B. G. Pratt Div. Gabriel Chem. Ltd., 204 21st Ave., Paterson NJ 07509. PRATT 3610 FOGGING CONCENTRATE. Active Ingredients: Pyrethrins 3%; Piperonyl butoxide, technical 6%; N-octyl bicycloheptene dicarboximide 10%; Petroleum distillate 81%. Method of Support: Application proceeds under 2(c) of interim policy. PM17

EPA File Symbol 21270-RE. E. Targosz & Co., 736 Estes, Schaumburg IL 60172. CONSERVE II. Active Ingredients: Didecyl dimethyl ammonium chloride 2.5%; Tetrasodium ethylenediamine tetraacetate 3.0%; Sodium carbonate 1.5%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 21270-RR. E. Targosz & Co., 736 Estes, Schaumburg IL 60172. TARGOSZ GERMICIDE PLUS. Active Ingredients: Octyl Decyl Dimethyl Ammonium Chloride 3.750%; Dioctyl Dimethyl Ammonium Chloride 1.875%; Didecyl Dimethyl Ammonium Chloride 1.875%; Alkyl (C14 50%, C12 40%, C16 10%) Benzyl Dimethyl Ammonium Chloride 5.000%; Tetrasodium Ethylenediamine Tetraacetate 3.420%; Isopropyl Alcohol 3.000%; Ethyl Alcohol 1.000%. Method of Support: Application proceeds under 2(b) of interim policy. PM31

EPA File Symbol 27588-E. Water Conditioning Consultants, PO Box 8208, 1651 E. Edinger Ave., Fountain Valley CA 92708. FORMULA 30 CONTAINS 2.25% ELEMENTAL COPPER. Active Ingredients: Copper Sulfate 5.625%. Method of Support: Application proceeds under 2(c) of interim policy. PM24

EPA Reg. No. 2935-363. Wilbur-Ellis Co., Agricultural Chem. Div., Old Highway 99 at Cedar, PO Box 1286, Fresno CA 93715. RED-TOP METHYL PARATHION 5 SPRAY. Active Ingredients: O,O-Dimethyl O-p-nitrophenyl thiophosphate 54.5%; Xylene 40.5%. Method of Support: Application proceeds under 2(c) of interim policy. PM12

EPA File Symbol 5427-AN. Wright Chem. Corp., 1319 Wabansia Ave., Chicago IL 60622. WRICO-TQA. Active Ingredients: n-alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethyl benzyl ammonium chlorides 20.0%; n-bis (tributyltin) oxide 4.0%. Method of Support: Application proceeds under 2(c) of interim policy. PM31

REPUBLISHED ITEMS

The following represent changes to the list of Applications Received published in the FEDERAL REGISTER February 28, 1975 (40 FR 8598):

EPA File Symbol 11556-LR. Cutter Animal Health Lab., Div. Bayvet Corp., PO Box 390, Shawnee KS 66201. MY PAL INSECTICIDE SHAMPOO. Method of Support: Application proceeds under 2(b) of interim policy rather than 2(c) as cited.

EPA File Symbol 569-AT. Haver-Lockhart Lab., Div. Bayvet Corp., PO Box 390, Shawnee KS 66201. SENDRAN INSECTICIDE SHAMPOO FOR DOGS AND CATS. Method of Support: Application proceeds under 2(b) of interim policy rather than 2(c) as cited.

The following represents a change to the list of Applications Received published in the FEDERAL REGISTER February 27, 1975 (40 FR 8380):

EPA File Symbol 11556-LN. Cutter Animal Health Lab., Div. Bayvet Corp., PO Box 390, Shawnee KS 66201. MY PAL TICK AND FLEA DAB-ON. Method of Support: Application proceeds under 2(b) of interim policy rather than 2(c) as cited.

[FR Doc.75-7898 Filed 3-26-75;8:45 am]

[FRL 351-5; OPP-180013A]

TENNESSEE VALLEY AUTHORITY

Amendment to Specific Exemption To Use 2,4-D To Control Eurasian Watermilfoil

On May 29, 1974, the Environmental Protection Agency (EPA) granted a specific exemption to the Tennessee Valley Authority (TVA) to use the butoxyethanol ester of 2,4-dichlorophenoxy acetic acid (2,4-D) for control of Eurasian watermilfoil (*Myriophyllum spicatum* L.). This control program was to take place in the waters of eight TVA reservoirs on the Tennessee River and its tributaries.

On March 5, 1975, the EPA received an application from the TVA requesting that the specific exemption granted be renewed for calendar year 1975. The 1975 control program calls for using 397,800 pounds of 2,4-D to treat the eight reservoirs mentioned previously. These reservoirs contain 284,600 acres of water surface; 9,870 surface acres of this total contain Eurasian watermilfoil infestations which require herbicide treatment during the coming season.

This application is in accordance with the provisions of section 18 (40 CFR Part 166) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat 793 U.S.C. 136). Part 166 was issued on December 3, 1973 (38 FR 33303), and prescribes the requirements for exemption of Federal and State agencies for the use of pesticides under emergency conditions.

This notice does not indicate a decision by this Agency on the application. Interested parties may review the application in the Office of the Director, Registration Division (WH-567), Office of Pesticide Programs, EPA, 401 M St. SW., Room E-347, Washington, D.C. 20460.

Dated: March 19, 1975.

JAMES L. AGEE,
Assistant Administrator for Water and Hazardous Materials.

[FR Doc.75-7900 Filed 3-26-75;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 20260, 20261; File Nos. 5850-C2-P-(3)-70, 1104-C2-P-70; FCC 75R-116]

ANSWERPHONE, INC. AND THE MOUNTAIN STATES TELEPHONE AND TELEGRAPH CO.

Memorandum Opinion and Order Enlarging Issues

In the matter of applications of Answerphone, Inc., Denver, Colorado, and the Mountain States Telephone and Telegraph Company, Denver, Colorado, for construction permits to establish new air-ground facilities in the Domestic Public Land Mobile Radio Service.

1. The above-captioned mutually exclusive applications for construction permits to establish new air-ground facilities in the Domestic Public Land Mobile Radio Service (DPLMRS) in Denver, Colorado, were designated for hearing by Commission Memorandum Opinion and Order, 39 FR 43245, published on December 11, 1974, on the following issues:

(a) To determine on a comparative basis the nature and extent of services proposed by each applicant.

(b) To determine, in light of the evidence adduced pursuant to the foregoing issues, which, if either, of the above-captioned applicants would better serve the public interest, convenience and necessity.

Now before the Review Board is a motion to clarify and enlarge issues,[1] filed December 27, 1974, by Answerphone, Inc. (Answerphone) seeking clarification of the above-designated issues and addition of the following issues against the Mountain States Telephone and Telegraph Company (Mountain Bell):

a. To determine the manner in which each applicant proposes to provide for management arrangement at the local level and the effect of such management on the efficiency of the proposed service.

b. To determine the plans of each applicant for the establishment of procedures necessary to permit local aircraft operators to obtain access to the system and its plans to promote an efficient, high quality service to the area.

c. To determine, in light of the Government's antitrust action against American Telephone and Telegraph Company and its subsidiaries and the Commission's decision in *Chastain et al. v. AT&T*, 43 FCC 2d 1079, 28 RR 2d 1343 (1973), recon. den., 49 FCC 2d 749, 31 RR 2d 1487 (1974), whether the Mountain States Telephone and Telegraph Company should be disqualified from being the licensee of its proposed station.

2. Answerphone, in support of the requested issues, essentially relies on the same allegations as are contained in a recent series of motions to clarify and enlarge issues involving Bell System operating company stations[2] and non-Bell stations in proceedings for construction permits to establish new air-ground DPLMRS facilities.[3] Since we have already considered and ruled on almost identical requests for issues predicated on the same allegations and arguments in a Memorandum Opinion and Order, James D. and Lawrence D. Garvey, d/b/a Radiofone, FCC 75R-111, adopted this same date, no useful purpose would be served by reiterating our disposition here.

3. Accordingly, *it is ordered*, That the petition for acceptance of late-filed motion to clarify and enlarge issues, filed December 27, 1974, by Answerphone, Inc., is granted; and

4. *It is further ordered*, That the motion to clarify and enlarge issues, filed December 27, 1974, by Answerphone, Inc., is granted to the extent indicated herein, and is denied in all other respects; and

5. *It is further ordered*, That the issues in this proceeding are enlarged by the addition of the following issue:

To determine the effect of the Commission's decision in *Chastain et al.* v. *AT&T*, 43 FCC 2d 1079, 28 RR 2d 1343

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[1] Also before the Review Board are the following related pleadings: (a) petition for acceptance of late-filed motion to clarify and enlarge issues, filed December 27, 1974, by Answerphone; (b) opposition, filed January 9, 1975, by the Common Carrier Bureau; (c) opposition, filed January 9, 1975, by Mountain Bell; and (d) reply, filed January 21, 1975, by Answerphone. Answerphone's petition for acceptance of its late-filed motion to clarify and enlarge issues is unopposed, it contains an adequate showing of good cause for the brief delay in filing, and it will therefore be granted.

[2] Approximately 88 percent of Mountain Bell's stock is owned by the American Telephone and Telegraph Company.

[3] See Memorandum Opinion and Orders designating: (1) the air-ground applications of James D. and Lawrence D. Garvey, d/b/a Radiofone and South Central Bell Telephone Company, 39 FR 42025, published December 4, 1974; (2) the air-ground applications of Answerphone, Inc. and the Mountain States Telephone and Telegraph Company, 39 FR 43245, published December 11, 1974; and (3) the air-ground applications of Roy M. Teel d/b/a Houston Radiophone Service and Southwestern Bell Telephone Company, 39 FR 43583, published December 26, 1974.

(1973), *recon. den.*, 49 FCC 2d 749, 31 RR 2d 1487 (1974), on the basic and/or comparative qualifications of the Mountain States Telephone and Telegraph Company to be a Commission licensee.

6. *It is further ordered,* That the burden of proceeding with the introduction of evidence under the issue added herein shall be upon Answerphone, Inc., and the burden of proof shall be upon the Mountain States Telephone and Telegraph Company.

7. *It is further ordered,* That if favorable action is taken on the application of the Mountain States Telephone and Telegraph Company for construction of an air-ground station in Denver, Colorado, any such grant will be made subject to the following condition:

This grant is without prejudice to whatever action, if any, the Commission may deem appropriate as a result of the pending civil action entitled *United States* v. *American Telephone and Telegraph Company, Western Electric Company, Inc., and Bell Telephone Laboratories, Inc.*, (Civil No. 74-1698), filed November 20, 1974, in the United States District Court for the District of Columbia.

Adopted: March 17, 1975.

Released: March 21, 1975.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

[FR Doc.75-7924 Filed 2-26-75;8:45 am]

CABLE TELEVISION TECHNICAL ADVISORY COMMITTEE (CTAC) STEERING COMMITTEE

Meeting

Pusuant to section 10 of the Federal Advisory Act, (5 U.S.C. App. I § 10) (Supp. II, 1972), notice is hereby given of a meeting of the CTAC Steering Committee on April 15, 1975, to be held at the Bacchus Room, Marriott Hotel, New Orleans, Louisiana. The meeting is scheduled to commence at 2 p.m.

The agenda is as follows:

(1) Review and approval of Final Steering Committee Report.

(2) New Business.

(3) Adjournment.

Any member of the public may attend or file a written statement with the Committee either before or after the meeting. Any member of the public wishing to make an oral statement must consult with the Committee prior to the meeting. Inquiries may be directed to Mr. A. M. Rutkowski, FCC, 1919 M St. NW. Washington, D.C. 20554-(202) 632-9797.

Dated: March 20, 1975.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

[FR Doc.75-7923 Filed 3-26-75;8:45 am]

FEDERAL COUNCIL ON THE AGING

TASK FORCE ON SERVICES TO THE FRAIL ELDERLY

Meeting

The Federal Council on the Aging was established by the 1973 amendments to the Older Americans Act of 1965 (Pub. L. 93-29), for the purpose of advising the President, the Secretary of Health, Education, and Welfare, the Commissioner on Aging, and the Congress on matters relating to the special needs of older Americans.

Notice is hereby given, pursuant to Pub. L. 92-463 that the Council Task Force on Services to the Frail Elderly will hold a meeting on April 16, 1975. The meeting will be in Room 4549 Donohoe Building, 400 Sixth Street, SW., Washington, D.C. from 10 a.m. to 3 p.m. Agenda: further development of issues in services to the frail elderly; clarification of the issues; elements of coordinated responsibility of efforts in the area of the problems of the frail elderly; assignment of community responsibility in the study of questions on the frail elderly; community linkages to be developed with other national bodies interested in this subject.

This meeting open for public observation.

Further information on the Council may be obtained from Cleonice Tavani, Executive Director, Federal Council on the Aging, Room 4022, Donohoe Building, 400 Sixth Street, SW., Washington, D.C. 20201, telephone: (202) 245-0441.

Dated: March 20, 1975.

CLEONICE TAVANI,
Executive Director,
Federal Council on the Aging.

[FR Doc.75-7950 Filed 3-26-75;8:45 am]

FEDERAL ENERGY ADMINISTRATION

RETAIL DEALERS ADVISORY COMMITTEE

Change in Meeting Date

This notice is given to advise of a change in date of the meeting for the Retail Dealers Advisory Committee. The Committee will meet at 9 a.m., Room 3400, 12th & Pennsylvania Avenue, NW., Washington, D.C., Friday, April 11, 1975, rather than Friday, March 28, 1975 as previously announced. A notice of meeting was published in the issue of March 14, 1975 (40 FR 11936).

Issued at Washington, D.C., on March 24, 1975.

ROBERT E. MONTGOMERY, Jr.,
General Counsel.

[FR Doc.75-8018 Filed 3-26-75;8:45 am]

TRANSFER PRICING REPORT

Exemption From Reporting for Certain Crudes

The Federal Energy Administration has received a request that sales and purchases for Argentina and Australia need not be reported on Schedule D of FEA's Transfer Pricing Report (FEA-F701-M-O). The request is based upon the following provision in the instructions for Schedule D:

> A firm may request of the Office of General Counsel of FEA, pursuant to Subpart G of Part 205 of 10 CFR, that certain sales or purchases need not be reported on the grounds that the crude oil is produced in countries for which no commercial volumes are exported to the United States. Firms should, however, report such sales and purchases unless the request is granted.

FEA has determined that no commercial volumes of crude oil produced in Argentina and Australia are exported to the United States. FEA has also determined that no commercial volumes of crude oil produced in Iraq are exported to the United States. Sales and purchases for these countries, accordingly, need not be reported on Schedule D of the Transfer Pricing Report until such time as FEA determines that commercial volumes are being exported to the United States or otherwise determines that reporting shall be required.

Dated: March 24, 1975.

ROBERT E. MONTGOMERY, Jr.,
General Counsel,
Federal Energy Administration.

[FR Doc.75-7925 Filed 3-26-75;8:45 am]

FEDERAL MARITIME COMMISSION

D.B. TURKISH CARGO LINES

Notice of Petition Filed

Notice is hereby given that the following petition has been filed with the Commission for approval pursuant to section 14b of the Shipping Act, 1916, as amended (75 Stat. 762, 46 U.S.C. 813a).

Interested parties may inspect a copy of the current contract form and of the petition, reflecting the changes proposed to be made in the language of said contract, at the Washington office of the Federal Maritime Commission, 1100 L Street, NW., Room 10126 or at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California and Old San Juan, Puerto Rico. Comments with reference to the proposed changes and the petition, including a request for hearing, if desired, may be submitted to the Secretary, Federal Maritime Commission, 1100 L Street, NW., Washington, D.C. 20573, on or before April 16, 1975. Any person desiring a hearing on the proposed modification of the contract form and/or the approved contract system shall provide a clear and concise statement of the matters upon which they desire to adduce evidence. An allegation of discrimination or unfairness shall be accompanied by a statement describing the discrimination or unfairness with particularity. If a violation of the Act or detriment to the commerce of the United States is alleged, the statement shall set forth with particularity the acts and circumstances said to

constitute such violation or detriment to commerce.

A copy of any such statement should also be forwarded to the party filing the petition, (as indicated hereinafter), and the statement should indicate that this has been done.

Notice of Modification of Dual Rate Contract Filed by:

Mr. E. J. McAteer
Charrier, McAteer & Fettig
1776 K Street, NW.
Washington, D.C. 20006

The proposed modification revises D.B. Turkish Cargo Lines' Merchant's Freight Contract to conform more closely to the form of contract contained in the Commission's General Order 19.

By Order of the Federal Maritime Commission.

Dated: March 24, 1975.

FRANCIS C. HURNEY,
Secretary.

[FR Doc.75-8034 Filed 3-26-75;8:45 am]

CERTIFICATES OF FINANCIAL RESPONSIBILITY (OIL POLLUTION)

Certificates Issued

Notice is hereby given that the following vessel owners and/or operators have established evidence of financial responsibility, with respect to the vessels indicated, as required by section 311(p)(1) of the Federal Water Pollution Control Act, and have been issued Federal Maritime Commission certificates of Financial Responsibility (Oil Pollution) pursuant to Part 542 of Title 46 CFR.

CERTIFICATE NO.	OWNER/OPERATOR AND VESSELS
01026	Terkildsen & Olsen A/S: *Okapi.*
01069	Oglebay Norton Co.: *Thomas Wilson.*
01426	Kuwait Shipping Company (S.A.K.): *IBN Rushd.*
01435	Chapman and Willan Limited: *Federal Wear.*
02146	Pittston Marine Transport Corporation: *Westchester.*
02198	Peninsular & Oriental Steam Navigation Company: *LNG Challenger.*
02218	Christian Haaland: *Nyholt.*
02319	A/R Seljan: *Caloric.*
02333	Diamond Shamrock Corporation: *DSC 553, DSC 554, STAR 516, STAR 514, STAR 515, STAR 517.*
02358	A/S Ganger Rolf-A/S Bonheur-A/S Gorga-Den Norske Middelhavslinje A/S-A/S Jelolinjen: *Sea Bure.*
02858	Intermarine Inc.: *Ivory.*
02949	Valley Towing Service Inc.: *Sinclair 7, Sinclair 9, Sinclair 16, Sinclair 17.*
02975	Venture Shipping (Managers) Limited: *Belladona Venture.*
03137	The Cunard Steam-Ship Company Limited: *Lucellum, Lucerna.*
03357	Kirno Hill Corporation: *Simandou.*
03474	Nippon Suisan K.K.: *Mineshima Maru, Shikishima Maru, Keiko Maru, Kashima Maru, Suzukaze Maru, Sachikaze Maru, Suzuka Maru, Shirane Maru, Okuni Maru.*
03597	Felicitas Rickmers-Linie Kommanditgesellschaft & Co.: *Sophie Rickmers, Paul Rickmers.*
03746	Midwest Towing Co. Inc.: *Gopher State.*
03879	Zapata Haynie Corporation: *Earl J. Conrad, Jr., Northumberland, Landcaster, John S. Dempster, Jr., Mance Lassiter, W. T. James, Jr., John D. Deihl, J. Frank Jett, Allen W. Haynie, Ammon G. Dunton, Breton Sound, Oyster Bayou, Zapata Trinity Bay, Sandy Point, Rachel Burton, Carl Burton, Zapata Shell Key, Zapata Timberlier Bay, Zapata Atchafalaya Bay, Barataria Bay, Terrebone Bay, Vermillion Bay, Tiger Point, Galveston Bay, Grand Calliou, Cote Blanche Bay, Marsh Island, Racoon Point, W. J. Burton, Q. O. Dunn, Willard P. Lebocuf, Crochet 300, ZMS-D-10, Crochet 250.*
03971	Korea Shipping Corporation: *Kim Hae.*
04113	Mon River Towing Inc.: *MRBL-88, MRBL-24, MRT-110.*
04240	Petroleo Brasileiro S.A.: *Alagoas, Amazonas, Amapa, Atalata.*
04314	Jadranska Slobodna Plovidba: *Podgora.*
04437	Lebeouf Bros. Towing Co., Inc.: *Creole 1, Creole 2, Creole 3.*
04488	Fukuju Kigyo Kabushiki Kaisha: *Fukuju Maru No. 11.*
04489	Otoshiro Gyogyo K.K.: *Otoshiro Maru No. 7, Otoshiro Maru No. 8.*
04544	Mr. Yosuke Kawaguchi: *Seishu Maru No. 18.*
04673	Antonio Menchaca, S.A.: *Acuario, Geminis.*
04803	Brent Towing Company, Inc.: *B-731.*
05347	Lofland Brothers Company: *Orville L. Fisher, Gulf Coast No. 2, No. 9, No. 10, No. 11.*
05401	Tracor Marine, Inc.: *F.V. Hunt, H.J.W. Fay.*
05577	Far Eastern Shipping Company: *Viluyles.*
05579	Black Sea Shipping Co.: *Kapitan Georgiy Bagley, Kapitan Lev Solovyev, Kapitan Alekseyev.*
05631	Manson Construction and Engineering Co.: *Manson No. 1.*
05767	Neptune Orient Lines Limited: *Neptune Jade.*
05773	Paducah Marine Ways Inc.: *MV-287.*
06073	Marine Drilling Co.: *J Storm 1, Stormdrill V, Cee Bee 15, Cee Bee 16, Cee Bee 17, Cee Bee 18, Cee Bee 19, Cee Bee 20, Cee Bee 21, Cee Bee 22, Vermillion Bay Rig 6, Rig 8, J. Storm III.*
06114	Masahei Yamamoto: *Seishumaru No. 28.*
06188	Idemitsu Tanker, K.K.: *Akama Maru, Miyata Maru, Tokuyama Maru.*
06248	Commercial Corporation "Sovrybflot": *Kwadrant, Polsk, Lira.*
06409	India Steamship Co. Ltd.: *Indian Prestige.*
06806	Korea Marine Transport Co., Ltd.: *Korean Pearl.*
06937	K.K. Usufuku Honten: *Shofuku Maru No. 68.*
06995	Novorossisk Shipping Company: *Maikop.*
07145	Dai-Ho Industrial Co. Ltd.: *Sunlight No. 26.*
07151	Sea Containers Chartering Ltd.: *Dorli.*
07290	Hollywood Terminals, Inc.: *Debbie.*
07307	Nagashiki Kisen K.K.: *Takushio Maru.*
07361	Mr. Yasohaci Nakamura: *Kaiamaru No. 55.*
07527	Korea Line Corporation: *Blue Bell.*
07593	Oleandrus Shipping Company Ltd.: *Hyacinth.*
07951	Addax Tanker Corporation: *Arabian Addax.*
08071	Anglo Nordic Bulkships (Management) Ltd.: *Nordic Leader, Nordic Mariner.*
08188	Caribbean Marine Service Company, Inc.: *Gina Anne.*
08457	Louisiana Towboat Co., Inc.: *Mr. Paul.*
08530	Prompt Shipping Corp. Ltd.: *Caspian Career.*
08885	Onestar shipping company S.A.: *Onestar.*
09021	Daeyang Shipping Corp. Ltd.: *Enterprise Pioneer.*
09267	Oy enso-Chartering AB: *Finnreel.*
09358	Zenith Dredge Company: *Duluth, Adele, Faith, No. 16, No. 17.*
09385	Leland Towing Corp.: *Glenda S, Joey Kulbeth.*
09395	Interoceangas Tankers Management, S.A.: *Galileo, Claude.*
09403	East & West Steamship Co. (1961): *Rustom.*
09433	Hinode Gyogyo Kabushiki Kaisha: *Hinode Maru No. 53.*
09456	Corinth Bay Shipping Company Limited: *Elmela.*
09457	Ajax Shipping Company Limited: *Eljumbo.*
09545	Maytide Line Co., Ltd.: *Yue on.*
09549	Poseidon Shipping Inc. Panama: *Aghios Gerassimos.*
09566	Houshin Kaiun K.K.: *Koshin Maru.*
09582	Citation Carriers Inc.: *Eastern Oak.*
09584	Dong Sung Marine Transport Co., Ltd.: *Dong Moon, Dong Moon No. 3.*
09621	Gatx Bulk-Carriers Belgium N.V.: *Martha.*
09622	Man Cheung Yuen Services Limited: *Everjust.*
09673	Duval Corporation: *Duval 1, Duval 2, Duval 3.*
09687	Gladders Barge Line, Inc.: *GWG 301, GWG 302, GWG 303, GWG 304.*
09691	Libra Maritima S.A.: *Shenandoah.*
09696	Thomas & Williamson, Partnership: *CC-209.*
09736	Efpaleion Compania Naviera S.A.: *Aegis Bravery.*
09741	New Spirit Line S.A.: *New Challenger, New Venture.*
09765	Compania de Navegacion Palmetta S.A.: *Palmetta.*
09814	Pesquera Chiriqui, S.A.: *Chiriqui.*
09816	Multitank Badenia Tankreederei Ahrenkiel GMBH & Co. KG: *Multitank Badenia.*
09817	Multitank Rhenania Tankreederei Ahrenkiel GMBH & Co. KG.: *Multitank Rhenania.*
09823	Afretamentomarin SA Panama: *Betis.*
09825	Evaworld Shipping Co., S.A.: *Eva Sun.*
09848	Armadores Mariverda, S.A.: *Mariheron.*
09854	K/S Bewa II: *Sonja Bewa.*
09855	K/S Bewa XI: *Lita Bewa.*
09856	K/S Bewa VII: *Betty Bewa.*
09857	K/S Bewa XII: *Alice Bewa, Kis Bewa.*
09860	K/S Bewa XV: *Haslach Bewa.*
09862	K/S Bewa XVII: *Wivi Bewa.*

Certificate No.	Owner/Operator and Vessels
09861	K/S Bewa XVI: *Conny Bewa.*
09863	K/S Bewa XVIII: *Sally Bewa.*
09864	K/S Bewa XIX: *Nina Bewa.*
09865	K/S Bewa XX: *Karin Bewa.*
09866	K/S Bewa XXIII: *Kirsten Bewa.*
09867	K/S Bewa XXV: *Rikke Bewa.*
09868	K/S Bewa XXVI: *Mette Bewa.*
09869	K/S Bewa XXVII: *Anne Bewa.*
09870	Corco Transportation Co., Inc.: *Marine Hope.*
09882	Cyclops Drilling Company: *Spirit of Webb.*
09887	Hyndae Enterprise Co., Ltd.: *Saloma.*
09894	Jaime Emilio Nunez: *Emma.*
09904	Onesky Shipping Company S.A.: *Onesky.*
09909	Alliance Carriers S.A.: *Grand Alliance.*
09910	Malucidez Armadora S.A.: *Filiatra Legacy.*
09917	Petroleum Products of Delaware, Inc.: *BCD–I, Husky 854.*

By the Commission.

FRANCIS C. HURNEY,
Secretary.

[FR Doc.75–8033 Filed 3–26–75;8:45 am]

FEDERAL POWER COMMISSION

[Docket Nos. E–9280, E–9281, E–9282, and E–9283]

ARIZONA PUBLIC SERVICE CO.

Order Accepting for Filing and Suspending Proposed Monthly Billing Adjustments Subject to Refund, and Granting Waiver of Notice Requirements

MARCH 21, 1975.

Arizona Public Service Company (APS), on February 21, 1975, filed proposed adjustments in its billing to Salt River Agricultural Improvement and Power District (SRP), Tucson Gas and Electric Company (TGE) and Citizens Utilities Company (CUC).[1] The proposed changes in monthly billing to each of the three customers are based on the automatic adjustment provisions in APS's rates, which are currently under investigation under section 206 of the Federal Power Act pursuant to our Order issued July 15, 1974, in Docket Nos. E–8621, et al. The proposed billing adjustments reflect a finalized ad valorem tax rate for 1974, adjustments for the same period covering a change in state income tax rates, and operation and maintenance expense adjustments.

APS states that the cumulative effect of the rate filings, including some months in which there were decreases, amounts to an estimated semiannual increase of $24,460 to TGE, and $24,188 to SRP over July, 1974 rates, and an estimated annual increase of $88,118 to CUC over December, 1973 rates. APS requests that the notice requirements in Section 35.11 of the Commission's Regulations be waived for their filing to allow effective dates as of the beginning of the respective billing months. APS states that the waiver of the notice requirements is necessary since it is impossible to anticipate an escalation until sometime after the end of the month involved, and also in order to eliminate multiplicity of monthly filings. APS further states that it agrees that the increases in charges resulting from this rate change filing shall be subject to refund pending final disposition upon the conclusion of the hearing in Docket Nos. E–8621, et al.

Notice of these rate filings was issued on March 6, 1975, with protests and petitions to intervene due on or before March 2, 1975. Comments, if any, in response to this notice will be treated by separate order.

In our July 15, 1974 order in Docket No. E–8621, we rejected previous billing adjustments filed by APS because of their failure to meet the notice requirements of the Commission's Regulations. However, we also provided that this action was without prejudice to APS filing a request that the rate change filings be accepted as of their proposed effective dates, subject to refund pending final disposition upon the conclusion of a hearing. Since APS has agreed in its present filing that the proposed changes shall be subject to refund pending the final disposition of the proceedings in Docket Nos. E–8621, et al., we believe that it would be in the public interest to grant APS's request for waiver of the notice requirements of the Commission's Regulations and to allow the proposed changes to become effective as of the beginning of the respective billing months, subject to refund pending final disposition upon the conclusion of the hearing in Docket Nos. E–8621, et al.

Meanwhile, in hearings convened in Docket Nos. E–8621, et al., upon Staff Counsel's motion proffered March 6, 1975, cross examination was postponed by the Presiding Judge until April 3, 1975, pending completion of informal negotiations which include Docket Nos. E–9280, et al.

Our review of the filing indicates that the proposed rates may result in excess revenues and that the proposed increases have not been shown to be just and reasonable and may be unjust, unreasonable, unduly discriminatory or preferential or otherwise unlawful. We shall therefore set the matter for hearing and require that the proposed changes, which we shall allow to become effective as hereinabove noted, be subject to refund pending final disposition upon the conclusion of the hearing in Docket Nos. E–8621, et al.

The Commission finds. (1) Good cause exists to grant waiver of the notice requirements of the Commission's Regulations with respect to APS's February 21, 1975 filings in Docket Nos. E–9280, et al.

(2) APS's proposed monthly billing adjustments filed on February 21, 1975, should be accepted for filing, subject to refund pending final Commission action in Docket Nos. E–8621, et al.

(3) The disposition of this proceeding should be expedited in accordance with the procedure set forth below.

The Commission orders. (A) APS's request for waiver of the notice requirements of the Commission's regulations is hereby granted.

(B) The proposed monthly billing adjustments, filed on February 21, 1975, are accepted for filing subject to hearing and refund pending final Commission action in Docket Nos. E–8621, et al. The proposed changes shall become effective as of the beginning of the respective billing months, as requested by APS.

(C) The procedural dates that have already been established in Docket Nos. E–8621, et al., shall apply to the changes proposed in APS's February 21, 1975 rate filings.

(D) The Commission Secretary shall cause prompt publication of this order in the FEDERAL REGISTER.

By the Commission.

[SEAL] MARY B. KIDD,
Acting Secretary.

[FR Doc.75–7927 Filed 3–26–75;8:45 am]

[Docket No. CP74–293]

INTERSTATE TRANSMISSION ASSOCIATES (ARCTIC), ET AL.

Supplement to Application

MARCH 20, 1975.

Take notice that on February 26, 1975, Interstate Transmission Associates (Arctic) (ITAA), Pacific Interstate Transmission Company (Pacific Interstate), 720 West Eighth Street, Los Angeles, California 90017, and Northwest Alaska Company[1] (Northwest Alaska), 315 East Second South, Salt Lake City, Utah 84111, (hereinafter sometimes referred to collectively as Applicants) filed in Docket No. CP74–293, pursuant to § 1.11 of the Commission's rules of practice and procedure (18 CFR 1.11), a supplement to their application filed in that docket on May 14, 1974, for a permit pursuant to Executive Order No. 10485 to construct, operate and maintain certain natural gas facilities in the vicinity of the international boundary between the United States and Canada near Kingsgate, British Columbia, all as more fully set forth in the supplement in this proceeding which is on file with the Commission and open to public inspection.

In conjunction with the application in Docket No. CP74–293, Applicants filed on May 14, 1974, a companion application in Docket No. CP74–292, pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of facilities to transport natural gas in interstate commerce from a point near Kingsgate through the states of Idaho, Washington, and Oregon to the Nevada-California border.

[1] See Appendix A, filed as part of the original document, for rate schedule designations.

[1] Northwest Alaska and Northwest Energy Company (Energy) filed on February 5, 1975, a motion to substitute Northwest Alaska for Energy in Docket Nos. CP74–292 and CP74–293, and, further, requested that said dockets be redesignated to reflect Northwest Alaska as one of the party applicants effective as of the date of said motion.

Applicants state that Northwest Alaska, as a wholly-owned subsidiary of Energy, has been designated by Energy to participate in the forming of ITAA with Pacific Interstate and, as now contemplated, Pacific Interstate and Northwest Alaska will form ITAA as a general partnership to be organized under the laws of the state of Utah.

By the instant supplement, Applicants request that Northwest Alaska be substituted for Energy in the application and submitted supplements to Exhibit A (Pro-Forma Articles of Partnership), Exhibit B (State Authorizations), Exhibit C (Partnership Officials), and Exhibit D (Subsidiaries and Affiliations) to conform the application to the aforementioned change.

Any person desiring to be heard or to make any protest with reference to said supplement should on or before April 4, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules. Persons who have heretofore filed protests, petitions to intervene, or notices of intervention in the instant docket or in the consolidated proceeding in Docket No. CP75-96, et al., need not file again.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7936 Filed 3-26-75;8:45 am]

[Docket No. E-8264]

MAINE PUBLIC SERVICE CO.

Compliance Filing

MARCH 21, 1975.

Take notice that on March 7, 1975 the Maine Public Service Company (MPSC) tendered for filing a proposed fuel adjustment clause which is intended to conform with Section 35.14 of the Commission's regulations as amended by Order No. 517. This latest filing is made pursuant to a letter of the Secretary of the Federal Power Commission, dated February 3, 1975. As additional explanation to the present filing, MPSC states that because of the cash-flow burden created by the thirteen-month lag in the present fuel adjustment clause the proposed clause is designed to apply a billing factor each month based on the excess cost of fuel in the previous month. MPSC further states that as there were $316,269 of excess costs unbilled at December 31, 1974, it has also included a special adder to recover such unbilled costs, at the effective date of the new fuel clause, over the following twelve-month period.

MPSC asks that inasmuch as this submission is a continuation of the initial filing under the above-referenced docket, the formal filing requirements of § 35.13 of the Commission's regulations be waived.

MPSC states that copies of this filing have been sent to all jurisdictional wholesale customers and to the Maine Public Utilities Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 2, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7929 Filed 3-26-75;8:45 am]

[Docket No. RP75-20 PGA 75-8]

MISSISSIPPI RIVER TRANSMISSION CORP.

Proposed Change in Rates

MARCH 21, 1975.

Take notice that Mississippi River Transmission Corporation (Mississippi) on March 10, 1975, tendered for filing Twenty-Ninth Revised Sheet No. 3A to its FPC Gas Tariff, First Revised Volume No. 1 to become effective April 1, 1975.

Mississippi states that the instant filing is being made pursuant to the provisions of Mississippi's purchased gas cost adjustment clause to its tariff to reflect rate change filings of Natural Gas Pipeline Company of America (Natural) and Trunkline Gas Company (Trunkline) and to reflect a change in Mississippi's deferred cost adjustment. Natural's and Trunkline's rate changes are proposed to become effective April 1, 1975. Mississippi also tendered Alternate Twenty-Ninth Revised Sheet No. 3A to become effective April 1, 1975. Mississippi states that such tariff sheet is being submitted in order to add the effect of the Natural and Trunkline rate changes and the deferred cost adjustment change to the rates contained on Alternate Twenty-Eighth Revised Sheet No. 3A which sheet was submitted in connection with Mississippi's motion to make rate change and tariff sheets effective at Docket No. RP75-20. Mississippi states further that Alternate Twenty-Ninth Revised Sheet No. 3A should be made effective April 1, 1975 if the Commission grants Mississippi's request that Alternate Twenty-Eighth Revised Sheet No. 3A go into effect at Docket No. RP75-20.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 10, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene unless such petition has previously been filed. Copies of the filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7930 Filed 3-26-75;8:45 am]

[Docket No. CI75-538]

MOBIL OIL CORP.

Application

MARCH 19, 1975.

Take notice that on March 10, 1975, Mobil Oil Corporation (Applicant), Three Greenway Plaza East, Houston, Texas 77046, filed in Docket No. CI75-538 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the sale for resale and delivery of natural gas in interstate commerce to Trunkline Gas Company (Trunkline) from specified properties in the Grand Isle Block 95 Field, offshore Louisiana, pursuant to the terms of a contract between the parties dated March 4, 1975, all as more fully set forth in the application, which is on file with the Commission and open to public inspection.

Applicant proposes to sell and deliver natural gas to Trunkline at Trunkline's pipeline on Applicant's central production platforms in the field, pursuant to the subject agreement. Applicant proposes to sell to Trunkline an estimated 3,600,000 Mcf of gas per month at 15.025 psia at the nationwide rate prescribed in § 2.56a of the Commission's general policy and interpretations (18 CFR 2.56a), although the contract price is 80.0 cents per Mcf.

Applicant states that it is advised that Trunkline will be required to install additional pipelines or other facilities requiring certification to take delivery of the subject gas and that Trunkline will make the necessary filings with the Commission.

Applicant states that the gas supply from the Grand Isle Block 95 Field will serve to alleviate the shortage on Trunkline's system in substantial respects and that such additional supply can be on line and producing during the 1975-1976 winter if regulatory determinations are not unduly protracted. Applicant suggests that such determinations be made within two to three months to permit adequate time for construction and completion of all required facilities.

According to the contract, Applicant has specifically reserved 25 percent of all gas produced in the subject acreage

for its own use. Applicant states, however, that it will not exercise its right at this time and that Trunkline has agreed to purchase Applicant's reserved gas on a temporary basis under the subject gas sales agreement until such time as Applicant exercises its right. Applicant, therefore, requests that the Commission provide in the certificate that is to issue in the instant proceeding that it will not be necessary for Applicant to seek abandonment authorization for the sales of its reserved gas if and when it exercises its right to such reserved gas and seeks implementation of transportation service for its reserved gas by Trunkline to a point of use by Applicant.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 10, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7931 Filed 3-26-75;8:45 am]

[Docket No. RP71-125 PGA75-8]

NATURAL GAS PIPELINE COMPANY OF AMERICA

PGA Filing To Track a Pipeline Supplier Rate Increase

MARCH 20, 1975.

Take notice that on March 4, 1975, Natural Gas Pipeline Company of America (Natural) submitted for filing as part of its FPC Gas Tariff, Third Revised Volume No. 1, Twenty-first Revised Sheet No. 5, and an alternate numbered tariff sheet (Second Substitute Nineteenth Revised Sheet No. 5), to be effective April 1, 1975.

Natural states the filing was made pursuant to the provisions of section 18, Purchased Gas Cost Adjustment, of the general terms and conditions of its FPC Gas Tariff, to track the increased cost of gas purchased, effective April 1, 1975, from Colorado Interstate Gas Company, a pipeline supplier to Natural. Colorado's filing was made on February 28, 1975 to track the effect on Colorado of the uniform national rate approved by the Commission in Opinion No. 699 *et seq.*

Natural states that as notice of the supplier filing was not received by Natural in time to permit it to meet the 45 day filing requirement of its PGA tariff provision, it requests that that provision be waived to permit Natural's PGA unit adjustment to become effective April 1, 1975.

In regards to the above mentioned alternate numbered tariff sheet (Second Substitute Nineteenth Revised Sheet No. 5) Natural requests that it be substituted for the tariff sheet filed on a contingent basis on February 25, 1975. This alternate sheet is being submitted in order to include the 0.43¢ unit adjustment filed for herein to the rate levels previously filed on that date to be effective April 1, 1975. Natural recognizes that the substitution of this alternate sheet is dependent on the Commission's acceptance of the conditions in its February 25, 1975 request for approval to defer to April 1, 1975 the PGA unit adjustments previously filed to be effective February 5, and March 1, 1975. Natural respectfully requests waiver of the Commission's regulations to the extent necessary to permit this substitution. There is no difference between the currently effective rates on the alternate tariff sheet and the twenty-first Revised Sheet No. 5 also submitted.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 8, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7932 Filed 3-26-75;8:45 am]

[Docket No. E-9319]

NORTHERN STATES POWER CO.

Interconnection and Interchange Agreement With United Power Association

MARCH 20, 1975.

Take notice that Northern States Power Company, on March 12, 1975, tendered for filing an interconnection and interchange agreement, dated March 5, 1975, with United Power Association.

United Power Association, Rural Cooperative Power Association, and Northern Minnesota Power Association were merged with United Power Association the surviving organization. Northern States states that the filed agreement incorporates the language and interconnections provided for in the present Interconnection and Interchange Agreements with Rural Cooperative Power Association and United Power Association, and adds interconnections near Corcoran, Minnesota, and St. Cloud, Minnesota.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions and protests should be filed on or before April 2, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7933 Filed 3-26-75;8:45 am]

[Docket No. E-9324]

NORTHERN STATES POWER CO.

Initial Rate Filing

MARCH 21, 1975.

Take notice that on March 13, 1975, Northern States Power Company (NSPC) tendered for filing a Short Term Power Agreement with the City of New Ulm, Minnesota. NSPC states that The Agreement provides that either party may purchase power from the other for periods of seven days or longer. NSPC further states that the rates for such purchases are the same as the rates contained in NSPC's Rate Schedule FPC No. 275.3.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 4, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7934 Filed 3-26-75;8:45 am]

[Docket No. CP75-266]

PANHANDLE EASTERN PIPE LINE CO.

Application

MARCH 21, 1975.

Take notice that on March 10, 1975, Panhandle Eastern Pipe Line Company (Applicant) filed in Docket No. CP75-266 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing Applicant to deliver to and exchange with Phillips Petroleum Company (Phillips) certain volumes of natural gas, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Applicant seeks authorization to exchange residue gas which Applicant proposes to have delivered to Phillips processing plant located in Weld County, Colorado. Pursuant to certain gas purchase and sales agreements Applicant states it has acquired the right to purchase gas from nine wells located in Weld County, Colorado. The application indicates that five of these nine wells are oil wells producing casinghead gas, and the balance are gas wells. The application states such wells are located approximately eighteen miles from Applicant's Colorado pipeline system, and the volumes of gas available are such that it is not now economically feasible to connect these wells to Applicant's existing facilities. Applicant states it has been advised by Phillips that the Phillips pipeline system has sufficient capacity to accommodate the gas produced from the five oil wells and that its plant has capacity to process gas produced from all nine wells.

The application indicates that Applicant and Phillips have entered into a gas exchange agreement under the terms of which Phillips will connect the five casinghead gas producing wells to its low pressure gathering system and will gather, compress and process such gas. Applicant proposes to pay Phillips for this service 8.5 cents per Mcf plus a fuel volume equal to 8 percent of the volume delivered to the plant. Applicant states the thermal equivalent of the residue gas attributable to the casinghead gas, up to 20,000 Mcf per day, will be redelivered by Phillips to Applicant through existing interconnecting facilities at Applicant's Sneed, Texas, Compressor Station.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 11, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a hearing or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7935 Filed 3-26-75;8:45 am]

[Docket No. E-9290]

PUBLIC SERVICE COMPANY OF NEW HAMPSHIRE

Revision of Wholesale Rates

MARCH 21, 1975.

Take notice that by letter dated March 12, 1975, Public Service Company of New Hampshire (Public Service) retendered for filing increased rates previously filed on February 26, 1975, to all of its firm wholesale for resale customers: the Towns of Ashland and Wolfeboro, New Hampshire; the New Hampton (New Hampshire) Village Precinct; Exeter & Hampton Electric Company; Concord Electric Company; and New Hampshire Electric Cooperative, Inc.

Public Service states that its filing is based on a 1973 cost of service study, and Public Service states that it is presently unable to develop a cost of service study for a test period consisting of split calendar years without considerable delay, primarily because entries to its plant accounts other than major items are not distributed to function until the end of a calendar year. Public Service states that the Secretary, by letter dated March 5, 1975, rejected Public Service's February 26, 1975, filing as based on the most recent available calendar year data rather than on the most recent 12 consecutive months of available data and as lacking a request for waiver. Public Service states that the calendar year 1973 data are the most recent available 12 consecutive months of cost of service data. Public Service asks for waiver of § 35.13 (b) (4) (iii).

Public Service asks that its February 26, 1975, filing be treated as incorporated by reference. There, Public Service states that, based on a 1973 test period, the proposed rates involve an increase of $992,840, or 8.61 percent above presently effective rates. Public Service states that the proposed rates represent the first step of a two step increase to bring its wholesale rates to the affected customers up to a compensatory level. According to Public Service the proposed rates would produce an overall return of 7.706 percent and a return on equity of 8.94 percent. Public Service requests that the increase be allowed to become effective on April 12, 1975.

Public Service states that the proposed rates are unchanged in basic structure and design from the rates presently in effect. The proposed rates, according to Public Service, involve the following changes in the present level of charges and present fuel adjustment clause:

1. An increase in the demand charge from $2.95 to $3.22 per kilovolt-ampere of billing demand;
2. An increase in the energy charge of 0.73 to 0.91 cents per kilowatt hour;
3. A revision of the fuel adjustment clause to conform with § 35.14 of the Commission's regulations under the Federal Power Act as effective January 1, 1975; and
4. An increase in the minimum charge. Public Service states that the presently effective minimum charge is equal to the billing demand charge but not less than $200. Public Service states that the proposed minimum charge is equal to the billing demand but not less than $300. Public Service states that this increase in minimum charge is proposed to bring the charge up to the level presently applicable to the Company's industrial customers served under retail rates and that no resale customers would be affected by the change in the minimum charge.

Any persons desiring to be heard or to make any protest with reference to said filing should, on or before April 8, 1975, file with the Federal Power Commission, Washington, D.C. 20002, petitions to intervene or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 C.F.R. 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules. The documents filed by Public Service Company of New Hampshire are on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7937 Filed 3-26-75;8:45 am]

[Project No. 796; Docket No. E-9305]

SALT RIVER PIMA-MARICOPA INDIAN COMMUNITY v. CITY OF PHOENIX, ARIZONA

Petition To Intervene and for Declaratory Order and Complaint

MARCH 20, 1975.

Public notice is hereby given that a filing captioned petition to intervene and petition for a declaratory order or in the alternative, a complaint was filed on February 3, 1975, by the Salt River Pima-Maricopa Indian Community (Petitioner) in Project No. 796 licensed by the City of Phoenix, Arizona. (Correspondence to: Mr. Philip J. Shea, 114 W. Adams, Suite 310, Phoenix, Arizona 85003).

The petition to intervene claims that the Commission did not have jurisdiction to issue a license covering the transmission line from the power distribution system of the Salt River Valley Water Users Association at Granite Reef Diversion Dam to the Fort McDowell Reservation because the line is a minor part of a project distribution system. The line, which is 7.76 miles in length, goes from the eastern boundary of petitioners reservation to the northern boundary. They ask that the Commission declare that it does not have jurisdiction and that the license be cancelled.

In its complaint the petitioner alleges that the City of Phoenix conveyed the licensed right-of-way and power transmission line to the Salt River Project Agriculture Improvement District (successor to Salt Water River Valley Water Users Association) on May 1, 1953 without the consent of the Commission. Petitioner further alleges that the Licensee is in violation of the license in that it suffered the District to increase the power capacity of the line to 69 kilovolts without Commission approval. It is also alleged that the line was enlarged without Commission approval by adding a new leg which runs from a point near the intersection of the original line and the north boundary of the reservation and then westerly along a line parallel to the north boundary for about 2 miles.

The relief requested in the complaint is that the Commission issue a show cause order as to why action should not be initiated for cancellation of the license.

Any person desiring to be heard or to make protest with reference to said application should on or before April 28, 1975, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to a proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules. The application is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7928 Filed 3-26-75;8:45 am]

[Docket No. E-8823]

SOUTH CAROLINA ELECTRIC & GAS CO.

Settlement Agreement

MARCH 21, 1975.

Take notice that on March 5, 1975, South Carolina Electric & Gas Company (SCE&G) tendered for filing an unexecuted Settlement Agreement (Settlement) agreed to by SCE&G and the Department of Public Utilities of the City of Orangeburg, South Carolina, and the Saluda Electric Cooperative, Inc., Berkeley Electric Cooperative, and Palmetto Electric Cooperative, Inc., all of the intervenors in the above-captioned case.

SCE&G states that approval of the Settlement will effectuate the following principal changes in SCE&G's rates:

(1) The demand charge will be $630.00 for the first 200 kw of billing demand and $3.15 for all additional kw of billing demand;

(2) The energy charge shall be $0.01046 for all kwh;

(3) The fuel clause attached to the Settlement will become the operative fuel clause.

SCE&G states that the Settlement fuel clause is designed to conform to the requirements of Section 35.14 of the Commission's regulations, as amended by Order No. 517.

SCE&G requests an effective date of August 4, 1974 and states that it will make appropriate refunds for the period from and after August 4, 1974. SCE&G finally states that as part of the Settlement, the intervenors have agreed to withdraw their interventions in this proceeding.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 22, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7939 Filed 3-26-75;8:45 am]

[Docket Nos. CI74-734, CI74-749, CI75-22, CI75-24, CP75-82, CP70-224]

SUPERIOR OIL CO., ET AL.

Order Providing for Hearing, Setting Procedures, Consolidating Proceedings, and Granting Rehearing

MARCH 20, 1975.

By order issued January 17, 1975, the Commission granted certificates of public convenience and necessity to The Superior Oil Company (Superior), Placid Oil Company (Placid), Kewanee Oil Company (Kewanee), and Ashland Oil Company (Ashland) in Docket Nos. CI74-734, CI74-749, CI75-22, and CI75-24, respectively, to sell natural gas to Michigan Wisconsin Pipe Line Company (Mich Wis) in Block 182, Vermilion Area, Federal Domain Offshore Louisiana. In the same order Mich Wis was granted a certificate of public convenience and necessity to construct and operate $944,980 worth of facilities to attach the entire production of such offshore gas from Block 182. In addition, the Commission amended Sea Robin Pipe Company's (See Robin) certificate of public convenience and necessity in Docket No. CP70-224 by authorizing the use of an additional delivery point on its system to effect an exchange of gas with Columbia Gas Transmission Corporation (Columbia), delivery of the volumes of gas supplied to Sea Robin by Mich Wis from Block 182 to a point on Sea Robin's system in Block 181, East Cameron Area.

By letter order dated December 20, 1974, temporary certificates were granted to each Applicant Mich Wis, Sea Robin, Ashland, Kewanee, and Superior accepted their temporary certificates on December 20, 1974, January 2, 1975, January 6, 1975, January 10, 1975, and January 20, 1975, respectively.

Applications for rehearing have been filed by Superior, Placid, and Ashland[1] on February 18, 1975, in which these Applicants seek modification of the Commission order of January 17, 1975, in their respective dockets. These Applicants object to the condition imposed by the Commission in ordering paragraph (J) upon their gas sales certificates. Said condition reads:

(J) The certificates issued in paragraph (A) above authorize the sale of warranted volumes of natural gas as specifically stated herein and in the applicable contracts. The applicants in these proceedings may not reduce said volumes by use of the reserve redetermination clauses of said contracts. Should any applicant desire to reduce the warranted volumes, it must file for Commission authorization pursuant to section 7(b) of the Natural Gas Act.

Superior, Placid and Ashland assert that the imposition of the warranty qualification in paragraph (J) serves to abrogate the Commitment of Gas Terms of their gas sale contracts. Superior further states that deletion of the warranty requirement from the Commission's certificate should allow the parties to reevaluate and adjust the volumetric ceilings themselves, as per their contracts, without need for Commission authorization under section 7(b).

Superior and Ashland contend in their applications for rehearing that their gas sales contracts specifically state, "seller shall have the right, but not the obligation, to commit * * *" the following volumes to Mich Wis:

Producer:[1]	*Volume (thousand cubic feet)*
Superior	5,376,000
Placid	3,112,000
Kewanee	1,866,000
Ashland	6,906,000

[1] These are the volumes of maximum dedication each producer is obligated to deliver under the gas sales contract to Mich Wis. As mentioned above Kewanee has filed no application for rehearing, and Placid does not join in the specific contentions of Superior and Ashland in its application for rehearing.

Therefore, each contract commits up to, but not in excess of, these quantities

[1] Kewanee has filed no application for rehearing of said order.

of reserves found in the specified reservoirs. The contracts provide that the contract term will be 20 years or until the stated quantity is delivered, whichever occurs first. In addition, no contract permits the seller to reserve any of the dedicated gas, except for gas required for operational needs by each producer. Daily contract quantity for each producer is 1,000 Mcf for each 3.65 million Mcf of established reserves for the first 5 years of delivery and 1,000 Mcf for each 7.3 million Mcf of established reserves thereafter.

A further provision in each of the contracts permits redeterminations of reserve levels to be made once a year. Where these redeterminations show the reservoirs to have originally contained less gas than previously thought, the volumetric ceiling in the appropriate contracts will be lowered accordingly. In no instance will the ceilings be raised from those initially fixed in the contracts. Where a redetermination in fact shows the volume of a producer's reserves to be less than last previously determined, said producer has the contractual right, but not the obligation, to commit additional reserves from other locations so as to enable Mich Wis to obtain an overall volume of gas approximately equal to the volume last previously determined.

We declined to permit the gas sales contracts to go into effect as written because we were concerned that

(1) The producers may withhold greater volumes than necessary to meet their "operational demands", or that (2) the redetermination provision may allow buyer and seller to jointly approve a lowered determination without opportunity for scrutiny, the effect of either or both of which may be to (a) lessen the utility, and thus inflate the cost over time, of the 2.6 miles of connecting pipeline, and/or (b) deprive the interstate market of badly needed gas supplies.

Our objective was to assure a dedicated supply of natural gas to the interstate market from offshore Louisiana by the imposition of the warranty qualification. We shall grant rehearing, however, to allow Placid, Superior and Ashland to demonstrate that the public interest is better served by allowing these contractual provisions to take effect. A further related issue in the hearing hereafter ordered is whether the upper ceiling volumetric limits proposed in Articles IV and V of the contracts are required by public convenience and necessity.

Notices of applications have been published in the FEDERAL REGISTER, and petitions to intervene have been filed by Columbia, Sea Robin and Southern Natural in Docket No. CP75-82. By the order issued on January 17, 1975, in this proceeding the petitions to intervene were granted by the Commission.

The Commission finds. The applications for rehearing by Placid, Superior and Ashland in this proceeding may be in the public interest.

The Commission orders. (A) Pursuant to the authority of the Natural Gas Act, particularly sections 7 and 15 thereof, the Commission's rules of practice and procedure, and the Regulations under the Natural Gas Act (18 CFR Chapter 1), a public hearing shall be held commencing May 13, 1975, at 10 a.m. (edt) in a hearing room of the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, concerning the applications listed at the head of this order.

(B) On or before April 24, 1975, Applicants and all persons in support of the applications shall each file their prepared testimony and exhibits comprising their case-in-chief upon all parties to this proceeding, the Office of Administrative Law Judges and Commission staff.

(C) The Presiding Administrative Law Judge designated by the Chief Administrative Law Judge for that purpose [see Delegation of Authority, 18 CFR 3.5(d)] shall prescribe such further procedures as may be warranted in consideration of matters involved in this proceeding.

(D) The applications for rehearing filed by Superior, Placid, and Ashland are granted by the Commission for purposes of further hearing.

(E) The proceedings in Docket Nos. CI74-734, CI74-749, CI75-22, CI75-24, CP75-82 and CP70-224 are hereby consolidated for hearing and decision, and will be designated as Superior Oil Co., et al., Docket No. CI74-734, et al.

By the Commission.

[SEAL] KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-7940 Filed 3-26-75;8:45 am]

[Docket No. RP75-19]

TEXAS GAS TRANSMISSION CORP.

Conference

MARCH 21, 1975.

Take notice that on Tuesday, April 15, 1975 a conference of all interested persons in the above-referenced docket will be convened at 10 a.m. in Room No. 5200 at the offices of the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426.

The conference will be held pursuant to § 1.18 (Conferences, Offers of Settlement) of the Commission's rules of practice and procedure (18 CFR 1.18). Customers and other interested persons will be permitted to attend, but if such persons have not previously been permitted to intervene by order of the Commission, such attendance at the conference will not be deemed to authorize such intervention as a party in the proceedings.

In accordance with the provisions of § 1.18 of the rules, all parties will be expected to come fully prepared to discuss the merits of all issues concerning the lawfulness of Texas Gas Transmission Corporation's proposed tariff changes, any procedural matters preparatory to a full evidentiary hearing, or to make commitments with respect to such issues and any offers of settlement or stipulations discussed at the conference. Failure to attend the conference shall constitute a waiver of all objections to stipulations and agreements reached by the parties in attendance at the conference.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-7941 Filed 3-26-75;8:45 am]

[Docket No. E-9317]

VERMONT ELECTRIC POWER COMPANY, INC.

Proposed Cancellation of Electric Contract

MARCH 20, 1975.

Take notice that on March 10, 1975, Vermont Electric Power Company, Inc. (Velco) tendered for filing a notice of termination for Velco's FPC Rate Schedule No. 154, Supplement No. 6 and FPC Rate Schedule No. 155, Supplement No. 6. These schedules are the contracts between the Village of Northfield, Vermont and Velco. Velco states that the reason for termination is Northfield's failure to pay its bill.

Copies of the filing have been sent to the appropriate state agency and to Northfield. The proposed date of termination is April 6, 1975.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 4, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken; but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-7942 Filed 3-26-75;8:45 am]

[Docket No. E-9317]

VERMONT ELECTRIC POWER CO., INC.

Termination

MARCH 21, 1975.

Take notice that on March 10, 1975, Vermont Electric Power Company, Inc. (Velco) tendered for filing in the above-captioned docket a notice of termination of FPC Rate Schedule No. 154, Supplement No. 6, and FPC Rate Schedule No. 155, Supplement No. 6.

Velco states that the Village of Northfield has failed to pay its bill for Vermont Yankee power for service rendered since April, 1974. Velco states that it has given the Village of Northfield ample notice of the seriousness of its failure to pay its bills and has given notice of its intention to terminate service if the bills are not paid. The March 10, 1975, filing finally states that subsequent to the preparation of the filing, Velco was advised orally that Northfield was mailing

a letter to Velco assuring prompt payment. Velco states if proper payment is received on or before April 6, 1975, it will not terminate service and will withdraw its March 10, 1975 filing.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before April 15, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7943 Filed 3-26-75;8:45 am]

[Docket No. CP75-83-2]

WESTERN LNG TERMINAL CO.

Supplement to Application

MARCH 21, 1975.

Take notice that on March 3, 1975 Western LNG Terminal Company (Applicant), 720 West Eighth Street, Los Angeles, California 90017, filed pursuant to section 1.11 of the Commission's rules of practice and procedure (18 CFR 1.11) and the Commission's order issued December 23, 1974, in Docket No. CP75-83 (52 FPC ____), its Los Angeles Harbor supplement to its application filed in Docket No. CP75-83 on September 17, 1974,[1] for a conditioned certificate of public convenience and necessity pursuant to section 7(c) of the Natural Gas Act authorizing the construction and operation of facilities at three proposed locations in southern California, namely, Los Angeles Harbor, Oxnard, and Point Conception, to received, unload, store, and vaporize liquefied natural gas (LNG) and authorizing the construction of pipeline facilities for the transportation of such vaporized LNG in interstate commerce, all as more fully set forth in the supplement which is on file with the Commission and open to public inspection.

The application of September 17, 1974, describes Applicant's terminal company concept, its advantages, and the required facilities. Applicant therein states that it would perform a service only, would not own any of the LNG or revaporized gas, and would not be in the business of selling such gas for resale purposes. Applicant would, however, engage in the transportation of natural gas in interstate commerce, it states. Further, in the application of September 17, 1974, Applicant states that it would make supplemental filings at the time agreements were entered into to provide terminal services and that the supplemental filings would set out the specific facilities required, cost estimates, tariff, financing, and other pertinent data.

Applicant, in the instant supplement, states that on September 18, 1974, it signed a letter agreement with Pacific Alaska LNG Company (Pacific Alaska) to provide terminal services for the latter's South Alaska LNG project.

On November 11, 1974, Pacific Alaska filed in Docket No. CP75-140 an application for a certificate of public convenience and necessity authorizing its project and showing that the South Alaska LNG project proposes to use Applicant's terminaling services. Pacific Alaska's application proposes a two-phase project. Phase I is to encompass facilities to liquefy, transport and sell 200,000 Mcf of natural gas per day and Phase II is to encompass the additional facilities for a second increment of 200,000 Mcf per day, for a total of 400,000 Mcf per day.

The order of December 23, 1974, granted interventions and established certain procedures to follow in carrying out Commission responsibilities in connection with Applicant's project. While mostly agreeing with the procedures suggested by Applicant, the Commission rejected Applicant's conditioned certificate request and indicated that it would not have sufficient record evidence at the completion of contemplated hearings, no matter how extensively such certificates might be conditioned. The Commission indicated, however, that it could proceed to examine issues of site location and safety, including an evaluation of the most environmentally advantageous locations for the three sites and issue a preliminary opinion on these limited issues after hearing, initial decision, and briefs.

Applicant states that on February 26, 1975, it entered into a definitive agreement to provide terminal service to Pacific Alaska at its proposed Los Angeles terminal site located in Los Angeles Harbor. Applicant further states that this agreement provides that Applicant will receive, unload, store, and vaporize in Phase I up to an annual agreed quantity of 74,018,000,000,000 Btu of liquefied natural gas, and in Phase II an additional annual agreed quantity of 74,891,000,000,000 Btu, and redeliver during each contract year the resulting volumes requested and designated by Pacific Alaska to Southern California Gas Company at a delivery point in Los Angeles, California.

Applicant requests authorization to construct and operate facilities in two phases at the Los Angeles Harbor site to receive, unload, store, and vaporize liquefied natural gas for Pacific Alaska at an average rate in Phase I of 200,000 Mcf per day and at an average rate of 400,000 Mcf per day in Phase II, and to construct pipeline facilities for and the transportation of the vaporized LNG from the Los Angeles Harbor site to the Los Angeles delivery point. Applicant states that its Los Angeles Harbor facilities will be located on a 94-acre site on the south side of Terminal Island and that the Los Angeles Harbor Department (Harbor Department) will provide a level site and build the ship-berthing facilities for the plant on city-owned land. These facilities will be leased to Applicant, it is stated, and Harbor Department will also dredge a channel and turning basin in the outer harbor to provide LNG ship access to the facilities. Applicant proposes to construct and operate, in two phases, facilities designed to receive LNG transported by ship, unload and transfer it into insulated storage tanks, and withdraw and vaporize it for delivery into gas transmission systems. Applicant states that the Phase I facilities will be capable of handling up to 200,000 Mcf of natural gas per day, with a peaking capacity of an additional 200,000 Mcf daily, and proposes, in addition, in Phase I to construct and operate a pipeline from the Los Angeles Harbor LNG terminal to existing transmission facilities in southern California. In Phase II, Applicant proposes to construct and operate the additional facilities consisting of four submerged-combustion gas-fired vaporizers with a peaking capacity of 400,000 Mcf per day. Applicant indicates that, upon completion of Phase II, the facilities will have an average capacity of 400,000 Mcf of gas per day and a peaking capacity of 800,000 Mcf daily.

Specifically, Applicant proposes to construct and operate in Phase I marine facilities to accommodate and unload an LNG ship of up to 165,000 cubic meters capacity.

Applicant also proposes to construct and operate in Phase I the following:

(1) An LNG transfer system which will carry the LNG from the ships to the storage tanks. This system, Applicant states, will consist of one 36-inch diameter insulated cryogenic line and one 16-inch vapor-return line.

(2) Two tanks of 550,000 barrels each which will be required at the site to handle the Pacific Alaska volumes. Each tank will have the following approximate dimensions: Diameter—240 feet; shell height—80 feet; overall height—129 feet.

(3) A vaporization plant which will consist of vaporizers, an odorizing and metering system, and required peripheral equipment. It will be situated adjacent to the LNG storage tanks.

(4) One 8-foot diameter seawater pipeline which will be constructed between the inner harbor and the LNG plant to deliver about 87,000 gallons per minute of harbor seawater for base load vaporization.

(5) 3.4 miles of 48-inch pipeline which will be used to transport gas from the Los Angeles Harbor LNG terminal. This line will tie into the existing gas transmission system of Southern California Gas Company.

Applicant states that for Phase II, four submerged-combustion gas-fired vaporizers will be constructed to provide additional capacity for vaporization at peak rates up to 800,000 Mcf per day.

The supplement indicates the total cost for the Phase I facilities is estimated to be $156,654,000 and the total capital cost for the Phase II facilities is estimated to be $7,970,000. Applicant presently proposes the issuance of first mortgage bonds by private sale and the sale

[1] The application was noticed in the FEDERAL REGISTER on October 9, 1974 (39 FR 36387).

of common stock to Pacific Lighting Corporation, its parent. Anticipated interim financing for capital improvements during the construction period will be provided by (1) construction loans from banks and from others, (2) open account advances from Pacific Lighting Corporation, and (3) the sale of common stock to Pacific Lighting Corporation. Applicant states that the actual financing plans and related costs will be determined by market conditions and other circumstances at the time of financing.

Applicant proposes to render its terminal service at the Los Angeles facility on a cost-of-service basis pursuant to its FPC tariff.

Any person desiring to be heard or to make any protest with reference to said supplement should on or before April 3, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7944 Filed 3-26-75;8:45 am]

[Docket No. E-9313]

WISCONSIN POWER & LIGHT CO.

Supplement to Wholesale Power Agreement

MARCH 21, 1975.

Take notice that on March 11, 1975, the Wisconsin Power & Light Company (WPL) tendered for filing with the Commission a supplement to its wholesale power agreement with the Adams-Marquette Electric Cooperative, dated May 28, 1970, as amended July 15, 1971. The supplement will, among other matters, provide an additional delivery point to the Adams-Marquette Electric Cooperative in the Town of Saratoga, Wood County, Wisconsin.

The supplement referred to in this notice was entered into by agreement dated November 22, 1974.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 1, 1975, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to the proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules. The application is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7945 Filed 3-26-75;8:45 am]

[Project No. 2197]

YADKIN, INC.

Application for Change in Land Rights

MARCH 20, 1975.

Public notice is hereby given that application was filed on February 2, 1975, under the Federal Power Act (16 U.S.C. 791a–825r) by Yadkin, Inc., Applicant (correspondence to: LeBoeuf, Lamb, Leiby & MacRae, Attorneys for Yadkin, Inc., One Chase Manhattan Plaza, New York, New York 10005), for permission to grant an easement to Fieldcrest Mills, Inc., to allow construction of an underground industrial wastewater outfall line within the boundary of the Yadkin Project No. 2197. The Yadkin Project is located on the lower stretch of the Yadkin-Pee Dee River in Stanly, Montgomery, Davidson, and Rowan Counties, North Carolina. The project affects navigable waters.

Applicant requests Commission approval to grant a fifty-foot wide right-of-way to Fieldcrest Mills, Inc. to construct and maintain an underground water line. The easement would be located parallel to, north of, and approximately fifty feet from Interstate Highway 85, and would extend from the project boundary (normal high water elevation of 655 feet), approximately 1300 feet to the Yadkin River mainstream, and would cover 1.46 acres.

The easement provides for an outfall line of 24-inch inside diameter asbestos cement pipe, the last 300 feet of which would be ductile iron pipe, to discharge at elevation 640 feet a maximum flow of 5.0 MGD effluent from Fieldcrest Mills' secondary treatment plant. Waste which formerly received only primary treatment would be further treated if the easement were granted. Fieldcrest Mills has not begun construction of the secondary treatment plant as yet.

The United States Environmental Protection Agency, Region IV, issued Fieldcrest Mills a National Pollutant Discharge Elimination System permit number N.C. 0005487 on October 25, 1973. North Carolina Department of Natural and Economic Resources issued to Fieldcrest Mills permit number 8024 on August 5, 1974, for construction of the secondary treatment plant and outfall line and to allow discharge into the Yadkin River.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 12, 1975 file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 and 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules. The application is on file with the Commission and is available for public inspection.

Take further notice that, pursuant to the authority contained in and conferred upon the Federal Power Commission by sections 308 and 309 of the Federal Power Act (16 U.S.C. 825 and 825h) and the Commission's rules of practice and procedure, specifically § 1.32(b) (18 CFR 1.32(b)), as amended by Order No. 518, a hearing may be held without further notice before the Commission on this application if no issue of substance is raised by any request to be heard, protest or petition filed subsequent to this notice within the time required herein and if the applicant or initial pleader requests that the shortened procedure of § 1.32 (b) be used. If an issue of substance is so raised or applicant or initial pleader fails to request the shortened procedure, further notice of hearing will be given.

Under the shortened procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant or initial pleader to appear or be represented at the hearing before the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7946 Filed 3-26-75;8:45 am]

FEDERAL RESERVE SYSTEM

COMMUNITY BANCSHARES CORP.

Formation of Bank Holding Company

Community Bancshares Corporation, Woodbury, New Jersey, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company through acquisition of 100 per cent of the voting shares (less director's qualifying shares) of the successor by merger to National Bank and Trust Company of Gloucester County, Woodbury, New Jersey. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the office of the Board of Governors or at the Federal Reserve Bank of Philadelphia. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than April 17, 1975.

Board of Governors of the Federal Reserve System, March 20, 1975.

[SEAL] THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc.75-7907 Filed 3-26-75;8:45 am]

IOWA STATE BANK AND TRUST CO.

Order Denying Acquisition of Assets of Bank

Iowa State Bank and Trust Company, Fairfield, Iowa ("Iowa Bank"), a member State bank of the Federal Reserve System, has applied for the Board's approval pursuant to the Bank Merger Act (12 U.S.C. 1828(c)) of the acquisition of the assets and assumption of the liabilities of Farmers Savings Bank, Packwood Iowa ("Farmers Bank"). As an incident to the proposal, the present office of Farmers Bank would become a branch of Iowa Bank.

As required by the Act, notice of the proposed transaction, in form approved by the Board, has been published and the Board has requested reports on competitive factors from the Attorney General, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation. The Board has considered the application and all comments and reports received in light of the factors set forth in the Act.

The relevant geographic market in this case is approximated by Jefferson County and the Richland portion of Keokuk County. Iowa Bank is located in Fairfield, the county seat of Jefferson County. Fairfield is the shopping and commercial center of Jefferson County. Farmers Bank is located in northwest Jefferson County, and is 15 miles distant from the nearest office of Iowa Bank. Customers of Farmers Bank shop and work in Fairfield. Accordingly, Iowa Bank is a convenient banking alternative for those customers. The record indicates that a significant amount of banking business of Iowa Bank is done with customers located in the service area of Farmers Bank. Conversely, the record indicates that a significant amount of banking business of Farmers Bank derives from customers located in Iowa Bank's service area.

Iowa Bank, with deposits of roughly $17.5 million,[1] is the second largest of five banks in the relevant banking market, and controls approximately 36.2 percent of the total deposits in commercial banks in the market. The largest bank in the relevant market controls approximately 41.8 percent of market deposits. Farmers Bank, with deposits of roughly $3.7 million, is the fourth largest bank in that banking market, and controls approximately 7.7 percent of market deposits. Consummation of the acquisition, therefore, would eliminate one of the limited number of competitors in the market, result in Iowa Bank controlling approximately 43.9 percent of the deposits, and thereby increase the already high level of concentration of banking resources in the market. Also, existing competition between Iowa Bank and Farmers Bank would be eliminated by the proposed acquisition. The effect of the proposed transactions would be a substantial lessening of competition in the relevant market. In its considerations of this application, the Board regards such a lessening of competition as an adverse factor.

On the basis of the foregoing and the other factors in the record, the Board concludes that the proposal would increase the level of banking concentration to an undesirable level, and eliminate existing competition between the institutions involved. Accordingly, under section 1828(c), unless such anticompetitive effects are clearly outweighed in the public interest by the probable effect of the transaction in meeting the convenience and needs of the community to be served, the statute requires denial of the application.

The financial and managerial resources and future prospects of Iowa Bank are satisfactory. Farmers Bank does appear to have a management succession problem that would be alleviated by consummation of the proposed transaction. Therefore, banking factors are consistent with approval of the application. While community needs for banking services are not going unmet, consummation would provide a source in Farmers Bank's service area for large loans that presently exceed Farmers Bank's lending limit. While these benefits might serve the convenience and needs of the relevant area, they would not outweigh the adverse effects this proposal would have on competition in the relevant market. Further, the parties to the proposed transaction have not satisfied their burden of demonstrating the absence of less anticompetitive means to achieve such benefits to the convenience and needs of the community to be served.

On the basis of all relevant facts contained in the record, and in light of the factors set forth in the Bank Merger Act (12 U.S.C. 1828(c)), it is the Board's judgment that the anticompetitive effects of the proposed acquisition are not clearly outweighed in the public interest by the probable effect of the transaction in meeting the convenience and needs of the community to be served. The Board concludes, therefore, that the proposed transaction is not in the public interest and, accordingly, the application is hereby denied.

By order of the Board of Governors,[2] effective March 19, 1975.

[SEAL] THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc.75-7908 Filed 3-26-75;8:45 am]

[1] All banking data are as of June 30, 1974.

[2] Voting for this Action: Vice Chairman Mitchell and Governors Sheehan, Bucher and Wallich. Absent and not voting: Chairman Burns and Governors Holland and Coldwell.

PEOPLES STATE HOLDING CO.

Formation of Bank Holding Company

People's State Holding Company, Westhope, North Dakota, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company through acquisition of 95.94 percent or more of the voting shares of Peoples State Bank, Westhope, North Dakota. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the office of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received not later than April 17, 1975.

Board of Governors of the Federal Reserve System, March 20, 1975.

[SEAL] THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc.75-7909 Filed 3-26-75;8:45 am]

GENERAL SERVICES ADMINISTRATION

[GSA BULLETIN FPMR H-24]

DISPOSAL OF EXCESS PERSONAL PROPERTY

Bulletin to Heads of Federal Agencies

1. *Purpose.* This bulletin advises agencies

1. *Purpose.* This bulletin advises agencies
of updated information concerning disposal of excess personal property.

2. *Expiration date.* This bulletin contains information of a continuing nature and will remain in effect until canceled.

3. *General.* Section 3(f) of the Federal Property and Administrative Services Act of 1949, as amended, (Act) defines "foreign excess property" as any excess property located outside the States of the Union, the District of Columbia, Puerto Rico, and the Virgin Islands. Pub. L. 93-594, approved January 2, 1975, amends section 3(f) of the Act by inserting after the words "Puerto Rico" the words "American Samoa, Guam, the Trust Territory of the Pacific Islands,". The effect of the change is that excess personal property located in American Samoa, Guam, and the Trust Territory of the Pacific Islands is subject to Title II of the Act, rather than Title IV of the Act. Accordingly, excess personal property located in American Samoa, Guam, and the Trust Territory of the Pacific Islands will now be processed in the same manner as excess personal property located in the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. An appropriate change to the Code of Federal Regulations amending the definition of "foreign excess property" will be issued at a later date.

4. *Agency implementation.* Federal agencies should follow the same procedures to acquire or dispose of excess personal property in these territories as used for other domestic excess personal property. Agency heads are requested to inform field offices and activities concerning the inclusion of these geographic areas in the Domestic Excess Personal

Property Program, and urge their full participation.

Dated: March 17, 1975.

M. J. TIMBERS,
Commissioner,
Federal Supply Service.

[FR Doc.75-7911 Filed 3-26-75;8:45 am]

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-367]

NORTHERN INDIANA PUBLIC SERVICE CO. (BAILLY GENERATING STATION, NUCLEAR 1)

Oral Argument

Notice is hereby given that, in accordance with the Atomic Safety and Licensing Appeal Board's order of March 21, 1975, oral argument on the appeals from the February 21, 1975 supplemental initial decision of the Licensing Board (slurry wall proceeding) has been calendared for 10 a.m. on Tuesday, April 1, 1975 in the Appeal Panel hearing room, fifth floor, East West Towers Building, 4350 East-West Highways, Bethesda, Maryland.

For the Atomic Safety and Licensing Appeal Board.

Dated: March 24, 1975.

MARGARET E. DU FLO,
Secretary to the
Appeal Board.

[FR Doc.75-8062 Filed 3-26-75;8:45 am]

[Operating License No. DPR-43; Docket No. 50-305]

WISCONSIN PUBLIC SERVICE CORP. ET AL. (KEWAUNEE NUCLEAR POWER PLANT)

Negative Declaration

The U.S. Nuclear Regulatory Commission (the Commission) has considered the issuance of a change to the Environmental Technical Specifications, Appendix B, of Facility Operating License No. DPR-43. This change would authorize the Wisconsin Public Service Corporation, Wisconsin Power and Light Company and Madison Gas and Electric Company (licensee) to operate the Kewaunee Nuclear Power Plant using a new all-volatile treatment (AVT) of the secondary coolant water in the steam generators which will result in an increase in the annual release from 125 to 325 tons of total solids consisting primarily of nontoxic sodium sulfate, and up to 300 pounds of ammonium hydroxide, the pH of which will be controlled within 6 to 9. The conversion from the original coordinated phosphate control process to the AVT process eliminates the discharge into Lake Michigan of a ton of phosphate each year, which causes eutrophication of lakes and fresh water bodies. No change in the concentration of the total solids discharged will occur.

The Commission's Division of Reactor Licensing has prepared an environmental impact appraisal for the proposed changes to the Environmental Technical Specifications, Appendix B, appended to Facility Operating License No. DPR-43, for the Kewaunee Nuclear Power Plant described above. On the basis of this appraisal presented in this document, we have concluded that an environmental impact statement for this particular action is not warranted because, pursuant to the Commission's regulations in 10 CFR Part 51 and the Council of Environmental Quality's guidelines, 40 CFR 1500.6, the Commission has determined that this change in Technical Specifications is not a major federal action significantly affecting the quality of the human environment. The environmental impact appraisal, is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555 and at the Kewaunee Public Library, 314 Milwaukee Street, Kewaunee, Wisconsin 54216.

Dated at Rockville, Maryland, this 20th day of March 1975.

For the Nuclear Regulatory Commission.

GEORGE W. KNIGHTON,
Chief, Environmental Projects
Branch No. 1, Division of Reactor Licensing.

[FR Doc.75-7752 Filed 3-26-75;8:45 am]

[Docket No. 50-305]

WISCONSIN PUBLIC SERVICE CORP. ET AL. (KEWAUNEE NUCLEAR POWER PLANT)

Issuance of Amendment to Facility Operating License

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 3 to Facility Operating License No. DPR-43, issued to Wisconsin Public Service Corporation, Wisconsin Power and Light Company, and Madison Gas and Electric Company, which revised Technical Specifications for operation of the Kewaunee Nuclear Power Plant, located in Kewaunee County, Wisconsin. The amendment is effective as of its date of issuance.

The amendment permits the licensee to increase the amount of demineralizer regenerant solids, primarily nontoxic sodium sulfate, from 125 to 325 tons discharged annually into Lake Michigan. The increase results from conversion from a coordinated phosphate control to all-volatile treatment of the secondary water in the steam generators for the purpose of reducing tube wastage in the generators. The upper limit on the average incremental increase in the concentration of total solids in the circulating water will remain the same at 2.0 parts per million (ppm). In addition, up to 300 pounds of ammonium hydroxide will be discharged annually in the blowdown from the steam generators. The concentration of this base will be controlled within a pH range of 6 to 9. About a ton of phosphates will be eliminated from being released annually into Lake Michigan. Present studies being conducted by the licensee of the discharges from the plant have indicated no deleterious effect on the aquatic life in the sampling area in the vicinity of the plant discharge. The results of present studies will be used to confirm this effect of the increase discharge of total solids.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment is not required since the amendment does not involve a significant hazards consideration.

For further details with respect to this action, see: (1) the application for the amendment dated October 3, 1974, (2) Amendment No. 3 to License No. DPR-43 with Change No. 5, and (3) the Commission's Negative Declaration with the supporting Environmental Impact Appraisal.

All of the above items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555 and at the Kewaunee Public Library, Kewaunee, Wisconsin 54216.

A copy of items (2) and (3) may be obtained upon request addressed to the United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland, this 20th day of March 1975.

For the Nuclear Regulatory Commission.

ROBERT A. PURPLE,
Chief, Operating Reactors
Branch No. 1, Division of Reactor Licensing.

[FR Doc.75-7753 Filed 3-26-75;8:45 am]

[Docket Nos. STN 50-483 and STN 50-486]

UNION ELECTRIC CO.
(CALLAWAY PLANT, UNITS 1 AND 2)

Availability of Final Environmental Statement

Pursuant to the National Environmental Policy Act of 1969 and the United States Nuclear Regulatory Commission's regulations in 10 CFR Part 51, notice is hereby given that the Final Environmental Statement prepared by the Commission's Office of Nuclear Reactor Regulation, related to the proposed construction of Callaway Plant, Units 1 and 2, is available for inspection by the public in the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C., the Fulton County Library, 709 Market Street, Fulton Missouri and the Olin Library of Washington University, Skinker and Lindell Boulevard, St. Louis,

Missouri. The Final Environmental Statement is also being made available at the Division of State Planning and Analysis, Office of Administration, Capitol Building, Jefferson City, Missouri and the Mid-Missouri Regional Planning Commission, 830 E. High Street, Jefferson City, Missouri.

The notice of availability of the Draft Environmental Statement for the Callaway Plant, Units 1 and 2, and request for comments from interested persons was published in the FEDERAL REGISTER on October 25, 1974 (39 FR 38021). The comments received from Federal, State, local and interested members of the public have been included as an appendix to the final environmental statement.

Copies of the Final Environmental Statement (Document No. NUREG 75/011) may be purchased, at current rates, from the National Technical Information Service, Springfield, Virginia 22161.

Dated at Rockville, Maryland, this 20th day of March 1975.

For the Nuclear Regulatory Commission.

GEORGE W. KNIGHTON,
Chief, Environmental Projects Branch No. 1, Division of Reactor Licensing.

[FR Doc.75-7750 Filed 3-26-75;8:45 am]

PENSION BENEFIT GUARANTY CORPORATION

[Chairman's Order No. 2]

CHAIRMAN OF THE BOARD ET AL.

Delegation of Authority and Assignment of Responsibility for Pension Benefit Guaranty Corporation

1. *Purpose.* To delegate authority and assign responsibility to the Executive Director.

2. *Background.* Title IV of the Employee Retirement Income Security Act of 1974 established the Pension Benefit Guaranty Corporation within the Department of Labor. In carrying out its functions under this Act the Corporation is administered by the Chairman of the Board of Directors in accordance with policies established by the Board. On September 3, 1974 the Chairman issued Order No. 1, entitled Delegation of Authority and Assignment of Responsibility for Pension Benefit Guaranty Corporation. The instant order supersedes Order No. 1.

3. *The Office of Executive Director.* There is to be an Executive Director for the Pension Benefit Guaranty Corporation who shall report to the Chairman. The Executive Director is empowered to appoint officers of the Corporation to act in his stead during his absence or disability. Persons so appointed or others authorized to act as Executive Director during a vacancy in that Office are governed by this Order.

4. *Delegation of Authority and Assignment of Responsibilities.* a. The Executive Director is delegated authority—including authority to redelegate—and assigned responsibilities except as hereinafter provided, for carrying out the administrative functions to be performed by the Chairman of the Board of Directors under Title IV, Employee Retirement Income Security Act of 1974. These functions shall include, but not be limited to, the power to administer oaths and affirmations, subpoena witnesses, compel their attendance, take evidence, and require the production of any books, papers, correspondence, memoranda, or other records which the Corporation deems relevant or material to an inquiry under Title IV, Employee Retirement Income Security Act of 1974.

b. The Executive Director shall exercise the authority and carry out the responsibility delegated above in accordance with pertinent Governmental regulations, the bylaws and regulations of the Corporation, and the policies of the Board of Directors.

c. The General Counsel shall have the responsibility for providing legal advice and assistance to the Board of Directors, the Chairman, the Advisory Committee and the Executive Director relating to the administration of Title IV and other pertinent parts of the Employee Retirement Income Security Act of 1974.

5. *Reservation of Authority.* The following functions are reserved to the Chairman:

a. Submission of reports and recommendations to the President and the Congress concerning the administration of Title IV, Employee Retirement Income Security Act of 1974.

b. The bringing of legal action, other litigation decisions under the Act, and the determination in each case whether legal proceedings are appropriate. The initial decisions as to such legal matters are to be made by the General Counsel. When agreement is not reached between the Executive Director and the General Counsel regarding the bringing of such proceedings, the Executive Director shall refer the matter to the Chairman for decision.

c. The authorizing of any contract or agreement which would transfer the performance of a substantial portion of the Corporation's duties to persons not directly employed by the Corporation.

6. *Effective Date.* This Order is effective immediately.

Dated: March 14, 1975.

PETER J. BRENNAN,
Chairman, Board of Directors.

[FR Doc.75-7914 Filed 3-26-75;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[File No. 812-3755]

COMSTOCK FUND, INC., ET AL.

Application for an Order To Permit an Offer of Exchange and Exemption

MARCH 20, 1975.

Notice is hereby given that Comstock Fund, Inc., Enterprise Fund, Inc., Fletcher Fund, Inc., Harbor Fund, Inc., Legal List Investments, Inc., and Pace Fund, Inc. (collectively referred to as "Shareholders Funds") each of which is registered as an open-end investment company under the Investment Company Act of 1940 ("Act") and Channing Company, Inc. ("CCI"), 2777 Allen Parkway, Houston, Texas 77019, (collectively referred to with the Shareholders Funds as "Applicants") have filed an application for an order (1) pursuant to section 11 (a) of the Act to permit the Shareholders Funds to offer to exchange their shares for shares of American General Reserve Fund, Inc. ("AGR") on a basis other than their relative net asset value per share at the time of the exchange and (2) pursuant to section 6(c) of the Act granting exemption from section 22(d) of the Act and Rule 22d-1 thereunder, in connection with such exchanges. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

CCI, as principal underwriter for each of the Shareholders Funds, maintains a continuous public offering of the shares of the Shareholders Funds at their respective net asset value plus a sales charge. The maximum sales charge is 8.5 percent on purchases of less than $10,000. The sales charge is reduced on larger purchases.

Shares of each of the Shareholders Funds may be exchanged for shares of any of the other Shareholders Funds on the basis of their relative net asset value per share at the time of the exchange without sales charge. There is a fee of $5 payable to the transfer agent.

AGR is an open-end investment company registered under the Act. Its registration statement under the Securities Act of 1933 with respect to a public offering of shares of its stock was declared effective on July 12, 1974. CCI is the principal underwriter for AGR. AGR offers its shares to the public at an offering price equal to the net asset value plus a sales charge of 1 percent of the offering price.

Each of the Shareholders Funds proposes to offer its shares to shareholders of AGR in exchange for shares of AGR on the following basis: (1) shares of AGR acquired through a share exchange with one of the Shareholders Funds or through reinvestment of dividends or distributions on such shares will be exchanged for shares of any of the Shareholders Funds on the basis of their relative net asset value per share at the time of the exchange; (2) shares of AGR purchased at the public offering price, or acquired through reinvestment of dividends or distributions on such shares, will be exchanged for shares of any of the Shareholders Funds on the basis of their relative net asset value per share at the time of the exchange, plus the sales charge described in the prospectus of each of the Shareholders Funds (maximum 8½ percent), less an amount equal to the sales charge previously paid on the AGR shares being exchanged. Applicants

state that as a result, a shareholder acquiring shares of one of the Shareholders Funds through an exchange of shares of AGR purchased would pay approximately the same overall sales charge that he would have paid had he directly purchased the same dollar amount of shares of one of the Shareholders Funds.

Channing Bond Fund, Inc., Channing Income Fund, Inc., Channing Securities, Inc., Channing Shares, Inc. and Channing Venture Fund, Inc. (the "Channing Funds"), and Equity Growth Fund of America, Inc., Equity Progress Fund, Inc. and Fund of America, Inc. ("Equity Funds"), in conjunction with CCI, previously filed applications to permit similar exchanges of AGR shares for shares of the Channing Funds and Equity Funds. The requested exemptions were granted by the Commission on July 25, 1974 and November 1, 1974 (Act Release Nos. 8435 and 8567, respectively).

Applicants state that there is currently an exchange privilege offered between the Channing and Shareholders group of funds, but not with the Equity Funds. If the proposed exchange offer is permitted, an AGR shareholder could exchange his shares for shares of one of any such group of funds, and thereafter among that group and AGR. In addition, an AGR shareholder electing to exchange his shares for shares of either the Channing or Shareholders group of funds could, thereafter, exchange among that group, the other group and AGR. He would not, however, be allowed to exchange shares of a fund in the Equity Funds for AGR shares and, thereafter, exchange such AGR shares for shares of a fund in either of the two remaining groups.

In the event a shareholder desires to exchange only a portion of his shares of AGR, those shares that may be exchanged at relative net asset value without sales charge will be exchanged first. The remaining shares to be exchanged will be selected from those shares which are entitled to be exchanged upon payment of the lowest additional sales charge.

Section 11(a) of the Act provides that it shall be unlawful for any registered open-end company or any principal underwriter for such company to make or cause to be made an offer to the shareholder of a security of such a company or of any other open-end investment company to exchange his security for a security in the same or another such company on any basis other than the relative net asset values of the respective securities to be exchanged unless the terms of the offer have first been submitted to and approved by the Commission.

Section 22(d) of the Act provides, in pertinent part, that no registered investment company or principal underwriter thereof shall sell any redeemable security issued by such company to any person except at a current offering price described in the prospectus. The sales charge described in the prospectus of each of the Shareholders Funds is greater than the sales charge which would be applicable to the proposed exchange offer.

Applicants state that the purpose of the proposed exchange offer is to permit a shareholder of AGR who changes his investment objective to change his investment to a different investment company without paying the full sales charge otherwise applicable. It is submitted that the exchange offer to AGR shareholders cannot be made at the relative net asset values of the Shareholders Fund to be acquired because the AGR shareholder would have paid substantially lower sales charges on his investment than similarly situated investors in the Shareholders Fund to be acquired. Applicants further submit that if shares of the Shareholders Funds could be acquired by an AGR shareholder at net asset value in an exchange, it is possible that the exchange would be in violation of section 22(d) of the Act since an investor would be able to purchase shares of one of the Shareholders Funds at a sales charge other than that described in its prospectus merely by purchasing shares of AGR and subsequently exchanging those shares at net asset value for shares of one of the Shareholders Funds.

Section 6(c) provides, in part, that the Commission by order upon application may conditionally or unconditionally exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision or provisions of the Act and the Rules promulgated thereunder, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person many, not later than April 15, 1975, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission should order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail (air mail if if the person being served is located more than 500 miles from the point of mailing) upon Applicants at the address stated above. Proof of such service (by affidavit, or in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the rules and regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management Regulation, pursuant to delegated authority.

[SEAL] GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc.75-7979 Filed 3-26-75;8:45 am]

[File No. 70-5652]

EASTERN UTILITIES ASSOCIATES, ET AL.

Proposed Stock Transactions

MARCH 20, 1975.

Notice is hereby given that Eastern Utilities Associates ("EUA"), P.O. Box 2333, Boston, Massachusetts, 02107, a registered holding company, and two of its electric utility subsidiary companies, Brockton Edison Company ("Brockton"), 36 Main Street, Brockton, Massachusetts, 02403, and Montaup Electric Company ("Montaup"), P.O. Box 391, Fall River, Massachusetts, 02722, have filed an application-declaration with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act") designating sections 6, 7, 9, 10 and 12(f) of the Act and Rules 43 and 44 as applicable to the proposed transactions. All interested persons are referred to the application-declaration, which is summarized below, for a complete statement of the proposed transactions.

Brockton proposes to increase its capital stock by $15,000,000 consisting of 600,000 additional shares of its common stock, par value $25.00 per share and to sell such additional shares to EUA at par value. This additional common stock will be pledged by EUA to The First National Bank of Boston as Trustee under EUA's Indenture and Deed of Trust dated as of October 1, 1953, as supplemented.

Montaup proposes to increase its capital stock by $7,700,000, consisting of 77,000 additional shares of its common stock, par value $100 per share, and to sell such additional shares to Brockton at par value.

Proceeds to Brockton from the sale of its stock to EUA will be applied to the repayment of open account advances from EUA in the amount of $7,300,000 and to making an open account advance in the amount of $7,700,000 from Brockton to Montaup. The advance from Brockton to Montaup will bear interest at a rate per annum equal to the rate at which EUA borrows funds on a short-term basis pursuant to authorization previously granted to EUA (Holding Company Act Release No. 18739). It is stated that if all requisite regulatory approvals for the sale of the additional Montaup stock to Brockton have been obtained prior to the sale of the new Brockton stock to EUA, the $7,700,000 portion of the proceeds to Brockton will be applied directly to purchase additional Montaup stock and the proposed open-account advance from Brockton to Montaup will not be made.

Proceeds to Montaup from the sale of its stock to Brockton will be applied to the repayment of open account advances from Brockton or payment of short-term

notes previously issued by Montaup pursuant to prior Commission approval (Holding Company Act Release No. 18739). Proceeds of the $7,700,000 loan from Brockton to Montaup will also be applied to payment of those short-term notes.

It is stated that the proposed issue and sale of the additional Brockton stock and the proposed open account advance from Brockton to Montaup are subject to the jurisdiction of the Department of Public Utilities of the Commonwealth of Massachusetts ("MDPU") and that the proposed issue and sale of the additional Montaup stock and the acquisition thereof by Brockton are also subject to MDPU approval. It is stated that no other state commission and no federal commission, other than this Commission, has jurisdiction over the proposed transactions. Fees and expenses to be incurred in connection with the proposed transactions will be supplied by amendment.

Notice is further given that any interested person may, not later than April 14, 1975, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said application-declaration which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail (air mail if the person being served is located more than 500 miles from the point of mailing) upon the applicants-declarants at the above-stated addresses and proof of service (by affidavit or, in case of an attorney-at-law, by certificate) should be filed with the request. At any time after said date, the application-declaration, as it may be amended, may be granted and permitted to become effective as provided in rule 23 of the general rules and regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

[SEAL] GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc.75-7980 Filed 3-26-75;8:45 am]

THE OPTIONS CLEARING CORP.

Proposed Amendments to Option Plans

Notice is hereby given that the Chicago Board Options Exchange, Inc. ("CBOE") and the American Stock Exchange, Inc. ("AMEX"), have filed proposed changes in their respective option plans pursuant to Rule 9b-1 under the Securities Exchange Act of 1934 (17 CFR 240.9b-1). The changes concern amendments to the By-Laws and Rules of the Options Clearing Corporation ("OCC"). The OCC proposes to amend subparagraphs (u) and (y) of and add new subparagraph (hhh) to Article I, Section 1 and amend Article VI, Section 3 of the By-Laws, and Rules 101, 604(c), 802, 803, 901, 912, 913(a), 913(d) and 1104 concerning obligations of clearing members.

The proposed amendments to Rules 101, 604(c) and 1104 would, according to OCC, permit clearing members to restrict the Clearing Corporation's rights with respect to letters of credit deposited for the purpose of margining customer accounts. Under the proposed amendments, such letters of credit (referred to as "restricted letters of credit") would be treated by the Clearing Corporation in substantially the same manner as bulk deposits of securities in customer accounts. Under the proposed amendments restricted letters of credit would not qualify as margin for any account other than the customers' account in which they were deposited; and, in the event of the suspension of the depositing clearing member, the proceeds from such letters of credit would be applied only to satisfy obligations arising out of such customers' account.

Under its present Rules, the Clearing Corporation is required to assign exercise notices filed prior to the expiration date of the exercised option at approximately 3 p.m., Chicago time, on the date of filing. Exercise notices filed on the expiration date are required to be assigned at approximately 12 noon, Chicago time, on the expiration date. Assignments made prior to the expiration date are effective as of the following business day (because trading is closed before the exercising and assigned clearing members receive notice of the assignment), whereas assignments made on the exercise date are effective as of that date.

Under the proposed amendment to Rule 803, all exercise notices, whether filed on or before the expiration date, would according to OCC be assigned at or before 7 a.m., Chicago time, on the following business day, and all assignments would be effective as of such following business day. OCC explains that the change is necessary because increases in the number of exercises have made it difficult, and at times impossible, for the Clearing Corporation to complete the assignment process within existing timeframes. The OCC further explains that the proposed amendments to Rules 802, 901, 912, 913(a) and 913(d) conform those Rules to the change in Rule 803, eliminate certain redundant provisions and clarify certain other provisions, without making any substantive change.

The proposed amendments to Article I, Section 1 and Article VI, Section 3 of the By-Laws would permit clearing members carrying accounts for exchange members registered as traders with their respective exchanges pursuant to a plan filed under Rule 11a-1 to obtain the same Clearing Corporation margin treatment as is accorded market-makers' and specialists' accounts. New subparagraph (hhh) of Article I, Section 1 defines the term "Registered Trader," and new subparagraph (e) of Article VI, Section 1 (replacing old subparagraph (e), which would be redesignated as subparagraph (f)) provides for registered trader's account, which would be treated in the same manner, and subject to the same restrictions, as market-maker's and specialist's account. References to market-makers and specialists, and their accounts, appear at many points throughout the By-Laws and Rules, so OCC determined that, in lieu of adding the term "registered trader" at each point where the other terms appear, the definitions of market-maker and specialist should be expanded to include registered traders. The amendments to subparagraphs (u) and (y) of Article I, Section 1 are intended to accomplish that result.

Rule 601(b) permits the values of options in long positions in a market-maker's account to be netted, to the extent set forth therein, against the values of options in short positions in that account for the purpose of determining required margin. OCC explains that this netting is permitted because the clearing member for which the account is maintained grants to the Clearing Corporation (with the consent of the market-maker) a lien on all long positions in the account for the purpose of securing the clearing member's obligations to the Clearing Corporation in respect of that account. Under the proposed amendment to Article VI, Section 3 of the By-Laws, clearing members according to the OCC would be required to grant similar lien on long positions in each registered trader's account (with the consent of the registered trader).

The proposed amendments will become effective upon April 28, 1975, or upon such earlier date as the Commission may allow unless the Commission shall disapprove the change in whole or in part as being inconsistent with the public interest or the protection of investors.

All interested persons are invited to submit their views and comments on the proposed amendments to OCC's By-Laws and Rules (plan) either before or after they have become effective. Written statements of views and comments should be addressed to the Secretary, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549. Reference should be made either to file number 10-54 or 10-26. The proposed amendments are, and all such comments will be, available for public inspection at the Public Reference Room of the Securities and Exchange Commission at 1100 L Street, NW., Washington, D.C.

[SEAL] GEORGE A. FITZSIMMONS,
Secretary.

FEBRUARY 27, 1975.

[FR Doc.75-7981 Filed 3-26-75;8:45 am]

SEC REPORT COORDINATING GROUP (ADVISORY)

Rescheduling of Public Meeting

Correction

In FR Doc. 75-7075 appearing on page 12168 in the middle column in the issue of Monday, March 17, 1975, make the following correction:

The last line of the second paragraph should read "commission rates".

INTERSTATE COMMERCE COMMISSION

[Notice No. 730]

ASSIGNMENT OF HEARINGS

MARCH 24, 1975.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC-C-8416, H. J. Moran, DBA Singing River Motor Freight—Investigation and Revocation of Certificate of Registration, April 16, 1975, at Jackson, Miss., is cancelled.

MC 109533 Sub 60, Overnite Transportation Company, now being assigned continued hearing April 15, 1975 (3 days), at The Venice Motel, Room 170, 431 Dual Highway, Hagerstown, Maryland.

MC 106920 Sub 54, Riggs Food Express, Inc., now being assigned April 14, 1975 (1 day), at Chicago, Illinois; in Room 1086A, Everett McKinley Dirksen Building, 219 South Dearborn Street.

MC 115767 Sub 4, Terminal Transfer, Inc., now assigned April 22, 1975, at Salem, Oregon; will be held in Room 4445, State Agriculture Building, 635 Capitol St. NE.

MC 45736 Sub 44, Guignard Freight Lines, Inc., MC 116514 Sub 32, Edwards Trucking, Inc., MC 117416 Sub 44, Newman and Pemberton Corp., MC 136285 Sub 9, Southern Intermodal Logistics, Inc., and MC 139822, Food Carrier, Inc., now assigned April 28, 1975, at Atlanta, Georgia, will be held in Room 305, 1252 West Peachtree Street NW.

MC 124154 Sub 62, Wingate Trucking Company, Inc., now assigned April 22, 1975, at Atlanta, Georgia will be held in Room 305, 1252 West Peachtree Street NW.

MC 127834 Sub 105, Cherokee Hauling and Rigging, Inc., now assigned April 24, 1975, at Atlanta, Georgia, will be held in Room 305, 1252 West Peachtree Street NW.

MC 130247, Colpitts Travel Agency of Rhode Island, now assigned April 15, 1975, at Providence, Rhode Island, will be held in Hearing Room, 2nd Floor, Division of Public Utilities, 169 Weybosset Street.

MC 139934 Sub 1, Walker Contract Carrier, Inc., now assigned May 14, 1975, at Tallahassee, Florida, has been postponed to June 3, 1975 (3 days), at Tampa, Florida; in a hearing room to be designated later.

MC-F-12264, Mayfield Transfer and Storage Co., Inc.—Purchase (portion)—Fred Olson Motor Service Company, now assigned May 5, 1975, at Chicago, Ill., is postponed to June 6, 1975, at Chicago, Ill.

MC 139495 Sub 12, National Carriers, Inc., application dismissed.

MC 139587 Sub 4, Brown Refrigerated Express, Inc., application dismissed.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-8024 Filed 3-26-75;8:45 am]

FOURTH SECTION APPLICATIONS FOR RELIEF

MARCH 24, 1975.

An application, as summarized below, has been filed requesting relief from the requirements of Section 4 of the Interstate Commerce Act to permit common carriers named or described in the application to maintain higher rates and charges at intermediate points than those sought to be established at more distant points.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the General Rules of Practice (49 CFR 1100.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

FSA No. 42959—*Joint Water-Rail Container Rates—Seatrain International, S.A.* Filed by Seatrain International, S.A. (No. WEE-8), for itself and the Seaboard Coast Line Railroad. Rates on general commodities, between rail carrier's terminal in Tampa, Florida, and ports in Europe. Grounds for relief—Water competition. Tariffs—Seatrain International, S.A., tariffs I.C.C. Nos. 9, 10, 11, 12, 13, and 14. Rates are published to become effective on April 21, 1975.

FSA No. 42960—*Cereal Food Preparations Within the Western District.* Filed by Southwestern Freight Bureau, Agent (No. B-524), for interested rail carriers. Rates on cereal food preparations, in carloads, as described in the application, from, to and between points in Colorado-Utah-Wyoming Committee, Illinois Rate Committee, Southwestern Freight Bureau and Western Trunk Line Committee territories. Grounds for relief—Revision in carload rates.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-8023 Filed 3-26-75; 8:45 am]

[Notice No. 254]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

MARCH 27, 1975.

Synopses of orders entered by the Motor Carrier Board of the Commission pursuant to sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 1132), appear below:

Each application (except as otherwise specifically noted) filed after March 27, 1972, contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application. As provided in the Commission's Special Rules of Practice any interested person may file a petition seeking reconsideration of the following numbered proceedings on or before April 16, 1975. Pursuant to section 17(8) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC-FC-75670. By order entered March 12, 1975, the Motor Carrier Board approved the transfer to W. J. Landes, doing business as Landes Garage, Staunton, Va., of the operating rights set forth in Certificate No. MC 124868, issued December 21, 1972, to Landes Wrecker Service, Inc., Staunton, Va., authorizing the transportation of wrecked and disabled motor vehicles and replacement vehicles therefor, by use of wrecker equipment only, in truckaway service, between points in Virginia: and between points in Virginia on the one hand, and, on the other, points in Delaware, Georgia, Maryland (except points in the Baltimore, Md., Commercial Zone as defined by the Commission), New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Vermont, West Virginia, and the District of Columbia. Harry J. Jordan, 1000 16th St. NW., Washington, D.C. 20036, attorney for applicants.

No. MC-FC-75714. By order of March 12, 1975, the Motor Carrier Board approved the transfer to Trout Run Transport, Inc., Trout Run, Pa., of the operating rights in Certificate No. MC 123663 issued April 16, 1974, to John H. Cerquozzi, Williamsport, Pa., authorizing the transportation of wooden products, with certain exceptions, from Picture Rocks, Pa., and points within 1 mile thereof, to points in New York, Connecticut, New Jersey, Maryland, and Delaware. Christian V. Graf, 407 North Front St., Harrisburg, Pa. 17101, Attorney for applicants.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-8025 Filed 3-26-75;8:45 am]

[Notice No. 24]

MOTOR CARRIER, BROKER, WATER CARRIER AND FREIGHT FORWARDER APPLICATIONS

MARCH 21, 1975.

The following applications (except as otherwise specifically noted, each applicant (on applications filed after March 27, 1972) states that there will be no significant effect on the quality of the human environment resulting from approval of its application), are governed

by Special Rule 1100.247[1] of the Commission's general rules of practice (49 CFR, as amended), published in the FEDERAL REGISTER issue of April 20, 1966, effective May 20, 1966. These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission within 30 days after date of notice of filing of the application is published in the FEDERAL REGISTER. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest under these rules should comply with section 247 (d) (3) of the rules of practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (including a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application, and describing in detail the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed), and shall specify with particularity the facts, matters, and things relied upon, but shall not include issues or allegations phrased generally. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one (1) copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or applicant if no representative is named. If the protest includes a request for oral hearing, such requests shall meet the requirements of section 247(d) (4) of the special rules, and shall include the certification required therein.

Section 247(f) of the Commission's rules of practice further provides that each applicant shall, if protests to its application have been filed, and on or before May 27, 1975, notify the Commission in writing (1) that it is ready to proceed and prosecute the application, or (2) that it wishes to withdraw the application, failure in which the application will be dismissed by the Commission.

Further processing steps (whether modified procedure, oral hearing, or other procedures) will be determined generally in accordance with the Commission's general policy statement concerning motor carrier licensing procedures, published in the FEDERAL REGISTER issue of May 3, 1966. This assignment will be by Commission order which will be served on each party of record. Broadening amendments will not be accepted after the date of this publication except for good cause shown, and restrictive amendments will not be entertained following publication in the FEDERAL REGISTER of a notice that the proceeding has been assigned for oral hearing.

[1] Copies of Special Rule 247 (as amended) can be obtained by writing to the Secretary, Interstate Commerce Commission, Washington, D.C. 20423.

No. MC 531 (Sub-No. 309), filed February 27, 1975. Applicant: YOUNGER BROTHERS, INC., 4904 Griggs Road, Houston, Tex. 77021. Applicant's representative: Mr. Wray E. Hughes (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Grape juice*, concentrate, in bulk, in tank vehicles, from Geneva, Ohio, to Anaheim, Calif.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Houston, Tex., or Los Angeles, Calif.

No. MC 4405 (Sub-No. 519), filed March 3, 1975. Applicant: DEALERS TRANSIT, INC., 2200 E. 170th Street, P.O. Box 361, Lansing, Ill. 60438. Applicant's representative: Robert E. Joyner, 2008 Clark Tower, 5100 Poplar Ave., Memphis, Tenn. 38137. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Trailers, semi-trailers,* and *trailer chassis* (except those designed to be drawn by passenger automobiles), in initial movements, in truckaway and driveaway service, from points in Pike County, Ohio, to points in the United States (except Alaska and Hawaii); (2) *tractors,* in secondary movements, in driveaway service, when drawing commodities named in (1) above in initial driveaway service, from points in Pike County, Ohio, to points in Arizona, Nevada, Oregon, and Vermont; (3) *truck and trailer bodies, trailer dolly converters, and cargo containers,* from points in Pike County, Ohio, to points in the United States (except Alaska and Hawaii); and (4) *materials and supplies* (except in bulk), and *parts* used in the manufacture, assembly and servicing of the commodities in (1) and (3) above, from points in Pike County, Ohio, to points in the United States (except Alaska and Hawaii).

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held on consolidated record with the similar application filed by Arco Auto Carriers, Inc. at Columbus, Ohio or Detroit, Mich.

No. MC 6078 (Sub-No. 80), filed February 24, 1975. Applicant: D. F. BAST, INC., P.O. Box 2288, Allentown, Pa. 18001. Applicant's representative: Bert Collins, Suite 6193, 5 World Trade Center, New York, N.Y. 10048. Authority sought to operate as a *common carrier* by motor vehicle, over irregular routes, transporting: *Commodities,* the transportation of which because of size or weight requires the use of special equipment, and *related materials and supplies* when moving in mixed loads therewith: (1) between points in the United States (except Alaska and Hawaii), restricted to shipments having a prior or subsequent movement by water or rail; and (2) between the plantsite and other facilities of Sun Shipbuilding Co., at Chester, Pa., on the one hand, and, on the other, points in the United States in and east of Minnesota, Iowa, Missouri, Arkansas, and Texas.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 9812 (Sub-No. 2), filed February 24, 1975. Applicant: C. F. KOLB TRUCKING COMPANY, INC., 1201 St. George Road, Evansville, Ind. 47711. Applicant's representative: Edwin J. Simcox, 601 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Plastic resins and plastic sheets,* (except in bulk), from Mt. Vernon, Ind., to points in Alabama, Arkansas, Florida, Georgia, Illinois, Iowa, (except Alaska and Hawaii), restricted Kansas, Kentucky, Michigan, Mississippi, Missouri, Ohio, Pennsylvania, Tennessee, West Virginia, and Wisconsin; and (2) *packaging and shipping materials,* from Chicago, Ill., St. Louis, Mo., and Louisville, Ky., to Mt. Vernon, Ind., restricted to traffic originating at or destined to the plant site and shipping facilities of General Electric Company at or near Mt. Vernon, Ind.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Indianapolis, Ind., or St. Louis, Mo.

No. MC 16903 (Sub-No. 40), filed March 5, 1975. Applicant: MOON FREIGHT LINES, INC., 120 West Grimes Lane, Bloomington, Ind. 47401. Applicant's representative: Walter F. Jones, Jr., 601 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Stone, marble, granite and slate,* (1) from points in Warren County, N.Y., to points in Connecticut, Illinois, Indiana, Maryland, Massachusetts, New Jersey, Ohio, Pennsylvania, Rhode Island, Virginia, and the District of Columbia; and (2) from points in Rutland County, Vt., to points in Warren County, N.Y.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Washington, D.C. or New York, N.Y.

No. MC 19311 (Sub-No. 29), filed February 24, 1975. Applicant: CENTRAL TRANSPORT, INC., 34200 Mound Road, Sterling Heights, Mich. 48077. Applicant's representative: Robert D. Schuler, 100 West Long Lake Road, Suite 102, Bloomfield Hills, Mich. 48013. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment) serving the plantsite and facilities of Guardian Industries Corp., located at or near Upper Sandusky, Ohio, as an off route point in connection with applicant's authorized regular route operations.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Detroit, Mich.

No. MC 28060 (Sub-No. 30), filed February 24, 1975. Applicant: WILLERS,

INC., doing business as WILLERS TRUCK SERVICE, 1400 North Cliff Avenue, P.O. Box 944, Sioux Falls, S. Dak. 57101. Applicant's representative: Bruce E. Mitchell, 3379 Peachtree Road, Northeast, Suite 375, Atlanta, Ga. 30326. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs*, from the plantsite and storage facilities utilized by Beatrice Foods at or near Denver, Colo., to points in Nebraska, North Dakota and South Dakota.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Denver, Colo.

No. MC 30844 (Sub-No. 531), filed February 20, 1975. Applicant: KROBLIN REFRIGERATED XPRESS, INC., 2125 Commercial Street, Waterloo, Iowa 50702. Applicant's representative: Paul Rhodes (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meat, meat products, meat by-products and articles distributed by meat packinghouses*, as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the plantsite and storage facilities of or utilized by Farmland Foods, Inc., located at or near Crete, Nebr., to points in Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and West Virginia, restricted to the transportation of traffic originating at the above origin and destined to the above-named destinations.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Omaha, Nebr., or Washington, D.C.

No. MC 30844 (Sub-No. 532), filed February 20, 1975. Applicant: KROBLIN REFRIGERATED XPRESS, INC., 2124 Commercial Street, Waterloo, Iowa 50702. Applicant's representative: Paul Rhodes (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, and meat by-products, and articles distributed by packing houses*, as described in Section A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificate*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), (a) from Wichita, Kans., to points in Alabama, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia, West Virginia, and Wisconsin; and (b) from Dodge City, Kans., to points in Connecticut, Maine, Massachusetts, New Hampshire, New York, and Rhode Island.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Kansas City, Mo. or Washington, D.C.

No. MC 35320 (Sub-No. 146), filed February 20, 1975. Applicant: T. I. M. E.-DC, INC., P.O. Box 2550, Lubbock, Tex. 79408. Applicant's representative: Kenneth G. Thomas (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), serving Santa Claus, Ind. and points in its commercial zone as off-route points in connection with applicant's regular route authority between Louisville, Ky. and Evansville, Ind.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at New York, N.Y.

No. MC 35628 (Sub-No. 371), filed February 24, 1975. Applicant: INTERSTATE MOTOR FREIGHT SYSTEM, 134 Grandville, S.W., Grand Rapids, Mich. 49502. Applicant's representative: Edward Malinzak, 900 Old Kent Building, Grand Rapids, Mich. 49502. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk and those requiring special equipment), serving the site of the Western Electric Company at the junction of New York Highway 422 and Maple Street, Elma Township (Erie County), N.Y., as an off-route point in connection with carrier's regular route operations via Buffalo, N.Y.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Buffalo, N.Y., or Detroit, Mich.

No. MC 50307 (Sub-No. 75), filed February 24, 1975. Applicant: INTERSTATE DRESS CARRIERS, INC., 247 West 35th Street, New York, N.Y. 10001. Applicant's representative: Herbert Burstein, One World Trade Center, New York, N.Y. 10048. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wearing apparel and materials, supplies and equipment* used in the manufacture thereof, between Frederick, Md., on the one hand, and, on the other, points in Hazleton, Bath, Bangor, and Scranton, Pa.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at New York, N.Y.

No. MC 51146 (Sub-No. 417), filed February 24, 1975. Applicant: SCHNEIDER TRANSPORT, INC., 2661 South Broadway, Green Bay, Wis. 54304. Applicant's representative: Neil A. DuJardin, P.O. Box 2298, Green Bay, Wis. 54306. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Such merchandise*, as is dealt in by discount and variety stores (except foodstuffs, furniture, and commodities in bulk); and (2) *Foodstuffs* (except in bulk), and *furniture*, in mixed loads, with the commodities in (1) above, from the facilities of S. S. Kresge Company, located at Savannah, Ga., and points in its Commercial Zone, to the facilities of S. S. Kresge Company, located at points in Minnesota and Wisconsin, restricted to traffic originating at and destined, the described facilities of S. S. Kresge Company.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.

No. MC 51146 (Sub-No. 418), filed February 27, 1975. Applicant: SCHNEIDER TRANSPORT, INC., 2661 South Broadway, Green Bay, Wis. 54304. Applicant's representative: Neil A. DuJardin, P.O. Box 2298, Green Bay, Wis. 54306. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Metal containers and metal container ends*, and (2) *accessories and equipment* used in connection with the manufacture and distribution of metal containers and metal container ends, when moving with metal containers and metal container ends, from the plant and warehouse sites of the National Can Corporation at Archbold and Zanesville, Ohio, to points in the United States (except Alaska and Hawaii), restricted to traffic originating at the plant and warehouse sites of the National Can Corporation.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Chicago, Ill.

No. MC 52460 (Sub-No. 166), filed February 24, 1975. Applicant: ELLEX TRANSPORTATION, INC., 1420 W. 35th Street, P.O. Box 9515, Tulsa, Okla. 74107. Applicant's representative: Steve B. McCommas (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meat, meat products, meat by-products, and articles distributed by meat packinghouses* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the plantsite and storage facilities of or utilized by Farmland Foods, Inc., located at or near Crete, Nebr., to points in Arkansas, Colorado, Illinois, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, New Mexico, Oklahoma, Tennessee, Texas, and Wisconsin.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Kansas City, Mo.

No. MC 56244 (Sub-No. 37), filed February 24, 1975. Applicant: KUHN TRANSPORTATION COMPANY, INC., P.O. Box 98, Rural Delivery No. 2, Gardners, Pa. 17324. Applicant's representative: John M. Musselman, P.O. Box 1146, 410 North Third Street, Harrisburg, Pa. 17108. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such merchandise as is dealt in by retail, wholesale and chain grocery food business houses* (except commodities in bulk

and frozen foods), from Biglerville and Gardners, Pa., and Inwood, W. Va., to points in Illinois, Indiana, Iowa, Kentucky, Michigan, Missouri, Ohio, Pennsylvania, New York, N.Y., Baltimore, Md., and points in that part of West Virginia on and north of U.S. Highway 50.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Harrisburg, Pa., or Washington, D.C.

No. MC 59117 (Sub-No. 47), filed February 24, 1975. Applicant: ELLIOTT TRUCK LINE, INC., 101 East Excelsior, P.O. Box 1, Vinita, Okla. 74301. Applicant's representative: Wilburn L. Williamson, 280 National Foundation Life Bldg., 3535 Northwest 58th, Oklahoma City, Okla. 73112. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid fertilizer and liquid fertilizer materials*, in bulk, in tank vehicles, from the plantsite of Agrico Chemical Company located at or near Verdigris, Okla., to points in Arkansas, Kansas, Louisiana, Missouri and Texas.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Dallas, Tex., or Kansas City, Mo.

No. MC 61445 (Sub-No. 6), filed February 25, 1975. Applicant: CONTRACTORS TRANSPORT CORP., 5800 Farrington Avenue, Alexandria, Va. 22304. Applicant's representative: Daniel B. Johnson, 1123 Munsey Building, 1329 E Street NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Commodities* which because of size or weight require the use of special equipment, handling or rigging, (2) *commodities* which do not require the use of special equipment when such commodities are accessorial to or parts of shipments of commodities in (1) above, and (3) *materials, supplies and equipment* used in the erection, installation, dismantling or removal of commodities in (1) above, between points in Delaware, Maryland, West Virginia, Virginia, the District of Columbia; that part of North Carolina bounded by the North Carolina-Virginia state line, the Atlantic Ocean and Northampton, Halifax, Nash, Edgecombe, Pitt, Beaufort and Hyde Counties, N.C., including points within such counties; points in Kentucky in and east of Lewis, Fleming, Rowan, Morgan, Wolf, Lee, Owsley, Clay, Knox, and Bell Counties, Ky.; and points in Hawkins, Washington, Sullivan and Johnson Counties, Tenn.

NOTE.—Applicant states that the above authority could be joined with the authority held in MC 61445 (Sub-No. 4) at Troutville or Roanoke, Va. to provide a through service on commodities which because of size or weight require the use of special equipment, handling or rigging which are also iron and steel articles, from points in the above territory, to points in North Carolina, South Carolina and Tennessee.

If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 61592 (Sub-No. 341), filed February 24, 1975. Applicant: JENKINS TRUCK LINE, INC., P.O. Box 697, Rural Route 3, Jeffersonville, Ind. 47130. Applicant's representative: E. A. DeVine, P.O. Box 737, 101 First Avenue, Moline, Ill. 61265. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber and lumber products, wood products and particle board* (except commodities in bulk), between the ports of entry on the International Boundary line between the United States and Canada at or near Blaine, Lynden and Sumas, Wash., on the one hand, and, on the other, points in Oregon and Washington.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Seattle, Wash.

No. MC 61592 (Sub-No. 342), filed February 24, 1975. Applicant: JENKINS TRUCK LINE, INC., P.O. Box 697, Rural Route 3, Jeffersonville, Ind. 47130. Applicant's representative: E. A. DeVine, P.O. Box 737, 101 First Avenue, Moline, Ill. 61265. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Agricultural machinery and equipment and component parts*, from points in Crisp, Lee and Dougherty Counties, Ga., to points in the United States (except Alaska and Hawaii); and (2) *component parts and materials* used in the manufacture of agricultural machinery and equipment (except commodities in bulk), from points in the United States (except Alaska and Hawaii), to points in Crisp, Lee, and Dougherty Counties, Ga.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Atlanta, Ga.

No. MC 65802 (Sub-No. 59), filed March 3, 1975. Applicant: LYNDEN TRANSPORT, INC., P.O. Box 433, Lynden, Wash. 98264. Applicant's representative: James T. Johnson, 1610 IBM Bldg., Seattle, Wash. 98101. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities*, between Fairbanks, Alaska and Prudhoe Bay, Alaska: From Fairbanks over Alaska Highway 2 to Livengood, thence over unnumbered highway to Prudhoe Bay, and return over the same route, serving all intermediate points, and serving all off-route points in Alaska located within 100 miles of the unnumbered highway between Livengood and Prudhoe Bay.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Anchorage, Alaska or Seattle, Wash.

No. MC 71459 (Sub-No. 48), filed February 21, 1975. Applicant: O. N. C. FREIGHT SYSTEMS, a corporation, 2800 West Bayshore Road, Palo Alto, Calif. 94303. Applicant's representative: Martin J. Rosen, 140 Montgomery Street, San Francisco, Calif. 94104. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between Questa, N. Mex. and Albuquerque, N. Mex.: from Questa over New Mexico Highway 38 to junction U.S. Highway 64, thence over U.S. Highway 64 to junction New Mexico Highway 68, thence over New Mexico Highway 68 to junction U.S. Highway 84, thence over U.S. Highway 84 to junction U.S. Highway 85, thence over U.S. Highway 85 to Albuquerque, and return over the same route, serving all intermediate points and their commercial zones, and serving the following as off-route points: Espanola, N. Mex.; the facility of the Amalia Lumber Company located eight miles east and north of Costilla, N. Mex.; the facilities of the Chad Land Company located approximately 2½ miles east of the junction of U.S. Highway 64 and New Mexico Highway 38; the facility of the Angel Fire Construction Company located approximately 3 miles east of the junction of U.S. Highway 64 and New Mexico Highway 38; and the facilities of the Angel Fire Ski Resort and Country Club located approximately 4½ miles east of the junction of U.S. Highway 64 and New Mexico Highway 38.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Taos or Albuquerque, N. Mex.

No. MC 71460 (Sub-No. 12), filed February 19, 1975. Applicant: SOUTHERN FORWARDING COMPANY, a corporation, 728 Alston Street, Memphis, Tenn. 38101. Applicant's representative: W. D. Kirkpatrick, P.O. Box 114, Bowling Green, Ky. 42101. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, livestock, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment): Serving the plantsite of The Firestone Tire and Rubber Company, at or near Nashville, Tenn., as an off-route point in connection with applicant's presently authorized routes at Nashville, Tenn.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Nashville, Tenn.

No. MC 72140 (Sub-No. 65), filed February 24, 1975. Applicant: SHIPPERS DISPATCH, INC., 1216 West Sample Street, South Bend, Ind. 46619. Applicant's representative: Richard L. Andrysiak (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, household goods, as defined by the Commission, Classes A and B explosives, commodities in bulk and those requiring special equipment), serving the plant site and warehouse facilities of the Ford Motor Company, Romeo, Mich., as an off-route point in connection with applicant's regular route authority at Detroit, Mich.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Chicago, Ill., or Washington, D.C.

No. MC 72140 (Sub-No. 66), filed February 25, 1975. Applicant: SHIPPERS DISPATCH, INC., 1216 West Sample Street, South Bend, Ind. 46619. Applicant's representative: Richard L. Andrysiak (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the S. S. Kresge Company located at Haggerty and Joy Roads, Canton Township (Wayne County), Mich., as an off-route point in connection with applicant's regular route operations at Detroit, Mich.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Detroit, Mich., or Washington, D.C.

No. MC 82063 (Sub-No. 57), filed March 7, 1975. Applicant: KLIPSCH HAULING CO., a corporation, 119 East Loughborough, St. Louis, Mo. 63111. Applicant's representative: E. Stephen Heisley, Suite 805, 666 11th St. NW., Washington, D.C. 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid fertilizer*, in bulk, in tank vehicles, from Forrest City, Ark., to points in Georgia, Alabama, Missouri, Illinois, Oklahoma, Tennessee, North Carolina, South Carolina, Texas, Louisiana, Florida, Mississippi, Kentucky, and Arkansas.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Memphis, Tenn.

No. MC 85255 (Sub-No. 56), filed March 4, 1975. Applicant: PUGET SOUND TRUCK LINES, INC., P.O. Box 24526, 3720 Airport Way S., Seattle, Wash. 98124. Applicant's representative: Clyde H. MacIver, 1900 Peoples National Bank Building, 1415 Fifth Avenue, Seattle, Wash. 98171. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Metal cans, combination metal and fibreboard cans*, and *can parts:* (1) between points in Multnomah, Marion, Hood River, Polk, Lane, Washington and Clatsop Counties, Oreg., on the one hand, and, on the other, points in that part of Washington in and west of Okanogan, Grant, Franklin and Walla Walla Counties; and (2) between points in Polk County, Oreg., on the one hand, and, on the other, points in Washington.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Portland, Oreg. or Seattle, Wash.

No. MC 95490 (Sub-No. 37), filed February 26, 1975. Applicant: UNION CARTAGE COMPANY, a corporation, 9-A Southwest Cutoff, Worcester, Mass. 01604. Applicant's representative: Leonard A. Jaskiewicz, 1730 M Street NW., Suite 501, Washington, D.C. 20036. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Malt beverages (beer) and related advertising materials;* from South Volney, New York, to points in Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and the District of Columbia; and (2) *materials, supplies and equipment* used in the manufacture, sale and distribution of malt beverages, including returned empty malt beverage containers, from points in Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont and the District of Columbia, to South Volney, N.Y.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Boston, Mass. or Washington, D.C.

No. MC 102401 (Sub-No. 19), filed February 24, 1975. Applicant: TAYLOR HEAVY HAULING, INC., 20601 West Ireland Rd., South Bend, Ind. 46613. Applicant's representative: Walter F. Jones, Jr., 601 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Insulated pipe manhole containers and fittings, attachments and accessories* used in the installation and manufacture thereof, between Niles, Mich., on the one hand, and, on the other, points in Illinois, Indiana, Kentucky, Missouri, Ohio, Tennessee, West Virginia and Wisconsin, restricted to traffic originating at or destined to the plant site of Ric-Wil, Incorporated, located at or near Niles, Mich.; and further restricted to traffic which because of size or weight requires the use of special equipment or special handling.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Cleveland, Ohio, or Washington, D.C.

No. MC 105733 (Sub-No. 51), filed February 21, 1975. Applicant: H. R. RITTER TRUCKING CO., INC., 928 East Hazelwood Avenue, Rahway, N.J. 07065. Applicant's representative: Chester A. Zyblut, 1522 K Street NW., Washington, D.C. 20005. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Solvents and petro-chemicals*, in bulk, in tank vehicles, from Staten Island, N.Y., to points in Louisiana, Alabama, Florida, Texas, Mississippi, Georgia, North Carolina, South Carolina, Kentucky, West Virginia, Pennsylvania, Ohio, Michigan and Illinois, restricted to traffic having a prior movement in foreign commerce.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at New York, N.Y., or Washington, D.C.

No. MC 106674 (Sub-No. 160), filed February 19, 1975. Applicant: SCHILLI MOTOR LINES, INC., P.O. Box 123, Remington, Ind. 47977. Applicant's representative: Jerry L. Johnson (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Foodstuffs*, non-frozen, from the plantsite of the Morgan Packing Company located at or near Austin, Ind., to points in Oklahoma and Texas, restricted against commodities in bulk; and (2) *flour, prepared mixes*, and *bases* for prepared mixes, in containers, from East St. Louis, and Millstadt, Ill., to points in Alabama, Florida, Georgia, Louisiana, Mississippi, and Texas.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill. or Indianapolis, Ind.

No. MC 106674 (Sub-No. 161), filed February 24, 1975. Applicant: SCHILLI MOTOR LINES, INC., P.O. Box 123, Remington, Ind. 47977. Applicant's representative: Jerry L. Johnson (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Building, wall, or insulating boards and accessories*, from the plantsite and facilities of Grefco, Inc., Division of General Refractories at Florence, Ky., to points in Illinois, Indiana, and St. Louis, Mo.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Chicago, Ill., or Indianapolis, Ind.

No. MC 107993 (Sub-No. 36), filed February 26, 1975. Applicant: J. J. WILLIS TRUCKING COMPANY, a corporation, P.O. Box 5328, Terminal Station, Dallas, Tex. 75222. Applicant's representative: J. G. Dail, Jr., 1111 E Street NW., Washington, D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Buses*, self-propelled and non-self-propelled, *and related parts*, from points in Los Angeles County, Calif., to points in Arizona, Arkansas, Colorado, Kansas, Louisiana, Nevada, New Mexico, Texas, and Utah.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Los Angeles, Calif.

No. MC 108382 (Sub-No. 24), filed February 18, 1975. Applicant: SHORT FREIGHT LINES, INC., 459 South River Road, Bay City, Mich. 48706. Applicant's representative: Michael M. Briley, 300 Madison Avenue, Toledo, Ohio 43604. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Automobile parts and accessories and pallets, tubs, bins, racks and trays* used in the transportation of automobile parts and accessories, between the plantsite and facilities of Hancock Industries, Inc., located at or near Roscommon, Mich., on the one hand, and, on the other, Indianapolis and New Castle, Ind.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Toledo, Ohio or Washington, D.C.

No. MC 108449 (Sub-No. 384), filed February 24, 1975. Applicant: INDIANAHEAD TRUCK LINES, INC., 1947 West County Road C, St. Paul, Minn. 55113.

Applicant's representative: W. A. Myllenbeck (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Sugar*, from the plantsite and warehouse facilities of Southern Minnesota Beet Sugar Coop., at or near Renville, Minn., to points in Minnesota, Iowa, Wisconsin and Illinois.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at St. Paul, Minn., or Chicago, Ill.

No. MC 109708 (Sub-No. 62), filed February 28, 1975. Applicant: INDIAN RIVER TRANSPORT CO., doing business as INDIAN RIVER TRANSPORT, INC., P.O. Box 966, Okeechobee, Fla. 33472. Applicant's representative: James E. Wharton, 17th Floor, CNA Bldg., P.O. Box 231, Orlando, Fla. 32802. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (A) *Citrus products*, in bulk, in tank vehicles, from points in Florida, to points in Alabama, Arkansas, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, Minnesota, South Dakota, North Dakota, Nebraska, and California; and (B) *Alcoholic beverages*, in bulk, in tank vehicles, from Miami and Ft. Pierce, Fla., to points in California.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Orlando, Tampa, or Jacksonville, Fla.

No. MC 110567 (Sub-No. 8), filed March 3, 1975. Applicant: SOONER TRANSPORT CORPORATION, a corporation, Third at Keosauqua Way, P.O. Box 855, Des Moines, Iowa 50309. Applicant's representative: E. Check (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid fertilizer and liquid fertilizer materials*, in bulk, in tank vehicles, from the plantsite of Agrico Chemical Company at or near Verdigris, Okla., to points in Arkansas, Kansas, Louisiana, Missouri and Texas.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either Kansas City, Mo. or Dallas, Tex.

No. MC 111375 (Sub-No. 73), filed March 3, 1975. Applicant: PIRKLE REFRIGERATED FREIGHT LINES, INC., P.O. Box 3358, Madison, Wis. 53704. Applicant's representative: Charles E. Dye (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irreguluar routes, transporting: *Dairy products and pizza topping*, from points in California, to points in Illinois, Indiana, Michigan, Minnesota, Nebraska and Wisconsin.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Denver, Colo. or Chicago, Ill.

No. MC 111401 (Sub-No. 444), filed March 3, 1975. Applicant: GROENDYKE TRANSPORT, INC., 2510 Rock Island Blvd., P.O. Box 632, Enid, Okla. 73701. Applicant's representative: Alvin J. Meiklejohn, Jr., Suite 1600 Lincoln Center, 1660 Lincoln Street, Denver, Colo. 80203. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Dried distillers solubles*, in bulk, from Atchison, Kans., to Oklahoma City, Okla.; (2) *soybean meal*, in bulk, from Fredonia, Kans., to Oklahoma City, Okla.; (3) *wheat middlings*, in bulk, from Wichita, Kans., to Oklahoma City, Okla.; and (4) *inedible tallow*, in bulk, in tank vehicles, from Las Cruces, N. Mex., to points in Texas.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Dallas, Tex., or Oklahoma City, Okla.

No. MC 111545 (Sub-No. 212), filed March 3, 1975. Applicant: HOME TRANSPORTATION COMPANY, INC., 1425 Franklin Road, Marietta, Ga. 30062. Applicant's representative: Robert E. Born, P.O. Box 6426, Station A, Marietta, Ga. 30062. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic pipe, and valves, fittings, and couplings*, from the plantsite or shipping facilties of SEDCO Company at or near Auburndale, Fla., to points in Alabama, Connecticut, Georgia, Illinois, Louisiana, Massachusetts, Michigan, Missouri, Nebraska, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas and Virginia.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Tampa or Miami, Fla.

No. MC 111729 (Sub-No. 518), filed February 19, 1975. Applicant: PUROLATOR COURIER CORP., 2 Nevada Drive, Lake Success, N.Y. 11040. Applicant's representative: John M. Delany (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Exposed and processed film and prints, complimentary replacement film, incidental dealer handling supplies, and advertising material* (except motion picture film used primarily for commercial theater and television exhibition), between Dallas, Tex., on the one hand, and, on the other, points in New Mexico; (2) *ophthalmic goods*, from Dallas, Tex., to Enid, Muskogee, Oklahoma City, and Tulsa, Okla.; and (3) *business papers, records, and audit and accounting media* of all kinds, from Dallas, Tex., to Enid, Muskogee, Oklahoma City, and Tulsa, Okla.

NOTE.—Common control may be involved. Applicant holds contract carrier authority in MC 112750 and Subs thereunder, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Dallas, Tex.

No. MC 112304 (Sub-No. 96), filed February 27, 1975. Applicant: ACE DORAN HAULING & RIGGING CO., a corporation, 1601 Blue Rock Street, Cincinnati, Ohio 45223. Applicant's representative: John D. Herbert (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Road building*, earth moving, *construction equipment, cranes and attachments, accessories, and parts of such commodities;* and (2) *parts, materials, and supplies* used in construction of items in (1) above, between the plantsites and warehouse facilities of Grove Manufac- warehouse facilities of Grove Manufac- Pa., on the one hand, and, on the other, points in the United States including Alaska, but excluding Hawaii.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either Washington, D.C. or Philadelphia, Pa.

No. MC 112822 (Sub-No. 368), filed Feb. 28, 1975. Applicant: BRAY LINES INCORPORATED, 1401 N. Little Street, P.O. Box 1191, Cushing, Okla. 74023. Applicant's representative: Charles D. Midkiff (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid fertilizer and fertilizer materials*, in bulk, and in tank vehicles, from the plantsite of Agrico Chemical Company, at or near Verdigris, Okla., to points in Arkansas, Kansas, Louisiana, Missouri, and Texas.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Oklahoma City, Okla.

No. MC 112989 (Sub-No. 41), filed February 20, 1975. Applicant: WEST COAST TRUCK LINES, INC., Route 4, Box 194-R, Eugene, Oreg. 97405. Applicant's representative: Michael D. Crew, 620 Blue Cross Bldg., 100 S. W. Market St., Portland, Oreg. 97201. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Crushers, crusher attachments, crusher parts, crusher attachment parts, and equipment* used in conjunction with crushers, from points in Lane County, Oreg., to points in the United States, including Alaska but excluding Hawaii.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Portland, Oreg.

No. MC 113362 (Sub-No. 282), filed March 3, 1975. Applicant: ELLSWORTH FREIGHT LINES, INC., 310 East Broadway, Eagle Grove, Iowa 50533. Applicant's representative: Raymond W. Ellsworth, P.O. Box 227, Seneca, Pa. 16346. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Candy and confectionery*, from the plant site and storage facilities of Confectionery Consolidaters Inc., located at Linden, N.J., to points in Pennsylvania, Ohio, Michigan, Indiana, Illinois, Iowa, Minnesota, Missouri and Wisconsin.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Washington, D.C., or New York, N.Y.

No. MC 113362 (Sub-No. 283), filed March 3, 1975. Applicant: ELLSWORTH

FREIGHT LINES, INC., 310 East Broadway, Eagle Grove, Iowa 50533. Applicant's representative: Raymond W. Ellsworth, P.O. Box 227, Seneca, Pa. 16346. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Candy and confectionery*, from the plant site and storage facilities of Henry Heide Candy Co., located at New Brunswick, N.J., to points in Ohio, Michigan and Pennsylvania.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Washington, D.C., or New York, N.Y.

No. MC 113410 (Sub-No. 93), filed February 24, 1975. Applicant: DAHLEN TRANSPORT, INC., 1680 Fourth Ave., Newport, Minn. 55055. Applicant's representative: Leonard A. Jaskiewicz, 1730 M Street NW., Washington, D.C. 20036. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Sugar*, in bulk, from Hillsboro and Wahpeton, N. Dak., to points in Iowa, Minnesota and Wisconsin.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Minneapolis or St. Paul, Minn.

No. MC 113828 (Sub-No. 227), filed February 24, 1975. Applicant: O'BOYLE TANK LINES, INCORPORATED, P.O. Box 30006, Washington, D.C. 20014. Applicant's representative: William P. Sullivan, Federal Bar Building West, 1819 H Street NW., Washington, D.C. 20006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquefied petroleum gas*, between the facilities of the Carolina Pipeland Company at or near Tirzah (York County), S.C., on the one hand, and, on the other, points in Virginia, North Carolina and South Carolina.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 116077 (Sub-No. 365), filed February 24, 1975, Applicant: ROBERTSON TANK LINES, INC., 2000 West Loop South, Suite 1800, Houston, Tex. 77027. Applicant's representative: Pat H. Robertson, P.O. Box 1945, 500 West Sixteenth St., Austin, Tex. 78767. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Liquid sulphur trioxide*, in bulk, in tank vehicles, from Houston, Tex., to points in Ohio, Michigan, Illinois, Georgia, New Jersey, Pennsylvania and Washington; and (2) *Salt Cake*, in bulk, from Weeks, La., to points in Florida.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Dallas, Tex., or New Orleans, La.

No. MC 117068 (Sub-No. 42), filed February 24, 1975. Applicant: MIDWEST SPECIALIZED TRANSPORTATION, INC., P.O. Box 6418, North Hwy. 63, Rochester, Minn. 55901. Applicant's representative: Paul F. Sullivan, 711 Washington Bldg., Washington, D.C. 20005. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Materials and supplies* used in the manufacture of hydraulic excavators (except commodities in bulk and commodities which because of size or weight require special equipment), from points in Michigan, Illinois, Indiana, and Wisconsin to Winona, Minn.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Chicago, Ill., or Washington, D.C.

No. MC 117068 (Sub-No. 43), filed February 14,. 1975. Applicant: MIDWEST SPECIALIZED TRANSPORTATION, INC., P.O. Box 6418, North Highway 63, Rochester, Minn: 55901. Applicant's representative: Paul F. Sullivan, 711 Washington Bldg., Washington, D.C. 20005. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (a) *compressors;* (b) *cranes and excavators;* (c) *paving, road construction and maintenance machinery and equipment;* and (d) *rock drills*, from Michigan City, Mich., Lexington and Bowling Green, Ky., Mattoon, Ill. and Claremont, N.H., to points in Minnesota.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill., or Minneapolis, Minn.

No. MC 119176 (Sub-No. 13), filed Feb. 24, 1975. Applicant: THE SQUAW TRANSIT COMPANY, a corporation, P.O. Box 9368, Tulsa, Okla. 74107. Applicant's representative: Clayte Binion, 1108 Continental Life Building, Fort Worth, Tex. 76102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Off-highways vehicles*, and *parts, attachments, materials and accessories*, for off-highway vehicles, between Tulsa, Okla., on the one hand, and, on the other, points in Oklahoma, Colorado, Kansas, Nebraska, Arkansas, Illinois, Indiana, Kentucky, Louisiana, Missouri, New Mexico, Ohio, Texas, Michigan, Nevada, Tennessee, Alabama, Georgia, Florida, Mississippi, and ports of entry on the International Boundary line between the United States and Canada in Montana and North Dakota, restricted to shipments originating at or destined to, the facilities of Unit Rig and Equipment Company, at Tulsa, Okla.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Tulsa or Oklahoma City, Okla.

No. MC 119726 (Sub-No. 53), filed Feb. 27, 1975. Applicant: N.A.B. TRUCKING CO., INC., 3220 Bluff Road, Indianapolis, Ind. 46217. Applicant's representative: H. Frederick Heller (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Medical care products and materials, equipment and supplies*, used in the manufacture or preparation of medical care products, between points in North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Texas, Minnesota, Iowa, Missouri, Arkansas, Louisiana, Wisconsin, Michigan, Illinois, Indiana, Ohio, Pennsylvania, Kentucky, West Virginia, Virginia, Tennessee, North Carolina, South Carolina, Mississippi, Alabama, Georgia, and Florida.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Indianapolis, Ind., Chicago, Ill., or Washington, D.C.

No. MC 119726 (Sub-No. 55), filed February 19, 1975. Applicant: N.A.B. TRUCKING CO., INC., 3220 Bluff Rd., Indianapolis, Ind. 46217. Applicant's representative: H. Frederick Heller (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Household and commercial appliances, parts, accessories, and attachments* for household and commercial appliances, from Ripon, Wis., Searcy, Ark., and Bensenville, Ill., to points in North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Texas, Minnesota, Iowa, Missouri, Arkansas, Louisiana, Wisconsin, Illinois, Michigan, Indiana, Ohio, Kentucky, Pennsylvania, West Virginia, Virginia, Tennessee, North Carolina, South Carolina, Mississippi, Alabama, Georgia, and Florida.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Indianapolis, Ind., or Milwaukee, Wis.

No. MC 119934 (Sub-No. 202), filed February 24, 1975. Applicant: ECOFF TRUCKING, INC., 625 East Broadway, Fortville, Ind. 46040. Applicant's representative: Robert W. Loser II, 1009 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Molasses and blends* in bulk, in tank vehicles, from New Orleans, La., and points within 15 miles thereof, to points in Alabama, Arkansas, Colorado, Idaho, Illinois, Maryland, Michigan, Mississippi, and Wisconsin.

NOTE.—Applicant holds contract carrier authority in MC 128161 and Sub 1, therefore dual operations may be involved. Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Indianapolis, Ind., or New Orleans, La.

No. MC 120737 (Sub-No. 30), filed February 18, 1975. Applicant: STAR DELIVERY & TRANSFER, INC., P.O. Box 39, Canton, Ill. 61520. Applicant's representative: Donald W. Smith, Suite 2465, One Indiana Square, Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Materials, equipment and supplies*, used in the manufacture and distribution of agricultural machinery, implements and parts as described in Appendix XII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, from points in Wisconsin, Michigan, Iowa, Missouri, Mississippi, Alabama, Georgia, Illinois, Tennessee, Indiana, Ohio, Pennsylvania, Virginia, North Carolina, South Carolina, Kentucky, Minnesota, and Nebraska, to the plantsite and warehouse facilities of International Harvester Company at Canton, Ill.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.

No. MC 124692 (Sub-No. 145), filed February 24, 1975. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, Mont. 59801. Applicant's representative: James B. Hovland, 425 Gate City Building, Fargo, N. Dak. 58102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles*, from Duluth, Minn., to points in North Dakota, South Dakota, Nebraska, Idaho, Oregon, Washington, Utah, Montana, Wyoming, Wisconsin, Michigan, Indiana, Ohio, Iowa, Illinois, and Minnesota.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at St. Paul, Minn.

No. MC 125120 (Sub-No. 5), filed February 21, 1975. Applicant: TWIN STATE SAND & GRAVEL CO., INC., Elm Street, West Lebanon, N.H. 03784. Applicant's representative: E. Stephen Heisley, Suite 805, 666 Eleventh St. NW., Washington, D.C. 20001. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Rock salt*, in bulk, between points in New Hampshire and points in Vermont, restricted to the transportation of traffic moving under a continuing contract or contracts with Cargill, Incorporated, of Minneapolis, Minn., and International Salt Company.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Concord, N.H., or Montpelier, Vt.

No. MC 125474 (Sub-No. 46), filed March 3, 1975. Applicant: BULK HAULERS, INC., P.O. Box 3601, Wilmington, N.C. 28401. Applicant's representative: Elliott Bunce, 618 Perpetual Building, Washington D.C. 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Contaminated ethylene glycol*, in bulk, in tank vehicles, between the plantsite of Fiber Industries, Inc., at or near Darlington, S.C., on the one hand, and, on the other, the plantsite of Fiber Industries, Inc., at or near Fiberton, N.C.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 125687 (Sub-No. 15), filed February 26, 1975. Applicant: EASTERN STATES TRANSPORTATION, INC., 1060 Lafayette Street, York, Pa. 17405. Applicant's representative: S. Harrison Kahn, Suite 733 Investment Building, Washington, D.C. 20005. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Malt beverages and related advertising materials*, from South Volney, N.Y., to points in Connecticut, Delaware, the District of Columbia, Maryland, Massachusetts, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; and (2) *materials, supplies, and equipment* used in the manufacture, sale, and distribution of malt beverages, including *returned empty malt beverage containers*, from points in Connecticut, Delaware, the District of Columbia, Maryland, Massachusetts, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont, to South Volney, N.Y.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C.

No. MC 126739 (Sub-No. 10), filed February 21, 1975. Applicant: MAHNEN-SMITH TRUCKING SERVICE, INC., Van Buren, Ind. 46991. Applicant's representative: Robert W. Loser II, 1009 Chamber of Commerce Building, Indianapolis, Ind. 46204. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Popcorn* packaged with cooking oil, and (2) *popcorn*, exempt from economic regulation under Section 203(b)(6) of the Interstate Commerce Act, when transported in mixed shipments with popcorn packaged with cooking oil, from the plant site and warehouse facilities of Weaver Popcorn Company, Inc., located at or near Van Buren, Ind., to points in Connecticut, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, West Virginia, and Wisconsin; (3) *commodities* used or useful in the processing, storage, and packaging of popcorn; and, (4) *popcorn*, exempt from economic regulation under Section 203(b)(6) of the Interstate Commerce Act, when transported in mixed shipments with commodities used or useful in the processing, storage, and packaging of popcorn, between the plant site and warehouse facilities of Weaver Popcorn Company, Inc., located at or near Van Buren, Ind., on the one hand, and, on the other, the plant site and warehouse facilities of Weaver Popcorn Company, Inc., located at or near Ulysses, Kans., and Murray, Ky.; (5) *commodities* used in or useful in the processing, storage, and packaging of popcorn, from points in Michigan, Ohio, Illinois, and St. Louis, Mo., to the plant site and warehouse facilities of Weaver Popcorn Company, Inc., located at or near Van Buren, Ind., under a continuing contract, or contracts, with Weaver Popcorn Company, Inc.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Indianapolis, Ind., or Chicago, Ill.

No. MC 128086 (Sub-No. 5), filed February 28, 1975. Applicant: A & M HAULING, INC., 2024 Trade Street, P.O. Box 1027, Missoula, Mont. 59801. Applicant's representative: W. E. Seliski (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pre cut log buildings* knocked down, *and materials and supplies* used in the construction and erection thereof, from the facilities of Real Log Homes, Inc., located at or near Missoula, Mont., to points in and west of Ohio, Kentucky, Tennessee, Arkansas, and Texas.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Missoula, Billings, or Helena, Mont., or Spokane or Seattle, Wash., or Portland, Oreg.

No. MC 128273 (Sub-No. 167), filed January 6, 1975. Applicant: MIDWESTERN DISTRIBUTION, INC., P.O. Box 189, Fort Scott, Kans. 66701. Applicant's representative: Harry Ross (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Home laundry washers and dryers, refrigerators, freezers, ranges, ovens, range hoods, dish washers, garbage disposers, waste compactors, room air conditioners, cooking surface units and other household appliances and parts and accessories* for household appliances, from Louisville and Appliance Park, Ky., to points in Montana, Wyoming, Colorado, New Mexico, North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Iowa, Missouri, Arkansas, Wisconsin, Illinois, Indiana, Ohio, West Virginia, Pennsylvania, New York, Maryland, and Tennessee.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Louisville, Ky.

No. MC 128273 (Sub-No. 175), filed February 21, 1975. Applicant: MIDWESTERN DISTRIBUTION, INC., P.O. Box 189, Fort Scott, Kans. 66701. Applicant's representative: Harry Ross, 1403 S. Horton St., Fort Scott, Kans. 66701. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Electrical and mechanical apparatus, parts and accessories* for electrical and mechanical apparatus, and *such other merchandise* as is dealt in by hardware distributors and/or industrial supply houses, from the plantsite and storage facilities of W. W. Grainger, Inc., located at Bensonville, Chicago, and Elk Grove Village, Ill., to points in Minnesota, North Dakota, South Dakota, Iowa, Nebraska, Kansas, Missouri, Oklahoma, Arkansas, Louisiana, and Texas.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Washington, D.C., or Chicago, Ill.

No. MC 128273 (Sub-No. 177), filed February 19, 1975. Applicant: MIDWESTERN DISTRIBUTION, INC., P.O. Box 189, Fort Scott, Kans. 66701. Applicant's representative: Harry Ross, 1403 S. Horton St., Fort Scott, Kans. 66701. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and petroleum products, vehicle body sealer, sound deadener compound, and related advertising materials and supplies* when shipped with one or more of the other commodities (except commodities in bulk), from Bradford, Petrolia, Emlenton, Rouseville, Karns City, Farmers Valley, and Reno, Pa.,

Buffalo, N.Y., St. Marys, and Congo, W. Va., to points in New Mexico, Utah, Arizona, California, Nevada, Wyoming, Montana, Idaho, Washington, and Oregon.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Washington, D.C., or San Francisco, Calif.

No. MC 128375 (Sub-No. 130), filed March 3, 1975. Applicant: CRETE CARRIER CORP., P.O. Box 81228, Lincoln, Nebr. 68501. Applicant's representative: Ken Adams (same address as applicant). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Motor vehicle parts, equipment, and accessories*, (1) from Atlanta, Ga., and its Commercial Zone, to points in Florida, North Carolina, South Carolina, Alabama, Mississippi, and Louisiana; (2) from North Kansas City, Mo., and its Commercial Zone, to points in Colorado, Utah, Montana, Nebraska, Iowa, Kansas, and Wyoming; (3) from Dallas, Tex., and its Commercial Zone, to points in New Mexico and Oklahoma; (4) from Columbus, Ohio and its Commercial Zone, to points in Michigan, and Indiana; (5) from Bensenville, Ill., and its Commercial Zone, to points in Iowa, Minnesota, Wisconsin, South Dakota, North Dakota, and Michigan; and (6) from Leetsdale, Pa., and its Commercial Zone, to points in Maryland, New York, New Jersey, Connecticut, Rhode Island, Massachusetts, Vermont, New Hampshire, and Maine, under contract with Maremont Corporation, restricted (a) to movements moving from facilities of the Maremont Corporation, under continuing contract with the Maremont Corporation, (b) to traffic having a prior movement inbound to said origins by contract or private carriage from Maremont plants or facilities located at Ripley, Nashville, Pulaski, or Loudon, Tenn., and (c) to shipments stopped to both partially load and partially unload at the named origins and moving in conjunction with service already authorized to be performed by the applicant.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill., or Lincoln, Nebr.

No. MC 129697 (Sub-No. 4), filed March 3, 1975. Applicant: RAUL TAMAYO A. AND JOSE ALFONSO GRIJALVA, a partnership, Avenue Juarez—544, Ensenada, Baja, Calif., Republic of Mexico. Applicant's representative: Milton W. Flack, 4311 Wilshire Boulevard, Suite 300, Los Angeles, Calif. 90010. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Fiber containers and open top tin cans*, nested, with or without tops, from points in Los Angeles and Orange Counties, Calif., to the port of entry on the International Boundary line between the United States and the Republic of Mexico, at or near San Ysidro, Calif., under contract with Pesquera Peninsular, S.A.; Pesquera Matancitas, S.A.; and Pesquera Del Pacifico, S.A., of Ensenada, Baja, California, Mexico.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at San Diego, Calif.

No. MC 133330 (Sub-No. 7), filed March 5, 1975. Applicant: HALVOR LINES, INC., 510 Lonsdale Building, Duluth, Minn. 55802. Applicant's representative: Andrew R. Clark, 1000 First National Bank Building, Minneapolis, Minn. 55402. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Packaged petroleum products*, from Eveleth, Minn., to points in the United States (except Alaska and Hawaii), under contract with Performance Products, Inc.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Minneapolis, Minn.

No. MC 133523 (Sub-No. 5), filed February 24, 1975. Applicant: EUGENE STONE TRUCKING, INC., 11449 Valley View Road, Northfield, Ohio 44067. Applicant's representative: Richard H. Brandon, 220 West Bridge Street, P.O. Box 97, Dublin, Ohio 43017. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), in shipper owned trailers, between points in Connecticut, Delaware, the District of Columbia, Maryland, Massachusetts, Maine, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia, under a continuing contract or contracts with The Standard Oil Company of Ohio and its subsidiaries.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Columbus, Ohio or Washington, D.C.

No. MC 133666 (Sub-No. 12), filed February 27, 1975. Applicant: JACOBSON TRANSPORT, INC., 1112 Second Avenue South, Wheaton, Minn. 56296. Applicant's representative: Alvin J. Meiklejohn, Jr., Suite 1600 Lincoln Center, 1660 Lincoln Street, Denver, Colo. 80203. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Molasses*, in bulk, between points in North Dakota, Minnesota, South Dakota, Iowa, Wisconsin, Illinois, Nebraska, Kansas, and Missouri.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C., or Chicago, Ill.

No. MC 133689 (Sub-No. 58), filed February 27, 1975. Applicant: OVERLAND EXPRESS, INC., 651 First St. SW., New Brighton, Minn. 55112. Applicant's representative: Robert P. Sack, P.O. Box 6010, West St. Paul, Minn. 55118. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen potatoes, and potato products*, from Minneapolis and St. Paul, Minn., to points in North Carolina and South Carolina, restricted to shipment originating at and destined to, the above origins and destinations.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Minneapolis, Minn.

No. MC 134405 (Sub-No. 26), filed February 19, 1975. Applicant: BACON TRANSPORT COMPANY, a corporation, P.O. Box 1134, Ardmore, Okla. 73401. Applicant's representative: Wilburn L. Williamson, 280 National Foundation Life Building, 3535 NW. 58th, Oklahoma City, Okla. 73112. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid fertilizer and liquid fertilizer materials* in bulk, in tank vehicles, from the plantsite of Agrico Chemical Company at or near Verdigris, Okla., to points in Arkansas, Kansas, Louisiana, Missouri, and Texas.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Dallas, Tex., or Kansas City, Mo.

No. MC 134884 (Sub-No. 8) (Correction), filed January 31, 1975, published in the FEDERAL REGISTER issue of February 27, 1975, and republished as corrected this issue. Applicant: FARWEST FURNITURE TRANSPORT, INC., 6840 112th Ave. SE., Renton, Wash. 98055. Applicant's representative: Bruce E. Mitchell, Suite 375, 3379 Peachtree Rd. NE., Atlanta, Ga. 30326. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *New furniture* between points in Washington, Oregon, and Idaho, on the one hand, and, on the other, points in Colorado, New Mexico and Arizona; and (2) *new fixtures*, uncrated, between points in Washington, Oregon and Idaho, on the one hand, and, on the other, points in Colorado, New Mexico and Arizona.

NOTE.—The purpose of this republication is to correct the commodity description in part (2) of the application. If a hearing is deemed necessary, the applicant requests it be held at Seattle, Wash.

No. MC 134922 (Sub-No. 114), filed February 21, 1975. Applicant: B. J. McADAMS, INC., Rt. 6, Box 15, North Little Rock, Ark. 72118. Applicant's representative: Don Garrison (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Rubber and rubber products* (except commodities in bulk and those which because of size or weight require the use of special equipment), (1) from Oakland, Calif., to points in Atlanta, Ga., Columbus, Ohio, Dallas, Tex., and Flemington, N.J.; (2) from Flemington, N.J., to points in Atlanta, Ga., Columbus, Ohio, Wooster, Ohio, Dallas Tex., and points in California; (3) from Muscatine, Iowa, to points in Atlanta, Ga., Columbus, Ohio, Dallas, Tex., Flemington, N.J., and points in California; (4) from Findlay, Ohio, to points in Atlanta, Ga., Dallas, Tex., Flemington, N.J., and points in California; (5) from Borger, Tex., to

points in Flemington, N.J., Columbus, Ohio, and points in California; and (6) from Wooster, Ohio, and Columbus, Ohio, to points in California, restricted against the transportation of commodities in bulk and those which because of size or weight require the use of special equipment.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either San Francisco, Calif., or Little Rock, Ark.

No. MC 135423 (Sub-No. 4), filed February 24, 1975. Applicant: FRANKLIN GORDON, R.R. 1, Manilla, Ind. 46250. Applicant's representative: Robert W. Loser II, 1009 Chamber of Commerce Building, Indianapolis, Ind. 46004. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Animal and poultry feed and feed ingredients* (except liquid bulk shipments of lards, fats, tallows, oils, and greases, in tank vehicles), from Manistee and St. Louis, Mich., Minneapolis, Minn., Cleveland, Slinger, Janesville, and Cochrane, Wis., Des Moines, Buffalo, Marion, Cedar Rapids, Davenport and Muscatine, Iowa, Mobile, Ala., Omaha, Nebr., St. Louis, Marshall and Montgomery City, Mo., and points in Illinois on and north of Interstate Highway 64, to Rushville, Ind., restricted to a transportation service to be performed under a continuing contract, or contracts with Cargill, Inc., Nutrena Feed Division, of Minneapolis, Minn.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Indianapolis, Ind., or Columbus, Ohio.

No. MC 136053 (Sub-No. 3), filed February 25, 1975. Applicant: LOUIS CLAIRBORNE HUNT, doing business as L. C. HUNT AGENCY, 1616 Kent Street, Durham, N.C. 27707. Applicant's representative: Louis C. Hunt (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pharmaceutical materials, human blood, and human organs*, from Raleigh and Durham, N.C., Airport, to Chapel Hill, N.C., on traffic having an immediate prior out-of-state movement by air.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Raleigh, or Charlotte, N.C.

No. MC 136201 (Sub-No. 4), filed February 24, 1975. Applicant: ROCKY MOUNTAIN FEED INGREDIENTS SERVICE, INC., 1524 Lockwood Rd., Billings, Mont. 59101. Applicant's representative: Hugh Sweeney, P.O. Box 1321, Billings, Mont. 59103. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid animal feed*, in bulk, in tank vehicles, from Billings, Mont., to points in South Dakota.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Billings, Mont.

No. MC 136301 (Sub-No. 1), filed February 24, 1975. Applicant: MER-LOU TRANSPORTATION, INC., P.O. Box 333, Millsboro, Del. 19966. Applicant's representative: John P. Bond, 2766 Douglas Road, Miami, Fla. 33133. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Pickle products*, in containers, *and material* used in the processing and manufacture of pickle products and related items, (a) between Millsboro, Del., on the one hand, and, on the other, Greenville, Miss.; (b) between Bridgeport, Imlay City and Memphis, Mich., on the one hand, and, on the other, Greenville, Miss.; and (2) *supplies and material* used in the process and manufacture of pickle products and related items, between Bridgeport, Imlay City and Memphis, Mich., on the one hand, and, on the other, Millsboro, Del., under a continuing contract or contracts with Vlasic Foods, Inc.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C., or Detroit, Mich.

No. MC 136318 (Sub-No. 31), filed February 19, 1975, Applicant: COYOTE TRUCK LINE, INC., P.O. Box 5627, High Point, N.C. 27262. Applicant's representative: David R. Parker, P.O. Box 82028, Lincoln, Nebr. 68501. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *New furniture*, from Los Angeles, Calif., to points in the United States (except Alaska and Hawaii); and (2) *returned, refused and rejected new furniture*, from points in the United States (except Alaska and Hawaii), to Los Angeles, Calif., under contract with Mission Furniture Manufacturing Co., restricted to traffic originating at or destined to, the facilities utilized by Mission Furniture Manufacturing Co., and further restricted to a transportation service to be performed under a continuing contract or contracts with Mission Furniture Manufacturing Co.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Los Angeles, Calif.

No. MC 136343 (Sub-No. 41), filed February 21, 1975, Applicant: MILTON TRANSPORTATION, INC., P.O. Box 355, Milton, Pa. 17847. Applicant's representative: George A. Olsen, 69 Tonnele Avenue, Jersey City, N.J. 07306. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Materials and supplies* used in the agricultural water treatment, food processing, wholesale grocery and institutional supply industry, when moving in mixed shipments with salt, and (2) *mineral mixtures*, in containers, when moving in mixed shipments with salt, from Rittman, Ohio, to points in Pennsylvania on and east of U.S. Highway 220 and points in New Jersey, restricted in (1) above against the transportation of materials and supplies in excess of 25 percent of the total weight on which charges are assessed.

NOTE.—Common control and dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C. or New York, N.Y.

No. MC 136378 (Sub-No. 8), filed March 3, 1975. Applicant: R & L TRUCKING CO., INC., 105 Rocket Avenue, Opelika, Ala. 36801. Applicant's representative: Robert E. Tate, P.O. Box 517, Evergreen, Ala. 36401. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Syrup, alcohol, vinegar, barbeque sauce, mineral oil, flavoring, turpentine, and cooking oils* (except in bulk), from Trussville, and Opelika, Ala., to points in Georgia, Florida, Tennessee, Mississippi, South Carolina, Louisiana, Arkansas, Texas, North Carolina and Kentucky, under contract with Webb-pak, Inc.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Montgomery, Ala., or Atlanta, Ga.

No. MC 136407 (Sub-No. 8), filed February 27, 1975. Applicant: COORS TRANSPORTATION COMPANY, a corporation, 5101 York Street, Denver, Colo. 80216. Applicant's representative: Leslie R. Kehl, Suite 1600 Lincoln Center Bldg., 1660 Lincoln Street, Denver, Colo. 80203. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Cleaning and bleaching compounds, animal litter, and liquid cooking oils*, from the plant-site and facilities of The Clorox Company located at or near Kansas City, Mo., to points in Colorado, under a continuing contract or contracts with The Clorox Company.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Denver, Colo.

No. MC 136602 (Sub-No. 6), filed March 6, 1975. Applicant: ARIZONA WESTERN TRANSPORT, INC., P.O. Box F (Guadalupe Rd.), Chandler, Ariz. 85224. Applicant's representative: A. Michael Bernstein, 1327 United Bank Bldg., Phoenix, Ariz. 85012. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fertilizer*, in bulk, and *ammonium nitrate*, in bulk, from points in Arizona, to points in San Diego, Riverside and Imperial Counties, Calif.

NOTE.—Applicant holds contract carrier authority in MC 136983, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at either Phoenix, Ariz., or San Francisco, Calif.

No. MC 136711 (Sub-No. 18), filed March 3, 1975. Applicant: DAVID G. McCORKLE, doing business as McCORKLE TRUCK LINE, 2780 S. High, P.O. Box 95181, Oklahoma City, Okla. 73109. Applicant's representative: G. Timothy Armstrong, 280 National Foundation Life Bldg., 3535 N.W. 58th Street, Oklahoma City, Okla. 73112. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Coal*, (a) from points in Arkansas, to points in Alabama, Kansas, Kentucky, Louisiana, Missouri, Oklahoma, Tennessee and Texas; (b) from points in Kansas, to

points in Arkansas, Missouri, and Oklahoma; (c) between points in Kansas, restricted to traffic having a prior or subsequent movement by rail or water; (d) from points in Missouri, to points in Arkansas, Kansas and Oklahoma; and (e) between points in Missouri, restricted to traffic having a prior or subsequent movement by rail or water.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Oklahoma City, Okla.

No. MC 138104 (Sub-No. 22), filed March 5, 1975. Applicant: MOORE TRANSPORTATION CO., INC., 3509 N. Grove Street, Fort Worth, Tex. 76106. Applicant's representative: J. Michael Alexander, 136 Wynnewood Professional Building, Dallas, Tex. 75224. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles, aluminum articles, iron and steel tanks, aluminium tanks*, and *parts, attachments and accessories* for iron and steel tanks and aluminum tanks, between points in Liberty County, Tex., on the one hand, and, on the other, points in Louisiana, Arkansas, Oklahoma, New Mexico, Kansas, Missouri, and Mississippi.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Birmingham, Ala. or Washington, D.C.

No. MC 138104 (Sub-No. 23), filed March 3, 1975. Applicant: MOORE TRANSPORTATION CO., INC., 3509 N. Grove St., Fort Worth, Tex. 76106. Applicant's representative: Bernard H. English, 6270 Firth Rd., Fort Worth, Tex. 76116. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Ferro. manganese, and Silicon manganese*, in bulk, in dump vehicles, from Houston, Tex., to the plantsite and storage facilities of Chaparral Steel Company, located near Midlothian, Tex.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Dallas, or Forth Worth, Tex.

No. MC 138225 (Sub-No. 3), filed February 28, 1975. Applicant: HEDRICK ASSOCIATES, INC., Rural Route 2, Box 10A2, Douglas Road, Far Hills, N.J. 07931. Applicant's representative: William P. Jackson, Jr., 919 Eighteenth Street NW., Washington, D.C. 20006. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Swimming pool liners, inflatable pool covers and water mattresses*, from the facilities of R. L. Kuss and Co., in Findlay, Ohio, to points in Pennsylvania, New Jersey, and New York; and (2) *vinyl sheeting*, from points in Pennsylvania, New Jersey, and New York, to the facilities of R. L. Kuss and Co., Inc., in Findlay, Ohio, restricted to the shipments originating at or destined to the facilities of R. L. Kuss and Co., Inc. and further restricted to the transportation of shipments under a continuing contract or contracts with R. L. Kuss and Co., Inc.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Columbus, Ohio, or Washington, D.C.

No. MC 138438 (Sub-No. 13) (Correction), filed February 3, 1975, published in the FEDERAL REGISTER issue of March 6, 1975, and republished, as corrected, this issue. Applicant: D. M. BOWMAN, INC., 15 East Oak Ridge Drive, Route 9, Box 26, Hagerstown, Md. 21740. Applicant's representative: Charles E. Creager, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Brick*, from Richlands, Glasgow, Marion, Richmond, Somerset and Salem, Va., to points in Pennsylvania.

NOTE.—The purpose of this republication is to indicate the correct docket number assigned to this proceeding as MC 138438 (Sub-No. 13) in lieu of MC 138438 (Sub-No. 12) as previously published. Applicant holds contract carrier authority in MC 117613, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 138471 (Sub-No. 4), filed January 13, 1975. Applicant: DANIEL J. LEONARD, doing business as LEONARD TRUCKING, 1878 Delameter Road, Castle Rock, Wash. 98611. Applicant's representative: David C. White, 2400 S.W. Fourth Avenue, Portland, Oreg. 97201. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Malt beverages*, from Azusa, Los Angeles, San Francisco, and Van Nuys, Calif., to Aberdeen, Bingen, Olympia, Raymond, and Vancouver, Wash.; (2) *wine*, from Elk Grove, Calif., to Olympia, Wash.; and (3) *wooden shakes and shingles*, from points in Washington on and west of U.S. Highway 97, to points in California, restricted to traffic originating at the named origin and destined to the named destinations.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Portland, Oreg.

No. MC 138875 (Sub-No. 25), filed February 24, 1975. Applicant: SHOEMAKER TRUCKING CO., a corporation, 11900 Franklin Rd., Boise, Idaho 83705. Applicant's representative: Frank L. Sigloh, P.O. Box 7651, Boise, Idaho 83705. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Diatomaceous earth;* and (2) *materials and supplies*, used in the mining, processing, and distribution of diatomaceous earth, between the plantsite of West and Southern Mining and Minerals, Inc., near Westfall (Malheur County), Oreg., on the one hand, and, on the other, points in Minnesota, Iowa, Missouri, Arkansas, Louisiana, Texas, Oklahoma, Kansas, Nebraska, South Dakota, North Dakota, Montana, Wyoming, Colorado, New Mexico, Arizona, Utah, Idaho, Washington, Oregon, California, and Nevada, restricted to traffic originating at named origin and destined to named destinations.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Boise or Weiser, Idaho.

No. MC 138941 (Sub-No. 7), filed February 28, 1975. Applicant: COUNTRY WIDE TRUCK SERVICE, INC., 1110 South Reservoir St., Pomona, Calif. 91766. Applicant's representative: K. Edward Wolcott, 1600 First Federal Bldg., Atlanta, Ga. 30303. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Plastic articles* (except in bulk), from Wayne, Ontario and Monroe Counties, N.Y., to Chicago, Ill., under a continuing contract with Mobile Chemical, Plastic Division.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at either Buffalo, N.Y., or Washington, D.C.

No. MC 139123 (Sub-No. 5), filed February 25, 1975. Applicant: GLOUCESTER DISPATCH, INC., Kelly Road, Box 127, Plaistow, N.H. 03865. Applicant's representative: Ignatius C. Goode (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods*, in boxes, cases, cartons (except in bulk), from the plantsite and warehouses of the Kitchens of Sara Lee, located at or near Chicago and Deerfield, Ill., to points in Connecticut, Maine, Massachusetts, New Jersey, New York, Rhode Island, and Vermont.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.; Boston, Mass.; or Concord, N.H.

No. MC 139380 (Sub-No. 1), filed March 6, 1975. Applicant: STIDHAM TRUCKING INC., 645 West Lennox Street, P.O. Box 308, Yreka, Calif. 96097. Applicant's representative: John Paul Fischer, 140 Montgomery Street, San Francisco, Calif. 94104. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, forest products, and building materials*, from points in Humboldt, Trinity, and Siskiyou Counties, Calif., to points in Jackson, and Josephine Counties, Oreg.

NOTE.—Applicant holds contract carrier authority in MC 135655, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at either Yreka, or San Francisco, Calif.

No. MC 139495 (Sub-No. 40), filed February 28, 1975. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th Street, P.O. Box 1358, Liberal, Kans. 67901. Applicant's representative: Herbert Alan Dubin, 1819 H Street NW., Washington, D.C. 20006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such merchandise, materials, equipment, and supplies* as are dealt in by manufacturers and distributors of home products, from the plantsite and storage facilities of Stanley Home Products, Inc., located at or near Easthampton, and Westfield, Mass., to points in Ohio, Michigan, Illinois, Iowa, Missouri, Colorado, Texas, California, and Washington.

NOTE.—Applicant holds motor. contract carrier authority in No. MC 133106 and subs thereunder, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 139713 (Sub-No. 2), filed February 18, 1975. Applicant: DONALD M. NASS, doing business as 136 High Street, Clinton, Wis. 53014. Applicant's representative: Nancy J. Johnson, 4506 Regent Street, Madison, Wis. 53705. Authority sought to operate as a *common carrier*, by motor vehicle over irregular routes, transporting: (1) *Malt beverages, advertising materials and promotional items* when shipped therewith, from Milwaukee, Wis., to Freeport and Rockford, Ill.; and (2) *return of containers and rejected shipments*, from the above named destination points, to Milwaukee, Wis.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Milwaukee, Wis. or Chicago, Ill.

No. MC 140425 (Sub-No. 1), filed March 3, 1975. Applicant: I.C.J. TRUCKING CO., a corporation, 1701 W. Fourth Plain Road, Vancouver, Wash. 98660. Applicant's representative: Lawrence V. Smart, Jr., 419 Northwest 23d Avenue, Portland, Oreg. 97210. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Scrap metal*, in dump vehicles, between points in Oregon and Washington.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Portland, Oreg.

No MC 140428 (Sub-No. 1), filed February 24, 1975. Applicant: KEITH GREEN, doing business as GREEN's TRUCKING, Highway 2 North, Williston, N. Dak. 58801. Applicant's representative: Fred E. Whisenand, 113 East Broadway, P.O. Box 1307, Williston, N. Dak. 58801. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Meats*, fresh and frozen, including scrap bones and scrap meats, refuse and hides and all products relating thereto, from the plant site of Williston Packing Company, Inc., at or near Williston, N. Dak., to Belgrade, St. Paul and Minneapolis, Minn. and points in Stearns, Pope, Kanlyohi, Washington, Dakota, Ramsey, Carver and Hennepin Counties, Minn., under a continuing contract or contracts with Williston Packing Company, Inc.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Williston, N. Dak.

No. MC 140473 (Sub-No. 2), filed February 24, 1975. Applicant: BARIBAULT OIL CO., INC., doing business as LYMAN BULK TRANSPORT, 610 Main Street, Watertown, Conn. 06779. Applicant's representative: John F. Phelan, 111 West Main Street, Waterbury, Conn. 06702. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Crushed stone, sand and gravel*, from Woodbury, Conn., to Somers, N.Y., under a continuing contract or contracts with McCleary Bros., Inc.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Waterbury or Hartford, Conn.

No. MC 140477 (Sub-No. 2), filed February 24, 1975. Applicant: SEABROUCK TRANSPORT, INC., P.O. Box 329, Crookston, Minn. 56716. Applicant's representative: James B. Hovland, 425 Gate City Building, Fargo, N. Dak. 58102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages and related advertising material and articles*, dealt in by wholesale malt beverage distributors, from Milwaukee, Wis.; Minneapolis and Shakopee, Minn.; and Peoria, Ill., to Minot and Williston, N. Dak., under contract with Morelli Distributing, Inc., at Minot, N. Dak., and All Star Distributing, at Williston, N. Dak.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Fargo, N. Dak., or St. Paul, Minn.

No. MC 140479 (Sub-No. 2), filed March 3, 1975. Applicant: JERRY L. FERRIL, doing business as LUMBER EXPRESS, Route 3, Box 422, Excelsior Springs, Mo. 64024. Applicant's representative: Donald J. Quinn, Suite 900, 1012 Baltimore, Kansas City, Mo. 64105. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Lumber and building materials*, between the site of Wickes Lumber Company at or near Excelsior Springs, Mo., on the one hand, and, on the other, Ankeny, Iowa; Omaha, Nebr.; points in Kansas on and east of U.S. Highway 81; and points in Iowa on and south of Interstate Highway 80, under a continuing contract or contracts with Wickes Lumber Company.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Kansas City, Mo.

No. MC 140499, filed December 13, 1974. Applicant: RANDOLPH COUNTY HAULING CO., INC., 819 Opdyke, Chester, Ill. 62233. Applicant's representative: John R. Bauer, 424 Lebanon Avenue, Belleville, Ill. 62222. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Concrete aggregates*, and *blacktop*, in dump vehicles, *sand, coal, farm products*, and *gravel and rock*, from the plantsite of the Perry County Quarry at or near Perryville, Mo., to points in Cape Girardeau, Madison, Perry, St. Genevieve, and St. Francis Counties, Mo., and points in Madison, St. Clair, Washington, Randolph, Perry and Jackson Counties, Ill.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either St. Louis, Mo. or Chicago, Ill.

No. MC 140538 (Sub-No. 2), filed February 21, 1975. Applicant: LESLIE NORMAN FRED, doing business as NORMAN FRED, DeSoto, Ill. 62924. Applicant's representative: John G. Gilbert, P.O. Box 1058, 231 West Main Street, Carbondale, Ill. 62901. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Milk and dairy products*, including cream, ice cream mix, cottage cheese, butter, ice creams, milk powder and milk substitutes, (1) from Carbondale, Ill., to points in St. Louis County, Mo.; and (2) from Carbondale, Ill., to points in Cape Girardeau, Scott, Mississippi and Stoddard Counties, Mo., and return, under a continuing contract or contracts with Prairie Farms Dairy, Inc.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Springfield, Ill.

No. MC 140550, filed January 13, 1975. Applicant: LEO VEST, doing business as L & F WRECKER SERVICE, R.F.D. 1, Buffalo, Mo. 65622. Applicant's representative: Turner White, 1736 East Sunshine, Springfield, Mo. 65804. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Wrecked and disabled motor vehicles*, from points in the United States, to Buffalo, Springfield and Mt. Vernon, Mo., restricted to a service by wrecker equipment only.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at either Kansas City or St. Louis, Mo.

No. MC 140568 (Sub-No. 1), filed March 5, 1975. Applicant: DELIVERIES UNLIMITED, INC., 125 Magazine Street, Boston, Mass. 02119. Applicant's representative: S. Harrison Kahn, Suite 733, Investment Bldg., Washington, D.C. 20005. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Computer parts*, between Nashua and Manchester, N.H., and Portland, Maine, on the one hand, and, on the other, Lowell, Lawrence and Framingham, Mass., under contract with Honeywell Information Systems, Inc., at Boston, Mass.

NOTE.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Boston, Mass.

No. MC 140616 (Sub-No. 2), filed February 14, 1975. Applicant: GEORGE WALDORFF, doing business as WALDORFF & SON, Rt. 1, Box 24, Altha, Fla. 32421. Applicant's representative: Sol H. Proctor, 1107 Blackstone Building, Jacksonville, Fla. 32202. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Fertilizer*, from points in Henry County, Ala.; Bainbridge, Ga.; and Yazoo City and Pascagoula, Miss., to Altha, Fla.; and (2) *slag* from Birmingham, Ala., to Altha, Fla., under a continuing contract or contracts with Altha Farmers Coop.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Tallahassee or Jacksonville, Fla.

No. MC 140637 (Correction), filed January 27, 1975 published in the FEDERAL REGISTER issue of March 6, 1975, and republished as corrected this issue. Applicant: BOB & RAY'S EXPRESS, INC., 3673 Hillside Ave., Cincinnati, Ohio 45204. Applicant's representative: Jack B. Josselson, 700 Atlas Bank Bldg., Cincinnati, Ohio 45202. Authority sought to operate as a *contract carrier*, by motor

vehicle, over irregular routes, transporting: (1) *New uncrated furniture and household furnishings and applicances,* from points in the Cincinnati, Ohio commercial zone to points in Indiana and Kentucky; and (2) *returned shipments on return,* under a continuing contract with McAlpin Company.

NOTE.—The purpose of this republication is to add the shipper's name, which was previously omitted. If a hearing is deemed necessary, the applicant requests it be held at Cincinnati, Ohio.

No. MC 140660 (Sub-No. 2), filed March 3, 1975. Applicant: DONALD W. COLE, Route No. 1, Winthrop, Minn. 55396. Applicant's representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, Nebr. 68501. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: (1) *Liquid fertilizer solutions and liquid feeds,* in bulk, in tank vehicles, from the plantsite and facilities of NaChurs Plant Food Co., located at or near Red Oak, Iowa, to points in Wisconsin, Illinois, Missouri, Minnesota, Kansas, Nebraska, South Dakota, North Dakota, Colorado, Wyoming, and Montana; and; (2) *ingredients,* utilized in the manufacture and production of the commodities specified in (1) above, in bulk, from points in Wisconsin, Illinois, Missouri, Minnesota, Kansas, Nebraska, South Dakota, North Dakota, Colorado, Wyoming, and Montana, to the plantsite and facilities of NaChurs Plant Food Co., located at or near Red Oak, Iowa, restricted in (1) and (2) above, to traffic originating at the named origins and destined to the named destinations.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Omaha, Nebr.

No. MC 140673, filed February 20, 1975. Applicant: OVERLAND CO., INC., Highway 20, Route 1, Lawrenceville, Ga. 30245. Applicant's representative: K. Edward Wolcott, 1600 First Federal Building, Atlanta, Ga. 30303. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in by retail discount stores (except foodstuffs), between the distribution center and warehouse facilities of the Zayre Corp. at Forest Park, Ga. and the retail stores of the Zayre Corp. at or near Birmingham, Bessemer and Hoover, Ala., Charlotte, Kannapolis, Winston-Salem, and Greensboro, N.C. and Memphis, Tenn. in nonradial movements, under a continuing contract or contracts with Zayre Corp.

NOTE.—Applicant holds common carrier authority in MC-133221 and Subs thereunder, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at either Boston, Mass. or Washington, D.C.

No. MC 140693, filed February 26, 1975. Applicant: BEER TRANSPORTATION COMPANY, a corporation, 1120 Germantown Avenue, Philadelphia, Pa. 19123. Applicant's representative: Leonard A. Jaskiewicz, 1730 M Street NW., Suite 501, Washington, D.C. 20036. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: (1) *Malt beverages (beer), and related advertising materials,* from South Volney, N.Y., to points in Delaware, Maryland, New Jersey, Pennsylvania, Virginia and District of Columbia; (2) *materials, supplies and equipment* used in the manufacture, sale and distribution of malt beverages, including returned empty malt beverage containers, from points in Delaware, Maryland, New Jersey, Pennsylvania, Virginia and District of Columbia, to South Volney, N.Y.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either Philadelphia, Pa. or Washington, D.C.

No. MC 140698, filed February 14, 1975. Applicant: MUCCI'S GARAGE, INC., 907 North Avenue, Syracuse, N.Y. 13206. Applicant's representative: Herbert M. Canter, 315 Seitz Building, 201 East Jefferson Street, Syracuse, N.Y. 13202. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Wrecked, disabled, inoperative, repossessed, or abandoned vehicles and replacement vehicles,* for wrecked, disabled, or inoperative vehicles, between points in Cayuga and Onondaga Counties, N.Y., on the one hand, and, on the other, points in Ohio, Pennsylvania, New Jersey, Vermont, Massachusetts, and Connecticut.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Syracuse, N.Y.

No. MC 140699, filed February 21, 1975. Applicant: JOHN H. CANTRELL, doing business as HOWARD CANTRELL WRECKER SERVICE, 1910 Dickerson Road, Nashville, Tenn. 37207. Applicant's representative: A. O. Buck, 618 Hamilton Bank Building, Nashville, Tenn. 37207. Authority sought to operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *Wrecked, disabled, stolen, repossessed and abandoned vehicles, and replacement vehicles therefor,* by use of wrecker equipment, between those points in Tennessee west of U.S. Highway 27, and east of the western traversal of the Tennessee River, on the one hand, and, on the other, points in the United States (except Alaska and Hawaii).

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Nashville, Tenn.

No. MC 140711, filed February 19, 1975. Applicant: EXPRESS LIMITED, INC., 1213 St. Louis Street, Louisville, Ky. 40201. Applicant's representative: Rudy Yessin, 314 Wilkinson Street, Frankfort, Ky. 40601. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: (1) *Malt beverages, non-alcoholic beverages,* and *related advertising materials,* from Evansville, Ind. and Indianapolis, Ind., to Louisville, Ky.; and (2) *rejected shipments, empty beer cases, empty shells, pallets, and empty containers,* from Louisville, Ky., to Evansville, Ind., under a continuing contract or contracts with G. Heileman Brewing Co., Inc.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Louisville or Frankfort, Ky.

No. MC 140712, filed February 20, 1975. Applicant: ROYCE WRIGHT, doing business as R. J. WRIGHT & SONS, Rural Route 3, Box 259, Portland, Ind. 47371. Applicant's representative: Robert W. Loser II, 1009 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: (1) *Fertilizer,* from the plant site and storage facilities of the Occidental Chemical Company, located at or near New Bremen, Ohio, to Bryant, Fairmount, and Lynn, Ind.; and (2) *fertilizer filler,* from Jay County, Ind., to the plant and storage facilities of the Occidental Chemical Company, located at or near New Bremen, Ohio, the above authority is restricted to operations performed under a continuing contract or contracts with the Occidental Chemical Company.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Indianapolis, Ind.

No. MC 140717, filed February 19, 1975. Applicant: JULIAN MARTIN, INC., 1490 S. 14th Street, Batesville, Ark. 72501. Applicant's representative: Theodore Polydoroff, 1250 Connecticut Ave. NW., Suite 600, Washington, D.C. 20036. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Meat, meat products, meat by-products, and articles distributed by meat packinghouses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk, in tank vehicles), from points in Colorado, Illinois, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nebraska, Oklahoma, Tennessee, Texas and Wisconsin to points in Memphis, Tenn., and Greenville, Miss., under a continuing contract with Distribuco, Incorporated.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Memphis, Tenn.

No. MC 140726, filed February 27, 1975. Applicant: EFC TRANSPORTATION COMPANY, INC., 6804 East 48th Avenue, Denver, Colo. 80216. Applicant's representative: Thomas J. Burke, Jr., 1600 Lincoln Center Building, 1660 Lincoln Street, Denver, Colo. 80203. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Abrasives and grinding wheel parts,* from Kingman, Ariz., Cave-in-Rock and Des Plaines, Ill., Fall River, Millbury, North Grafton, Worcester, and Shrewsbury, Mass., Belleville, Bound Brook, Camden, Keasbey, South Brunswick, and South Hackensack, N.J., Buffalo, Niagara Falls, North Tonawanda, Schenectady and Tonawanda, N.Y., Cleveland and Washington Courthouse, Ohio, Bowmanstown, Pittsburgh, and Philadelphia, Pa., to Marysville, Wash., under a continuing contract or contracts with Pacific Grinding Wheel Co., Inc., at Marysville, Wash.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Denver, Colo., or Seattle, Wash.

No. MC 140727, filed Feb. 27, 1975. Applicant: DELTA DRAYAGE & DISTRIBUTION COMPANY, INC., 208 North Mill Avenue, Dyersburg, Tenn. 38024. Applicant's representative: Robert L. Baker, 618 Hamilton Bank Building, Nashville, Tenn. 37219. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Fibreboard*, between Covington, Tenn., and Manchester, Conn., under contract with Colonial Fiber Company.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Manchester, Conn., or Washington, D.C.

APPLICATIONS OF PASSENGERS

No. MC 13492 (Sub-No. 11), filed February 24, 1975. Applicant: NORTH BOULEVARD TRANSPORTATION CO., a corporation, 9261 Kennedy Boulevard, North Bergen, N.J. 07047. Applicant's representative: William C. Mitchell, 370 Lexington Avenue, New York, N.Y. 10017. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Passengers and their baggage*, in the same vehicle with passengers, between points in the Borough of Fort Lee, N.J.: (1) From the junction of Bergen Boulevard (U.S. Highway 46) and North Avenue over North Avenue to Mediterranean Towers West Apartment building east of Bergen Boulevard, and return over the same route, serving all intermediate points; (2) From the Mediterranean Towers West Apartment building at the junction of North Avenue and Maple Street over Maple Street to junction Main Street, thence over Main Street to junction Bergen Boulevard (U.S. Highway 46), and return over the same route, serving all intermediate points; and (3) From the junction of Bergen Boulevard (U.S. Highway 46) and access road to Maple Street south of Main Street over access road to junction Maple Street, and return over the same route, serving all intermediate points.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Fort Lee or Newark, N.J.

No. MC 29601 (Sub-No. 16), filed February 24, 1975. Applicant: MIDWEST COACHES, INC., 216 North Second Street, Mankato, Minn. 56001. Applicant's representative: Val M. Higgins, 1000 First National Bank Bldg., Minneapolis, Minn. 55402. Authority sought to operate as a *common carrier*, by motor vehicle, over regular and irregular routes, transporting: (1) Regular route, *Passengers and their baggage, and express and newspapers* in the same vehicle, between the junction of U.S. Highways 14 and 59, north of Garvin, Minn., and Brookings, S. Dak., serving all intermediate points: From junction U.S. Highways 14 and 59 over U.S. Highway 14 to Brookings, and return over the same route; (2) Irregular route, *Passengers and their baggage*, in the same vehicle with passengers, and *baggage of passengers* in a separate vehicle, in charter operations and in round-trip sightseeing and pleasure tours, beginning and ending at Balaton, Florence, Tyler, and Lake Benton, Minn., Brookings, S. Dak., and the junction of U.S. Highway 14 and South Dakota Highway 13, known as Elkton Corner, and extending to points in the United States, including Alaska but excluding Hawaii.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Minneapolis, Minn.

No. MC 133048 (Sub-No. 4), filed January 27, 1975. Applicant: JAMES D. KINNEY AND B. R. LINDSEY, a partnership, doing business as PIONEER TRANSIT LINES, 234 West Yellowstone, Casper, Wyo. 82601. Applicant's representative: James D. Kinney (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Passengers, their baggage, express and newspapers*, in the same vehicle with passengers, between Medicine Bow and Laramie, Wyo.: From Medicine Bow, Wyo., over U.S. Highway 30 to Laramie, Wyo., and return over the same route, serving all intermediate points.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Casper, Wyo.

No. MC 139604 (Sub-No. 5), filed February 27, 1975. Applicant: CHERRY HILL TRANSIT, a corporation, 109 Brick Road, Cherry Hill, N.J. 08003. Applicant's representative: Raymond A. Thistle, Jr., Suite 1012, Four Penn Center Plaza, Philadelphia, Pa. 19103. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Passengers and their baggage*, between points in the Philadelphia, Pa. Commercial Zone and points in Delaware County, Pa., on the one hand, and, on the other, the Lakehurst Naval Air Station at or near Lakehurst, N.J., under a continuing contract or contracts with Lakehurst Commuter Transportation Corp.

NOTE.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Philadelphia, Pa.

No. MC 140319 (Sub-No. 2), filed February 18, 1975. Applicant: SALEM STAGE, INC., 819 Cedarbough, New Albany, Ind. 47150. Applicant's representative: Alki E. Scopelitis, 815 Merchants Bank Building, Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Passengers and express and baggage of passengers*, between Salem, Ind., and Louisville, Ky., serving all intermediate points: From Salem over Indiana State Highway 60, to Junction of Indiana State Highway 60 and Indiana State Highway 111, thence over Indiana State Highway 111 to the junction of U.S. Highway 460, thence over U.S. Highway 460 to Louisville, Ky., and return over the same route. (2) *Passengers, and their baggage*, in special or charter operations, in vehicles carrying 13 or less passengers, between points authorized to be served in part (1) above, on the one hand, and, on the other, points in the United States (including Alaska, but excluding Hawaii).

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Louisville, Ky., or Indianapolis, Ind.

BROKER APPLICATIONS

No. MC 130300, filed February 18, 1975. Applicant: GREAT HORIZONS DEVELOPMENT CORP., 5185 Broad Street, Gary, Ind. 46409. Applicant's representative: Donald R. Absher (same address as applicant). Authority sought to engage in operation, in interstate or foreign commerce, as a *broker* at Gary, Ind., to sell or offer to sell the transportation of *groups of passengers and their baggage*, in special and charter operations, in sightseeing tours, by motor or rail carriers, from points in Lake and Porter Counties, Ind., to points in the United States, including Alaska, but excluding Hawaii.

NOTE.—If a hearing is deemed necessary, the applicant requests it be held at Indianapolis, Ind., Chicago, Ill., or Washington, D.C.

No. MC 130303, filed February 25, 1975. Applicant: MISTURBI CORP., 3368 Washtenaw, Ann Arbor, Mich. 48104. Applicant's representative: Wilhelmina Boersman, 1600 First Federal Bldg., Detroit, Mich. 48226. Authority sought to engage in operation, in interstate or foreign commerce, as a *broker* at Ann Arbor, Mich., to sell or offer to sell the transportation of *Passengers and their baggage*, in round trip charter tours, by water carrier, motor, rail and air carriers: (1) between points in Illinois, Michigan, and Ohio; and (2) between ports located on the Great Lakes in Illinois, Michigan, Ohio, New York, Pennsylvania, Minnesota, and Wisconsin.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Detroit or Lansing, Mich.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-7875 Filed 3-26-75;8:45 am]

IRREGULAR-ROUTE MOTOR COMMON CARRIERS OF PROPERTY

Elimination of Gateway Letter Notices

MARCH 21, 1975.

The following letter-notices of proposals to eliminate gateways for the purpose of reducing highway congestion, alleviating air and noise pollution, minimizing safety hazards, and conserving fuel have been filed with the Interstate Commerce Commission under the Commission's gateway elimination rules (49 CFR 1065), and notice thereof to all interested persons is hereby given as provided in such rules.

An original and two copies of protests against the proposed elimination of any gateway herein described may be filed with the Interstate Commerce Commission on or before April 6, 1975. A copy

must also be served upon applicant or its representative. Protests against the elimination of a gateway will not operate to stay commencement of the proposed operation.

Successively filed letter-notices of the same carrier under these rules will be numbered consecutively for convenience in identification. Protests, if any, must refer to such letter-notices by number.

Applicant: BOS LINES, INC., P.O. Box 68, Cedar Rapids, Iowa 52406. Applicant's representative: Gene R. Prohushi (Same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods*, (A) from points in that part of Iowa west of a line beginning at the Iowa-Nebraska State line and extending along U.S. Highway 20 to the junction of unnumbered highway, thence along unnumbered highway through Holly Springs to the junction of Iowa Highway 141, thence along Iowa Highway 141 to junction U.S. Highway 71, thence along U.S. Highway 71 to junction Iowa Highway 92, thence along Iowa Highway 92 to junction Iowa Highway 148, thence along Iowa Highway 148 to junction U.S. Highway 34, thence along U.S. Highway 34 to junction Iowa Highway 25, thence along Iowa Highway 25 to junction Iowa Highway 2, thence along Iowa Highway 2 to junction U.S. Highway 35, thence along U.S. Highway 35 to the Iowa-Missouri State line, (1) to points in that part of Indiana south of a line beginning at the Illinois-Indiana State line and extending along Indiana Highway 26 to junction Indiana Highway 25, thence along Indiana Highway 25 to junction U.S. Highway 24, thence along U.S. Highway 24 to junction Indiana Highway 124, thence along Indiana Highway 124 to the Indiana-Ohio State line, (2) to points in that part of Michigan south of a line beginning at Lake Michigan and extending along U.S. Highway 94 to junction Michigan Highway 106, thence along Michigan Highway 106 to junction Michigan Highway 36, thence along Michigan Highway 36 to junction U.S. Highway 23, thence along U.S. Highway 23 to junction Michigan Highway 59, thence along Michigan Highway 59 to junction unnumbered highway, thence along unnumbered highway to Lake St. Clair.

(3) to points in that part of Ohio south and east of a line beginning at the Indiana-Ohio State line and extending along Ohio Highway 29 to junction U.S. Highway 75, thence along U.S. Highway 75 to junction U.S. Highway 224, thence along U.S. Highway 224 to junction Ohio Highway 13, thence along Ohio Highway 13 to junction Ohio Highway 162, thence along Ohio Highway 162 to junction Ohio Highway 4, thence along Ohio Highway 4 to junction U.S. Highway 20, thence along U.S. Highway 20 to junction Ohio Highway 61, thence along Ohio Highway 61 to junction Ohio Highway 113, thence along Ohio Highway 113 to junction Ohio Highway 58; thence along Ohio Highway 58 to Lake Erie; (B) from points in that part of Iowa west of a line beginning at the Iowa-Minnesota State line and extending along U.S. Highway 69 to the Iowa-Missouri State line, (1) to points in that part of Indiana south of a line beginning at the Illinois-Indiana State line and extending along U.S. Highway 40 to the Indiana-Ohio State line, (2) to points in that part of Ohio south of a line beginning at the Indiana-Ohio State line and extending along U.S. Highway 40 to junction Ohio Highway 285, thence along Ohio Highway 285 to junction U.S. Highway 70, thence along U.S. Highway 70 to junction U.S. Highway 40, thence along U.S. Highway 40 to the Ohio-West Virginia State line, (C) from points in that part of Iowa west of a line beginning at the Iowa-Minnesota State line and extending along U.S. Highway 63 to the Iowa-Missouri State line, to points in that part of Indiana south of a line beginning at the Illinois-Indiana State line and extending along U.S. Highway 460 to the Indiana-Kentucky State line; (D) from points in that part of Iowa west of a line beginning at the Iowa-Minnesota State line and extending along U.S. Highway 65 to junction U.S. Highway 20, thence along U.S. Highway 20 to junction Iowa Highway 214, thence along Iowa Highway 214 to junction Iowa Highway 175, thence along Iowa Highway 175 to junction Iowa Highway 14, thence along Iowa Highway 14 to junction Iowa Highway 5, thence along Iowa Highway 5 to the Iowa-Missouri State line, to points in that part of Ohio south of a line beginning at the Indiana-Ohio State line and extending along U.S. Highway 50 to the Ohio-West Virginia State line. The purpose of this filing is to eliminate the gateways of Marshall, Macon, Milan, Carrollton, and Moberly, Mo.

No. MC 29886 (Sub-No. E57), filed June 4, 1974. Applicant: DALLAS & MAVIS FORWARDING CO., INC., 4000 West Sample Street, South Bend, Ind. 46627. Applicant's representative: Charles Pieroni (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Self-propelled fork trucks*, the transportation of which, because of size or weight, require the use of special equipment, and *self-propelled fork trucks* each weighing 15,000 pounds or more, from Battle Creek, Mich., to points in Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New Jersey, Delaware, the District of Columbia, North Carolina, South Carolina, Georgia, Florida, Alabama, Tennessee, Mississippi, Louisiana, Arkansas, Illinois, Missouri, Iowa, Wisconsin, Minnesota, North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Texas, New Mexico, Colorado, Wyoming, Montana, Idaho, Utah, Arizona, California, Oregon, Nevada, Washington, those in Indiana on and west of Interstate Highway 65, those in Maryland on and east of Interstate Highway 95, those in New York on and east of Interstate Highway 81, those in Kentucky on, south and west of a line beginning at the Kentucky-Indiana State line and extending along Interstate Highway 65 to junction Kentucky Highway 61, thence along Kentucky Highway 61 to the Kentucky-Tennessee State line, and those in Virginia, on and south of a line beginning at the Virginia-West Virginia State line and extending along the Shenandoah-Rockingham County line, to junction U.S. Highway 211, thence along U.S. Highway 211 to the Virginia-District of Columbia line. The purpose of this filing is to eliminate the gateway of Benton Harbor, Mich.

No. MC 37203 (Sub-No. E12), filed May 31, 1974. Applicant: MILLSTEAD VAN LINES, INC., P.O. Drawer 878, Bartlesville, Okla. Applicant's representative: Thomas F. Sedberry, Suite 1102, Perry-Brooks Bldg., Austin, Tex. 78701. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Household goods*, as defined by the Commission, between points in Wyoming, on the one hand, and, on the other, points in that part of Texas on and east of a line beginning at the Texas-Oklahoma State line and extending along U.S. Highway 183 to its junction with U.S. Highway 377, thence along U.S. Highway 377 to its junction with U.S. Highway 87, thence along U.S. Highway 87 to its junction with U.S. Highway 81, thence along U.S. Highway 81 to the United States-Mexico International Boundary line. The purpose of this filing is to eliminate the gateways of Tulsa, Okla., and points in Oklahoma within 80 miles of Tulsa.

No. MC 51146 (Sub-No. E15) (Correction), filed November 2, 1974 published in the FEDERAL REGISTER December 10, 1974. Republished in the FEDERAL REGISTER February 11, 1975. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, Wisc. 54306. Applicant's representative: Neil A. DuJardin (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (36) *Paper and paper products* (except commodities in bulk) from points in Ohio on and within an area bordered on the north by U.S. Highway 35, on the west by U.S. Highway 27, on the south by Ohio Highway 129, and on the east by U.S. Highway 25 (except points in Hamilton and Middletown, Ohio and their Commercial Zones), to Memphis, Tenn., and points in North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Mississippi, Texas, Louisiana, Arkansas, Maine, New Hampshire, Vermont, New York, Massachusetts, Connecticut, Rhode Island, New Jersey, Delaware, Maryland, Virginia (except points west of U.S. Highway 21), North Carolina (except points west of a line beginning at the intersection of the North Carolina-Virginia State line and U.S. Highway 21, thence along U.S. Highway 21 to Sparta, thence along North Carolina Highway 18 to Roxboro, thence along North Carolina Highway 16 to its junction with U.S. Highway 321, thence along U.S. Highway 321 to the North Carolina-South Carolina State line), South Carolina (except points west of a line

beginning at the intersection of the North Carolina-South Carolina State line and U.S. Highway 321, thence along U.S. Highway 321 to its intersection with South Carolina Highway 72, thence along South Carolina Highway 72 to Greenwood, thence along U.S. Highway 25 to the Georgia-South Carolina State line), Missouri (except points east of a line beginning at the intersection of the Iowa-Missouri State line and U.S. Highway 136.

Thence along U.S. Highway 136 to the intersection of Missouri Highway 15, thence along Missouri Highway 15 to Mexico, thence along U.S. Highway 54 to Jefferson City, thence along U.S. Highway 63 to Cabool, thence along U.S. Highway 60 to Poplar Bluff, thence along U.S. Highway 67 to the Missouri-Arkansas State line, Alabama (except points north of a line beginning at the intersection of the Alabama-Mississippi State line and U.S. Highway 78, thence along U.S. Highway 78 to Hamilton, thence along U.S. Highway 278 to the Georgia-Alabama State line), and the District of Columbia. Restriction: The authority granted above is restricted against the transportation of pulpboard, pulpboard products, and waste paper. (The plant site of Laminated and Coated Products Div., of St. Regis Paper Co., at Troy, Ohio)*; (53) *paper and* paper products, (except commodities in bulk), from Newark and Rochester, N.Y., to points in Kansas, Oklahoma, Texas, Louisiana, North Dakota (except points east and south of a line beginning at the intersection of the International Boundary between Canada and North Dakota and U.S. Highway 281, thence along U.S. Highway 281 to its junction with North Dakota Highway 3, thence along North Dakota Highway 3 to its junction with U.S. Highway 2, thence along U.S. Highway 2 to its intersection with North Dakota Highway 14, thence along North Dakota Highway 14 to its junction with U.S. Highway 83, thence along U.S. Highway 83 to the North Dakota-South Dakota State line), South Dakota (except points east and south of a line beginning at the intersection of the North Dakota-South Dakota State line and U.S. Highway 83, thence along U.S. Highway 83 to its intersection with U.S. Highway 14, thence along U.S. Highway 14 to its intersection with South Dakota Highway 73, thence along South Dakota Highway 73 to the South Dakota-Nebraska State line), Nebraska (except points north and east of a line beginning at the intersection of the South Dakota-Nebraska State line and Nebraska Highway 61, thence along Nebraska Highway 61 to its intersection with U.S. Highway 30, thence along U.S. Highway 30 to its intersection with U.S. Highway 183, thence along U.S. Highway 183 to its intersection with U.S. Highway 6.

Thence along U.S. Highway 6 to its intersection with U.S. Highway 281, thence along U.S. Highway 281 to its insersection with Nebraska Highway 4, thence along Nebraska Highway 4 to Beatrice, thence along U.S. Highway 77 to the Nebraska-Kansas State line), Missouri (except points east and north of a line beginning at St. Joseph, thence along U.S. Highway 169 to its intersection with U.S. Highway 50, thence along U.S. Highway 50 to Sedalia, thence along U.S. Highway 65 to its intersection with Missouri Highway 14, thence along Missouri Highway 14 to West Plains, thence along U.S. Highway 63 to the Missouri-Arkansas State line), Arkansas (except points north and east of a line beginning at the intersection of the Missouri-Arkansas State line and U.S. Highway 63, thence along U.S. Highway 63 to its intersection with Arkansas Highway 1, thence along Arkansas Highway 1 to its intersection with U.S. Highway 49, thence along U.S. Highway 49 to the Arkansas-Mississippi State line), Mississippi (except points north and east of a line beginning at the intersection of the Arkansas-Mississippi State line and U.S. Highway 49, thence along U.S. Highway 49 to its junction with U.S. Highway 49E, thence along U.S. Highway 49E to Greenwood, thence along U.S. Highway 82 to the Alabama-Mississippi State line), and Alabama (except points north and east of U.S. Highway 82). (Paxinos, Pa., and the plant site of Laminated and Coated Products Div., of St. Regis Paper Co., at Troy, Ohio)*. The purpose of this filing is to eliminate the gateways marked with asterisks above. The purpose of this partial correction is to clarify the commodity descriptions. The remainder of this letter-notice will remain as previously published.

No. MC–61403 (Sub-No. E34) (Correction), filed May 31, 1974, republished in the FEDERAL REGISTER January 27, 1975. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, Tenn. 37662. Applicant's representative: Charles E. Cox (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (2) *Liquid chemicals*, in bulk, in tank vehicles, (a) from points in Tennessee on and east of U.S. Highway 85, to points in North Dakota on and east of U.S. Highway 85, and points in South Dakota, on and east of U.S. Highway 27 (Kingsport, Tenn., and Marshall, Ill.)*, and (b) from points in Tennessee on, east, and north of a line beginning at the Tennessee-Kentucky State line and extending along Interstate Highway 75 to Knoxville, thence along U.S. Highway 411 to Newport, thence along U.S. Highway 70 to the Tennessee-North Carolina State line, to points in Colorado east of U.S. Highway 85, points in Iowa, Kansas, and Nebraska (Kingsport, Tenn., and Marshall, Ill.)*. The purpose of this filing is to eliminate the gateways indicated by asterisks above. The purpose of this partial correction is to correct a highway description in (2) (a) above, and to expand the territorial description in (2) (b) above. The remainder of this letter-notice remains as previously published.

No. MC 100666 (Sub-No. E40), filed April 18, 1974. Applicant: MELTON TRUCK LINE, INC., 1129 Grimmett Drive, P.O. Box 7666, Shreveport, La. 71107. Applicant's representative: Richard W. Mays (Same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Composition board*, from points in Texas (except Pineland and Silsbee, and particle board from Diboll), to points in Indiana. The purpose of this filing is to eliminate the gateways of Irving, Tex., and Miami, Okla.; Irving, Tex., and Craig, Okla.; Pineland, Tex.; Silsbee, Tex.; and Acme, Tex., and Miami, Okla.

No. MC–107295 (Sub-No. E202), filed May 14, 1974. Applicant: PRE-FAB TRANSIT CO., P.O. Box 146, Farmer City, Ill. 61842. Applicant's representative: Dale L. Cox (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Prefabricated* and *precut buildings* or *houses*, complete, knocked down, or in sections and all component parts necessary to the construction, erection, or completion of such buildings or houses, when shipped with same, (1) from points in that part of West Virginia located in and east of Jackson, Kanawha, Boone, Wyoming, and McDowell Counties to points in that part of Georgia located in and south of Early, Baker, Mitchell, Colquitt, Cook, Berrien, Coffee, Bacon, Appling, Tattnall, Evans, Bulloch, and Effingham Counties; (2) from points in that part of West Virginia located in and east of Jackson, Kanawha, Boone, Wyoming, and McDowell Counties to points in that part of Kentucky located in and north of Carlisle, Graves, Marshall, Lyon, Caldwell, Hopkins, McLean, Ohio, Grayson, Hardin, Nelson, Spencer, Shelby, Henry, and Carroll Counties; (3) from points in West Virginia to points in Texas, Oklahoma, Louisiana, and to points in that part of Mississippi located in and west of Tunica, Quitman, Tallahatchie, Leflore, Humphreys, Yazoo, Hinds, Copiah, Jefferson, Adams, and Wilkinson Counties. The purpose of this filing is to eliminate the gateways of (1) Lumberton, N.C., (2) Lumberton, N.C., (3) points in Ohio, and (4) points in Tennessee and Arkansas.

No. MC 107295 (Sub-No. E203), filed May 14, 1974. Applicant: PRE-FAB TRANSIT CO., P.O. Box 146, Farmer City, Ill. 61842. Applicant's representative: Dale L. Cox (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Buildings*, complete, knocked down, or in sections, including all component parts, materials, supplies, and fixtures, and when shipped with such buildings, *accessories* used in the erection, construction, and completion thereof, (1) from points in Michigan to points in Arizona and New Mexico; (2) from points in the Lower Peninsula of Michigan to points in that part of California located in and south of San Luis Obispo, Kerns, and San Bernardino Counties; (3) from points in Michigan to points in Colorado, Nevada, Utah, and

Wyoming; and (4) from points in the Lower Peninsula of Michigan, to points in that part of Idaho located in and south of Nez Perce, Lewis, and Clearwater Counties. The purpose of this filing is to eliminate the gateways of (1) Pine Bluff, Ark.; (2) Pine Bluff, Ark.; (3) points in Wapello County, Iowa; and (4) points in Wapello County, Iowa.

No. MC 107403 (Sub-No. E409), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Nitro paraffines and derivatives* thereof, in bulk, in tank vehicles, from Sterlington, La., to points in Michigan (except those points that are both west of U.S. Highway 131 and south of Michigan Highway 89). The purpose of this filing is to eliminate the gateway of Ashland, Ky.

No. MC–107403 (Sub-No. E411), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Methanol*, in bulk, in tank vehicles, from Sterlington, La., to points in Ohio (except points west of U.S. Highway 62, and points south of U.S. Highway 40), and Michigan (except those points that are both west of U.S. Highway 27 south of U.S. Highway 10). The purpose of this filing is to eliminate the gateway of Ashland, Ky.

No. MC–107403 (Sub-No. E451), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles, from the facilities of American Cyanamid at Avondale, La., to points in Iowa, Minnesota, Wisconsin, and points in Nebraska east of U.S. Highway 83. The purpose of this filing is to eliminate the gateway of Mapleton, Ill.

No. MC 107403 (Sub-No. E545), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Creosote oil* in bulk, in tank vehicles, from the facilities of Witco Chemical Co., Inc., at or near Jasper, Tex., to points in Ohio (except points that are both west of U.S. Highway 68 and south of U.S. Highway 40). The purpose of this filing is to eliminate the gateways of Baton Rouge, La., and Ashland, Ky.

No. MC 107403 (Sub-No. E553), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Anhydrous ammonia and muriatic acid*, in bulk, in tank vehicles, from Freeport, Tex., to points in Alabama, Florida, Georgia, Illinois, Indiana, Kentucky, North Carolina, South Carolina, Wisconsin, Tennessee (except Kingsport, Tenn.), and Missouri (except those points west of U.S. Highway 63). The purpose of this filing is to eliminate the gateway of Baton Rouge, La.

No. MC–107403 (Sub-No. E568), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Creosote oil wood preservatives*, in bulk, in tank vehicles, from Lone Star, Tex., to points in Delaware, Maryland, New Jersey, New York, and Pennsylvania. The purpose of this filing is to eliminate the gateways of Greensboro, N.C., and Baton Rouge, La.

No. MC–107403 (Sub-No. E586), filed May 29, 1974. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Creosote oil*, in bulk, in tank vehicles, from Point Comfort, Tex., to points in Michigan (except those points that are both west of U.S. Highway 131 and south of Michigan Highway 89), and Ohio (except those points that are both west of U.S. Highway 23 and south of U.S. Highway 40). The purpose of this filing is to eliminate the gateways of Baton Rouge, La., and Ashland, Ky.

No. MC 107403 (Sub-No. E656), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above) Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Bicarbonate of soda* (dry), and *sodium carbonate* (monohydrated, dry), in bulk, in hopper and mechanical discharge type vehicles, from the facilities of Church and Dwight Co., Inc., at Syracuse, N.Y., to points in Kansas and Missouri. The purpose of this filing is to eliminate the gateways of Erie, Pa., Ashtabula County, Ohio, facilities of B.F. Goodrich Co., in Milan Township, Ind., and the facilities of Stepan Chemical Co., at or near Millsdale, Ill.

No. MC 107403 (Sub-No. E657), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above) Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum* and *petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 (except liquefied petroleum gas and except petroleum chemicals as defined in Appendix XV to the Description case above cited), in bulk, in tank vehicles, from the facilities of Flexi-Flo of Penn Central Transportation Co., at Rochester, N.Y., to points in Maryland, North Carolina, South Carolina, and Virginia. The purpose of this filing is to eliminate the gateway of McKean County, Pa.

No. MC 107403 (Sub-No. E658), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Bicarbonate of soda* (dry) and *sodium carbonate* (monohydrated, dry), in bulk, in hopper and mechanical discharge type vehicles, from the facilities of Church and Dwight Co., Inc., at Syracuse, N.Y., to points in New Hampshire and Maine. The purpose of this filing is to eliminate the gateway of Springfield, Mass.

No. MC 107403 (Sub-No. E661), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry calcium chloride*, in bulk, in tank vehicles, from points in New York east of New York Highway 14 to points in Illinois and Wisconsin. The purpose of this filing is to eliminate the gateways of Solvay, N.Y., Ashtabula, Ohio, and the facilities of B. F. Goodrich, Co., at Milan Township, Ind.

No. MC 107403 (Sub-No. E662), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry calcium chloride*, in bulk, in tank vehicles, from points in New York west of a line beginning at the Pennsylvania-New York State line and extending along New York Highway 14 to junction New York Highway 13, thence along New York Highway 13 to junction U.S. Highway 11, thence along U.S. Highway 11 to junction Interstate Highway 81, thence along Interstate Highway 81 to the St. Lawrence River, to points in Massachusetts, Vermont, Connecticut, Rhode Island, and New Hampshire. The purpose of this filing is to eliminate the gateway of Solvay, N.Y.

No. MC 107403 (Sub-No. E663), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry calcium chloride*, in bulk, in tank vehicles, from points in New York west of a line beginning at the New York-Pennsylvania State line and extending along New York Highway 14

to junction New York Highway 13, thence along New York Highway 13 to junction U.S. Highway 11, thence along U.S. Highway 11 to junction Interstate Highway 81, thence along Interstate Highway 81 to the St. Lawrence River, to points in Maine. The purpose of this filing is to eliminate the gateways of Solvay, N.Y., and Springfield, Mass.

No. MC 107403 (Sub-No. E666), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry calcium chloride*, in bulk, in tank vehicles, from the Michigan Counties of Lenawee, Monroe, Hillsdale, Jackson, Washtenaw, and Wayne, the Ohio Counties of Lucas, Wood, Fulton, Ottawa, Sandusky, Erie, Henry, Williams, and Defiance, and the Indiana Counties of Steuben, De Kalb, and Allen, to points in Maine. The purpose of this filing is to eliminate the gateways of Birmingham, Ala., Painesville, Ohio, Solvay, N.Y., and Springfield, Mass.

No. MC 107403 (Sub-No. E667), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Landsdowne, Pa. 19050. Applicants representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry calcium chloride*, in bulk, in tank vehicles, from those points in Pennsylvania and Maryland within 150 miles of Monongahela, Pa., to points in Maine. The purpose of this filing is to eliminate the gateways of Lewistown, Pa., Solvay, N.Y., and Springfield, Mass.

No. MC 107403 (Sub-No. E671), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals* (except calcium chloride), from the Michigan Counties of Lenawee, Monroe, Hillsdale, Jackson, Washtenaw, and Wayne, the Ohio Counties of Lucas, Wood, Fulton, Ottawa, Sandusky, Erie, Henry, Williams and Defiance and the Indiana Counties of Steuben, De Kalb, and Allen, to points in Connecticut, Massachusetts, New Hampshire, Rhode Island, and Vermont. The purpose of this filing is to eliminate the gateways of Birmingham, Ohio, Painesville, Ohio, and Solvay, N.Y.

No. MC 107403 (Sub-No. E672), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Landsdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals*, in bulk, in tank vehicles, from Solvay, N.Y., to points in Kansas and Missouri. The purpose of this filing is to eliminate the gateways of Ashtabula County, Ohio, the facilities of Stepan Chemical Co., at or near Millsdale, Ill., and the facilities of B. F. Goodrich Co., at Milan Township, Ind.

No. MC 107403 (Sub-No. E673), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Silicate of soda*, dry, in bulk, in tank or hopper-type vehicles, Skaneateles Falls, N.Y., to points in Kansas and Missouri. The purpose of this filing is to eliminate the gateways of Ashtabula County, Ohio, facilities of B. F. Goodrich Co., at Milan Township, Ind., facilities of Stepan Chemical Co., at or near Millsdale, Ill.

No. MC 107403 (Sub-No. E675), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Silicate of soda*, dry, in bulk, in tank or hopper-type vehicle, from Skaneateles Falls, N.Y., to points in Maryland. The purpose of this filing is to eliminate the gateway of Lewistown, Pa.

No. MC 107403 (Sub-No. E676), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Silicate of soda*, dry, in bulk, in tank or hopper type vehicles, from Skaneateles Falls, N.Y., to points in Wisconsin and Illinois. The purpose of this filing is to eliminate the gateways of Cleveland, Ohio, and facilities of B. F. Goodrich Co., at Milan Township, Ind.

No. MC 107403 (Sub-No. E677), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Silicate of soda*, dry, in bulk, in tank or hopper type vehicles, from Skaneateles Falls, N.Y., to points in Kentucky, Indiana, and Michigan. The purpose of this filing is to eliminate the gateway of Cleveland, Ohio.

No. MC 107403 (Sub-No. E678), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals*, in bulk, in tank vehicles, from Springfield, Mass., to points in Kansas. The purpose of this filing is to eliminate the gateways of Solvay, N.Y., Ashtabula, Ohio, facilities of B. F. Goodrich Co., at Milan Township, Ind., and facilities of Stepan Chemical Co., at or near Millsdale, Ill.

No. MC 107403 (Sub-No. E679), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals*, in bulk, in tank vehicles, from the facilities of the Flexi-Flo terminal of Penn Central at Beacon Park, Mass., to points in Kansas. The purpose of this filing is to eliminate the gateways of Springfield, Mass., facilities of Stepan Chemical Co., at or near Millsdale, Ill.

No. MC 107403 (Sub-No. E680), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals*, in bulk, in tank vehicles, from the Flexi-Flo terminal of Penn Central at Beacon Park, Mass., to points in Alabama, Delaware, Georgia, Iowa, Illinois, Indiana, Missouri, North Carolina, Pennsylvania, Kentucky, Maryland, Michigan, Minnesota, New Jersey, Ohio, South Carolina, Tennessee, Virginia, West Virginia, Wisconsin, New York, and District of Columbia. The purpose of this filing is to eliminate the gateway of Springfield, Mass.

No. MC 107403 (Sub-No. E681), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operates as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Commodities*, in bulk, in tank vehicles (except cement and liquefied petroleum gas), from the Flexi-Flo terminal of Penn Central at Rochester, N.Y., to those points in Ohio, West Virginia, Pennsylvania, and Maryland within 150 miles of Monongahela, Pa. The purpose of this filing is to eliminate the gateways of points in the Pennsylvania Counties of Warren, McKean, Potter, and Erie within 150 miles of Monongahela, Pa.

No. MC 107403 (Sub-No. E683), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry commodities* (except fly-ash and cement), in bulk, in tank vehicles, from the facilities of Flexi-Flo terminal of Penn Central at Rochester, N.Y., to points in Kentucky, Indiana, and Michigan. The purpose of this filing is to eliminate the gateways of Erie, Pa., and Ashtabula, Ohio.

No. MC 107403 (Sub-No. E684), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals*, in bulk, in tank vehicles (except cement and fly-ash), from the facilities of the Flexi-Flo

terminal of Penn Central at Rochester, N.Y., to points in Illinois and Wisconsin. The purpose of this filing is to eliminate the gateways of Erie, Pa., Ashtabula, Ohio, facilities of B. F. Goodrich at Milan Township, Ind.

No. MC 107403 (Sub-No. E685), filed January 31, 1975. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Applicant's representative: John Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry chemicals* (except cement), in bulk, in tank vehicles, from the Flexi-Flo terminal of Penn Central at Rochester, N.Y., to points in Maryland (except those within 150 miles of Monongahela, Pa.). The purpose of this filing is to eliminate the gateways of Lewistown, Pa., and Coudersport, Pa.

No. MC 107515 (Sub-No. E113) (Correction), filed May 29, 1974. Published in the FEDERAL REGISTER February 19, 1975. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, Ga. 33050. Applicant's representative: Bruce E. Mitchell, Suite 375, 3379 Peachtree Rd. NE., Atlanta, Ga. 30326. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products and meat by-products*, as described in Section A of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766, in vehicles equipped with mechanical refrigeration (except commodities in bulk, in tank vehicles, hides), from New York, N.Y., to points in Illinois on and south of a line beginning at the Indiana-Illinois State line, at Shawneetown, Ill., thence along Illinois Highway 13, to junction with Illinois Highway 149, thence along Illinois Highway 149 to its junction with Illinois Highway 3, thence along Illinois Highway 3 to Chester at junction of Illinois Highway 51, thence along Illinois Highway 51 to the Illinois-Missouri State line, that part of Missouri on and south of a line beginning at the Missouri-Illinois State line, thence along Missouri Highway 51 to junction U.S. Highway 61 at Perryville, Mo., thence north along U.S. Highway 61 to junction Missouri Highway 32, thence along Missouri Highway 32 to junction U.S. Highway 67 at Farmington, Mo., thence north along U.S. Highway 67 to junction Missouri Highway 8, thence along Missouri Highway 8 to junction U.S. Highway 66, thence along U.S. Highway 66 to junction Missouri Highway 64 at Lebanon, Mo., thence along Missouri Highway 64 to junction U.S. Highway 65, thence north along U.S. Highway 65 to the junction of U.S. Highway 54 at Preston, Mo., thence along U.S. Highway 54 to the Missouri-Kansas State line. The purpose of this filing is to eliminate the gateways of Richmond, Va., and Madison, Tenn. The purpose of this correction is to clarify highway description.

No. MC 107515 (Sub-No. E241) (Correction), filed May 29, 1974. Published in the FEDERAL REGISTER February 18, 1975. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, Ga. 33050. Applicant's representative: R. M. Tettlebaum, Suite 375, 3379 Peachtree Rd. NE., Atlanta, Ga. 30326. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such sandwich spreads as are considered dairly products*, as described in Section B of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except commodities in bulk, in tank vehicles), in vehicles equipped with mechanical refrigeration, from Omaha, Nebr., to the District of Columbia, Virginia (except points in Frederick County, Va.), points in Maryland on, south, and east of U.S. Highway 301. The purpose of this filing is to eliminate the gateway of Knoxville, Tenn. The purpose of this correction is to clarify territorial destination.

No. MC 108449 (Sub-No. E59), filed May 17, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Noyes, Minn., to points in Wisconsin. The purpose of this filing is to eliminate the gateways of Fargo, N. Dak., and St. Cloud and Minneapolis, Minn.

No. MC 108449 (Sub-No. E60), filed May 17, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Road C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Noyes, Minn., to points in Wisconsin. The purpose of this filing is to eliminate the gateways of Grand Forks, N. Dak., and McGregor, Minn.

No. MC–108449 (Sub-No. E61), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Eau Claire, Wis., and points within 20 miles thereof to points in South Dakota. The purpose of this filing is to eliminate the gateway of St. Cloud, Minn.

No. MC–108449 (Sub-No. E63), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Road C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum* and *petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Eau Claire, Wis., and points within 20 miles thereof, to points in Montana. The purpose of this filing is to eliminate the gateways of St. Cloud, Minn., and Jamestown, N. Dak.

No. MC 108449 (Sub-No. E83), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from the terminal of Duluth Petroleum Products about eight miles from Duluth, Minn., and points within two miles thereof, to points in Illinois. The purpose of this filing is to eliminate the gateways of St. Paul, Minn., and Dubuque, Iowa.

No. MC 108449 (Sub-No. E93), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Grand Forks, N. Dak., and points in North Dakota within 10 miles thereof, to points in Illinois. The purpose of this filing is to eliminate the gateways of the terminal of the Williams Brothers Pipe Line Company terminal in Kronewetter, Marathon County, Wis., the facilities of American Oil Company, Dubuque, Iowa, and Minneapolis, Minn.

No. MC 108449 (Sub-No. E94), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Wrenshall, Minn., to points in Nebraska. The purpose of this filing is to eliminate the gateways of the terminal of the Williams Brothers Pipe Line Company at or near Spencer or Spirit Lake, Iowa; Minneapolis, Minn., and Superior, Wis.

No. MC 108449 (Sub-No. E95), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Wrenshall, Minn., to points in Illinois. The purpose of this filing is to eliminate the

gateways of LaCrosse, Wis., and Dubuque, Iowa.

No. MC 108449 (Sub-No. E96), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Wrenshall, Minn., to points in Iowa. The purpose of this filing is to eliminate the gateways of Superior, Wis., and St. Paul, Minn.

No. MC 108449 (Sub-No. E97), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from LaCrosse, Wis., to points in the Upper Penninsula of Michigan. The purpose of this filing is to eliminate the gateways of Winona, Minn., and Eau Claire, Wis.

No. MC 108449 (Sub-No. E98), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from LaCrosse, Wis., to those points in Minnesota on and east of U.S. Highway 53. The purpose of this filing is to eliminate the gateway of St. Paul, Minn.

No. MC 108449 (Sub-No. E99), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Grand Forks, N. Dak., and points in North Dakota within 10 miles thereof, to those points in Minnesota on and east of a line beginning at Lake Superior and extending along U.S. Highway 61 to junction Minnesota Highway 210, thence along Minnesota Highway 210 to the Aitken County line, thence along the Aitken County line to junction Mille Lacs County line, thence along the Mille Lacs County line to junction Sherburne County line, thence along the Sherburne County line to junction Minnesota Highway 15, thence along Minnesota Highway 15 to junction U.S. Highway 212, thence along U.S. Highway 212 to junction U.S. Highway 71, thence along U.S. Highway 71 to the Iowa-Minnesota State line. The purpose of this filing is to eliminate the gateway of McGregor, Minn.

No. MC 108449 (Sub-No. E100), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 West County Road C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Grand Forks, N. Dak., and points in North Dakota within 10 miles thereof, to those points in Iowa on and east of a line beginning at the Minnesota-Iowa State line and extending along Iowa Highway 4 to junction Iowa Highway 175, thence along Iowa Highway 175 to junction U.S. Highway 71, thence along U.S. Highway 71 to junction U.S. Highway 6, thence along U.S. Highway 6 to junction U.S. Highway 59, thence along U.S. Highway 59 to the Iowa-Missouri State line. The purpose of this filing is to eliminate the gateways of St. Cloud and Minneapolis, Minn.

No. MC 108449 (Sub-No. E101), filed May 21, 1974. Applicant: INDIANHEAD TRUCK LINE, INC., 1947 W. County Rd. C, St. Paul, Minn. 55113. Applicant's representative: W. A. Myllenbeck (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Grand Forks, N. Dak., to points in Wyoming. The purpose of this filing is to eliminate the gateways of Fargo, N. Dak., and Aberdeen, S. Dak.

No. MC 110817 (Sub-No. E1), filed May 13, 1974. Applicant: E. L. FARMER & COMPANY, Odessa, Tex. Applicant's representative: James W. Hightower, 136 Wynnewood Professional Bldg., Dallas, Tex. 75224. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Machinery, materials, supplies*, and *equipment*, incidental to, or used in, the construction, development, operation, and maintenance, of facilities for the discovery, development, and production of natural gas and petroleum (except the picking up or stringing of pipe in connection with main or trunk pipe lines); (2) *Earth drilling machinery* and *equipment*, and *machinery, equipment, materials, supplies*, and *pipe* incidental to, used in, or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities to or from holes or wells; (3) *Machinery, equipment, materials*, and *supplies* used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transmission of natural gas, petroleum, their products and by-products, water, or sewerage, restricted to the transportation of shipments moving to or from pipeline rights of way, (a) between points in that part of Illinois south and east of a line beginning at Savannah, Ill., on the Mississippi River, thence along U.S. Highway 52 to junction Illinois Highway 26, thence along Illinois Highway 26 to the Illinois-Wisconsin State line, on the one hand, and, on the other, points in Nevada. The purpose of this filing is to eliminate the gateway of any point in Oklahoma or Texas.

No. MC 110817 (Sub-No. E2), filed May 13, 1974. Applicant: E. L. FARMER & COMPANY, Odessa, Tex. Applicant's representative: James W. Hightower, 136 Wynnewood Professional Bldg., Dallas, Tex. 75224. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Machinery, materials, supplies*, and *equipment*, incidental to, or used in, the construction, development, operation, and maintenance of facilities for the discovery, development, and production of natural gas and petroleum (except the picking up or stringing of pipe in connection with main or trunk pipe lines); (2) *Earth drilling machinery and equipment*, and *machinery, equipment, materials, supplies*, and *pipe* incidental to, used in, or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities to or from holes or wells; and (3) *Machinery, equipment, materials*, and *supplies* used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transmission of natural gas, petroleum, their products, and by-products, water, or sewerage, restricted to the transportation of shipments moving to or from pipeline rights of way, between points in Nevada, on the one hand, and, on the other, points in Missouri. The purpose of this filing is to eliminate the gateway of any point in Oklahoma or Texas.

No. MC 110817 (Sub-No. E3), filed May 13, 1974. Applicant: E. L. FARMER & COMPANY, Odessa, Tex. Applicant's representative: James W. Hightower, 136 Wynnewood Professional Bldg., Dallas, Tex. 75224. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Machinery, materials, supplies*, and *equipment*, incidental to, or used in, the construction, development, operation, and maintenance of facilities for the discovery, development, and production of natural gas and petroleum (except the picking up or stringing of

pipe in connection with main or trunk pipelines); (2) *Earth drilling machinery* and *equipment*, and *machinery, equipment, materials, supplies* and *pipe* incidental to, used in, or in connection, with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities to or from holes or wells; and (3) *Machinery, equipment, materials,* and *supplies* used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transmission of natural gas, petroleum, their products, and by-products, water, or sewerage, restricted to the transportation of shipments moving to or from pipeline rights of way, between points in Tennessee, on the one hand, and, on the other, points in Nevada. The purpose of this filing is to eliminate the gateway of any point in Oklahoma.

No. MC 110817 (Sub-No. E4), filed May 13, 1974. Applicant: E. L. FARMER & COMPANY, Odessa, Tex. Applicant's representative: James W. Hightower, 136 Wynnewood Professional Bldg., Dallas, Tex. 75224. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Machinery, materials, supplies,* and *equipment*, incidental to, or used in, the construction, development, operation, and maintenance of facilities for the discovery, development, and production of natural gas and petroleum (except the picking up or stringing of pipe in connection with main or trunk pipelines); (2) *Earth drilling machinery* and *equipment*, and *machinery, equipment, materials, supplies,* and *pipe*, incidental to, used in, or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities to or from holes or wells; and (3) *Machinery, equipment, materials,* and *supplies* used in or in connection with the construction, operation, repair, servicing maintenance, and dismantling of pipelines, other than pipelines used for the transmission of natural gas, petroleum, their products, and by-products, water, or sewerage, restricted to the transportation of shipments moving to or from pipeline rights of way, between points in Nevada, on the one hand, and, on the other, points in Arkansas. The purpose of this filing is to eliminate the gateway of any point in Oklahoma or Texas.

No. MC 110817 (Sub-No. E5), filed May 13, 1974. Applicant: E. L. FARMER & COMPANY, Odessa, Tex. Applicant's representative: James W. Hightower, 136 Wynnewood Professional Bldg., Dallas, Tex. 75224. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Machinery, materials, supplies,* and *equipment*, incidental to, or used in, the construction, development, operation, and maintenance of facilities for the discovery, development, and production of natural gas and petroleum (except the picking up or stringing of pipe in connection with main or trunk pipelines); (2) *Earth drilling machinery* and *equipment*, and *machinery, equipment, materials, supplies,* and *pipe*, incidental to, used in, or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities to or from holes or wells; and (3) *Machinery, equipment, materials,* and *supplies* used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transmission of natural gas, petroleum, their products, and by-products, water, or sewerage restricted to the transportation of shipments moving to or from pipeline rights of way, between points in Nevada, on the one hand, and, on the other, points in Mississippi. The purpose of this filing is to eliminate the gateway of any point in Oklahoma or Texas.

No. MC 112617 (Sub-No. E52), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles R. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles (except those of which are petroleum products and are listed in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209), in bulk, in tank vehicles, from Huntington, W. Va., to points in Mississippi, Iowa, Nebraska, Minnesota, and Louisiana. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112617 (Sub-No. E56), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals*, in bulk, in tank vehicles, from Sheffield, Ala., and points within 15 miles thereof, to points in Virginia. The purpose of this filing is to eliminate the gateway of points in Robertson County, Tenn.

No. MC 112617 (Sub-No. E63), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals*, in bulk, in tank vehicles, from points in Robertson County, Tenn., to points in that part of Michigan on and east of a line beginning at the Michigan-Ohio State line extending along U.S. Highway 23 to Mackinaw City, Mich., and points in Pennsylvania and West Virginia. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112617 (Sub-No. E64), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals*, in bulk, in tank vehicles, from points in Robertson County, Tenn., to points in Oklahoma, Texas, Louisiana, Kansas, Nebraska, Iowa, Minnesota, Wisconsin, and points within the St. Louis, Mo.-East St. Louis, Ill., commercial zone. The purpose of this filing is to eliminate the gateway of Calvert City, Ky.

No. MC 112617 (Sub-No. E69), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395,

Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Bituminous materials*, used in the construction and maintenance of highways, in bulk, in tank vehicles, from points in Kentucky to points in that part of Virginia on and east of a line beginning at the West Virginia-Virginia State line extending along U.S. Highway 33 to junction U.S. Highway 15, thence along U.S. Highway 15 to the North Carolina-Virginia State line. The purpose of this filing is to eliminate the gateway of refineries at or near Leach, Ky.

No. MC 112617 (Sub-No. E82), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals*, as described in Appendix XV to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from Seymour, Ind., and Freeman Field (near Seymour), Ind., to points in Nebraska, Kansas, Oklahoma, and Texas. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112617 (Sub-No. E84), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 (except petroleum products described in Appendices XIV and XV to the *Descriptions* case, *supra*), in bulk, in tank vehicles, from Seymour, Ind., and Freeman Field (near Seymour), Ind., to points in Rhode Island, Vermont, New Hampshire, Massachusetts, Connecticut, New Jersey, Delaware, and the District of Columbia. The purpose of this filing is to eliminate the gateway of refineries at or near Leach, Ky.

No. MC 112617 (Sub-No. E96), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquefied petroleum gases*, in bulk, in tank vehicles, from points in Butler County, Ohio, to points in Brooke, Hampshire, Hancock, Kanawha, Marion, Marshall, Monongalia, Pleasants, and Wetzel Counties, W. Va., and to points in that part of Virginia north and east of a line beginning at the West Virginia-Virginia State line. The purpose of this filing is to eliminate the gateway of the plant site of the Columbia Hydrocarbon Corporation at or near Siloam, Ky.

No. MC 112617 (Sub-No. E97), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, in bulk, in tank vehicles, from the pipeline terminal site of the Texas Eastern Transmission Corporation at or near Lebanon, Warren County, Ohio, to points in Alabama, Georgia, Mississippi, South Carolina, and Tennessee. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112617 (Sub-No. E106), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles, from West Henderson, Ky., to points in Virginia. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112617 (Sub-No. E107), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles E. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, as described in Appendix XIII to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 (except petroleum products described in Appendices XIV and XV to the *Descriptions* case, *supra*), in bulk, in tank vehicles, from Louisville, Ky., to points in New Hampshire, Rhode Island, and points in those parts of Connecticut and Massachusetts on and east of a line beginning at New Haven, Conn., extending along Interstate Highway 91 to the Massachusetts-Vermont State line. The purpose of this filing is to eliminate the gateways of Doe Run, Ky., Seymour, Ind., and refineries at or near Leach, Ky.

No. MC 112617 (Sub-No. E108), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles R. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals* and *petroleum products*, in bulk, in tank vehicles, from Louisville, Ky., to points in that part of Michigan on and north of a line beginning at Detroit, Mich., extending along Interstate Highway 96 to Muskegon, Mich., restricted against any transportation to or from points in Indiana within the Louisville, Ky., commercial zone. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112617 (Sub-No. E109), filed May 11, 1974. Applicant: LIQUID TRANSPORTERS, INC., P.O. Box 21395, Louisville, Ky. 40221. Applicant's representative: Charles R. Dunford (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Chemicals* and *petroleum products*, in bulk, in tank vehicles, from Louisville, Ky., to points in Perry, Spencer, and Warrick Counties, Ind., restricted against any transportation to or from points in Indiana within the Louisville, Ky., commercial zone. The purpose of this filing is to eliminate the gateway of Doe Run, Ky.

No. MC 112668 (Sub-No. E2) (Correction), filed May 16, 1974, published in the FEDERAL REGISTER February 4, 1975. Applicant: HARVEY R. SHIPLEY & SONS, INC., RFD, Finksburg, Md. 21048. Applicant's representative: Norman E. Shipley (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Salt*, in bulk, in dump vehicles (except feed ingredients, rock salt and rock salt compounds intended for use in the melting of ice and snow) from Retsof, N.Y., to points in Kent and Sussex Counties, Del. The purpose of this filing is to eliminate the gateway of Glyndon, Md. The purpose of this correction is to extend the territorial destination points.

No. MC 114019 (Sub-No. E348), (Correction), filed June 3, 1974, published in the FEDERAL REGISTER March 3, 1975. Applicant: MIDWEST EMERY FREIGHT SYSTEM, INC., 7000 S. Pulaski Rd., Chicago, Ill. 60629. Applicant's representative: Arthur J. Sibik (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fish and seafoods*, fresh or frozen, from points in that part of Massachusetts on and east of a line beginning at the New Hampshire-Massachusetts State line and extending along Massachusetts Highway 1A to junction Massachusetts Highway 3, thence along Massachusetts Highway 3 to junction with the Barnstable-Plymouth County line, points in Barnstable County, and those on, east, or south of U.S. Highway 6, points in that part of Rhode Island on, east, or south of U.S. Highway 1 to points in Minnesota. The purpose of this filing is to eliminate the gateway of Cleveland, Ohio. The purpose of this correction is to correct the destination point.

No. MC 114211 (Sub-No. E990), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery* and *parts* thereof (except commodities which because of size or weight require the use of special equipment and except commodities described in *Mercer Extension—Oil Field Commodities*, 74 M.C.C. 459), from Vinton, Iowa, to points in that part of Arizona on and south

of a line beginning at the New Mexico-Arizona State line extending along U.S. Highway 66 to junction Arizona-California State line; to points in that part of New Mexico on and south of a line beginning at the Texas-New Mexico State line extending along U.S. Highway 70 to junction U.S. Highway 380, thence along U.S. Highway 380 to junction U.S. Highway 85, thence along U.S. Highway 85 to junction U.S. Highway 60, thence along U.S. Highway 60 to junction New Mexico Highway 36, thence along New Mexico Highway 36 to junction New Mexico Highway 32, thence along New Mexico Highway 32 to junction Interstate Highway 40, thence along Interstate Highway 40 to the New Mexico-Arizona State line; and to points in that part of California on and south of a line beginning at the Arizona-California State line extending along U.S. Highway 66 to junction California Highway 58, thence along California Highway 58 to junction California Highway 99, thence along California Highway 99 to junction California Highway 140, thence along California Highway 140 to junction Interstate Highway 5, thence along Interstate Highway 5 to junction California Highway 152, thence along California Highway 152 to junction California Highway 1, thence along California Highway 1 to Santa Cruz, Calif., with no transportation for compensation on return except as otherwise authorized. The purpose of this filing is to eliminate the gateways of Nebraska City and Beatrice, Nebr., and Claremore, Okla.

No. MC 114211 (Sub-No. E991), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cast iron pressure pipe* and *fittings* and *accessories* therefor when moving with such pipe, from Bridgeton, N.J., and Macungie, Pa., to points in that part of Minnesota on and west of a line beginning at the Iowa-Minnesota State line extending along U.S. Highway 71 to junction U.S. Highway 10, thence along U.S. Highway 10 to junction U.S. Highway 59, thence along U.S. Highway 59 to the United States-Canada International Boundary line, with no transportation for compensation on return except as otherwise authorized. The purpose of this filing is to eliminate the gateway of the plant site of Griffin Pipe Company located at or near Council Bluffs, Iowa.

No. MC 114211 (Sub-No. E992), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Self-propelled farm machinery and parts* thereof, from Walford, Iowa, to points in that part of Wyoming on and west of a line beginning at the South Dakota-Wyoming State line extending along U.S. Highway 14 to junction Interstate Highway 90, thence along Interstate Highway 90 to junction U.S. Highway 16, thence along U.S. Highway 16 to junction U.S. Highway 20, thence along U.S. Highway 20 to junction U.S. Highway 26, thence along U.S. Highway 26 to junction Wyoming Highway 789, thence along Wyoming Highway 789 to junction Wyoming Highway 28, thence along Wyoming Highway 28 to junction U.S. Highway 187, thence along U.S. Highway 187 to junction Wyoming Highway 351, thence along Wyoming Highway 351 to junction U.S. Highway 189, thence along U.S. Highway 189 to the Utah-Wyoming State line; to points in that part of Utah on and west of a line beginning at the Utah-Wyoming State line extending along U.S. Highway 189 to junction Interstate Highway 15, thence along Interstate Highway 15 to junction Utah Highway 28, thence along Utah Highway 28 to junction U.S. Highway 89, thence along U.S. Highway 89 to the Arizona-Utah State line; to points in that part of Arizona on and west of a line beginning at the Utah-Arizona State line extending along U.S. Highway 89 to junction Interstate Highway 17, thence along Interstate Highway 17 to junction U.S. Highway 80, thence along U.S. Highway 80 to junction Arizona Highway 88, thence along Arizona Highway 88 to junction U.S. Highway 60, thence along U.S. Highway 60 to junction Arizona Highway 77, thence Arizona Highway 77 to junction U.S. Highway 89, thence along U.S. Highway 89 to the United States-Mexico International Boundary line; and to points in Montana, Washington, Oregon, California, Idaho, and Nevada, with no transportation for compensation on return except as otherwise authorized. The purpose of this filing is to eliminate the gateway of Minneapolis, Minn.

No. MC 114211 (Sub-No. E993), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery* and *parts* thereof (except commodities the transportation of which because of size or weight, requires special equipment), from Manchester, Iowa, to points in New Mexico (except Las Cruces, Demming, and Lordsburg), and to points in Texas (except Dallas, Ft. Worth, Houston, Galveston, Abilene, Sweetwater, Big Springs, Midland, Odessa, and El Paso), and to points in Louisiana, and to points in that part of Arkansas on and south of a line beginning at the Oklahoma-Arkansas State line extending along Interstate Highway 40 to junction U.S. Highway 71, thence along U.S. Highway 71 to junction Arkansas Highway 10, thence along Arkansas Highway 10 to junction U.S. Highway 65, thence along U.S. Highway 65 to junction U.S. Highway 82, thence along U.S. Highway 82 to the Arkansas-Mississippi State line; to points in that part of Mississippi on, south, and west of a line beginning at Clarksdale, Miss., extending along U.S. Highway 49E to junction Mississippi Highway 12, thence along Mississippi Highway 12 to junction Mississippi Highway 35, thence along Mississippi Highway 35 to junction Mississippi Highway 19, thence along Mississippi Highway 19 to the Mississippi-Alabama State line; to points in that part of Alabama on, south, and west of a line beginning at the Mississippi-Alabama State line extending along Alabama Highway 10 to junction U.S. Highway 43, thence along U.S. Highway 43 to junction U.S. Highway 84, thence along U.S. Highway 84 to junction Alabama Highway 55, thence along Alabama Highway 55 to junction U.S. Highway 331, thence along U.S. Highway 331 to the Alabama-Florida State line; and to points in that part of Florida on and west of a line beginning at the Alabama-Florida State line extending along U.S. Highway 331 to junction U.S. Highway 98, thence along U.S. Highway 98 to Panama City, Fla., with no transportation for compensation on return except as otherwise authorized. The purpose of this filing is to eliminate the gateways of Des Moines, Iowa, Tulsa, Okla., Martin City, Mo., and points in Kansas within 15 miles of Martin City, Mo.

No. MC 114211 (Sub-No. E994), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery* (except commodities which, because of size or weight, requires special equipment, and except commodities described in *Mercer Extension-Oil Field Commodities*, 74 M.C.C. 459), from Grinnell, Iowa, to points in that part of California on and south of a line beginning at the California-Arizona State line extending along U.S. Highway 66 to junction California Highway 58, thence along California Highway 58 to junction California Highway 99, thence along California Highway 99 to junction California Highway 59, thence along California Highway 59 to junction California Highway 152, thence along California Highway 152 to junction California Highway 1, thence along California Highway 1 to Santa Cruz, Calif., and points in that part of Arizona on and south of a line beginning at the New Mexico-Arizona State line extending along U.S. Highway 66 to the Arizona-California State line, with no transportation for compensation on return except as otherwise authorized. The purpose of this filing is to eliminate the gateways of Nebraska City, and Beatrice, Nebr., and Claremore, Okla.

No. MC 114211 (Sub-No. E995), filed July 3, 1974. Applicant: WARREN

TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery* (except, in each instance, commodities which because of size or weight, require the use of special equipment, and except commodities described in *Mercer Extension-Oil Field Commodities*, 74 M.C.C. 459), from Manchester, Iowa, to points in Arizona, New Mexico, and to points in that part of Louisiana on and west of a line beginning at the Arkansas-Louisiana State line extending along Louisiana Highway 551 to junction Louisiana Highway 143, thence along Louisiana Highway 143 to junction U.S. Highway 165, thence along U.S. Highway 165 to junction Louisiana Highway 1, thence along Louisiana Highway 1 to junction Louisiana Highway 20, thence along Louisiana Highway 20 to junction Louisiana Highway 24, thence along Louisiana Highway 24 to Houma, La.; to points in that part of Arkansas on and west of a line beginning at the Oklahoma-Arkansas State line extending along Arkansas Highway 16 to junction Arkansas Highway 23, thence along Arkansas Highway 23 to junction Arkansas Highway 10, thence along Arkansas Highway 10 to junction Arkansas Highway 7, thence along Arkansas Highway 7 to junction U.S. Highway 82, thence along U.S. Highway 82 to junction Arkansas Highway 275, thence along Arkansas Highway 275 to the Arkansas-Louisiana State line; to points in that part of California on and south of a line beginning at the Nevada-California State line extending along California Highway 3 to junction California Highway 168, thence along California Highway 168 to junction U.S. Highway 395, thence along U.S. Highway 395 to junction California Highway 120, thence along California Highway 120 to junction California Highway 49, thence along California Highway 49 to junction California Highway 12, thence along California Highway 12 to junction California Highway 1, thence along California Highway 1 to Salmon, Calif.; and to points in that part of Nevada on and south of a line beginning at the Arizona-Nevada State line extending along Interstate Highway 15 to junction U.S. Highway 95, thence along U.S. Highway 95 to junction Nevada Highway 3, thence along Nevada Highway 3 to the Nevada-California State line, with no transportation for compensation on return except as otherwise authorized. The purpose of this filing is to eliminate the gateways of Des Moines, Iowa, Claremore, Okla., Martin City, Mo., and points in Kansas within 15 miles of Martin City, Mo.

No. MC 114211 (Sub-No. E1147), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery and parts* thereof (except commodities the transportation of which, because of size or weight, require the use of special equipment, from McHenry County, Ill., to points in that part of Texas on and west of a line beginning at the Arkansas-Texas State line extending along Texas Highway 8 to junction Texas Highway 98, thence along Texas Highway 98 to junction U.S. Highway 67, thence along U.S. Highway 67 to junction U.S. Highway 259, thence along U.S. Highway 259 to junction Texas Highway 149, thence along Texas Highway 149 to junction U.S. Highway 96, thence along U.S. Highway 96 to Fort Arthur, Tex. (except Dallas, Fort Worth, Abilene, Houston, Galveston, Midland, Big Springs, Sweetwater, Odessa, and El Paso). The purpose of this filing is to eliminate the gateways of Des Moines, Iowa, Tulsa, Okla., Martin City, Mo., and points in Kansas within 15 miles of Martin City, Mo.

No. MC 114211 (Sub-No. E1148), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery* and *parts* thereof (except commodities the transportation of which because of size or weight, require the use of special equipment), from McHenry County, Ill., to points in that part of Texas on and west of a line beginning at the Arkansas-Texas State line extending along Texas Highway 8 to junction U.S. Highway 59, thence along U.S. Highway 59 to junction U.S. Highway 96, thence along U.S. Highway 96 to junction U.S. Highway 69, thence along U.S. Highway 69 to Port Arthur, Tex. (except Dallas, Fort Worth, Houston, Galveston, Midland, Big Springs, Sweetwater, Odessa, and El Paso). The purpose of this filing is to eliminate the gateways of Des Moines, Iowa, Tulsa, Okla., Martin City, Mo., and points in Kansas within 15 miles of Martin City, Mo.

No. MC 114211 (Sub-No. E1151), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Farm machinery and parts* thereof (except commodities which because of size or weight, require the use of special equipment), from McHenry County, Ill., to points in that part of California on, west, and south of a line beginning at the Nevada-California State line extending along U.S. Highway 6 to junction California Highway 120, thence along California Highway 120 to junction California Highway 49, thence along California Highway 49 to junction California Highway 16, thence along California Highway 16 to junction Interstate Highway 80, thence along Interstate Highway 80 to junction Interstate Highway 5, thence along Interstate Highway 5 to the California-Oregon State line; and to points in that part of Nevada on and west of a line beginning at the California-Nevada State line extending along U.S. Highway 6 to junction U.S. Highway 95, thence along U.S. Highway 95 to junction U.S. Highway 93, thence along U.S. Highway 93 to the Nevada-Arizona State line; to points in that part of Arizona on and south of a line beginning at the Nevada-Arizona State line extending along U.S. Highway 93 to junction U.S. Highway 66, thence along U.S. Highway 66 to the Arizona-New Mexico State line; to points in that part of New Mexico on and south of a line beginning at the Arizona-New Mexico State line extending along Interstate Highway 40 to junction U.S. Highway 666, thence along U.S. Highway 666 to junction U.S. Highway 550, thence along U.S. Highway 550 to junction U.S. Highway 64, thence along U.S. Highway 64 to junction U.S. Highway 85, thence along U.S. Highway 85 to the New Mexico-Colorado State line; and to points in that part of Oklahoma on and west of a line beginning at the Arkansas-Oklahoma State line, extending along U.S. Highway 70 to junction Oklahoma Highway 3, thence along Oklahoma Highway 3 to junction Indian Nation Tollway, thence along Indian Nation Tollway to junction U.S. Highway 75, thence along U.S. Highway 75 to junction U.S. Highway 64, thence along U.S. Highway 64 to junction U.S. Highway 177, thence along U.S. Highway 177 to the Oklahoma-Kansas State line, thence along the Oklahoma-Kansas State line to junction U.S. Highway 64, thence along U.S. Highway 64 to junction U.S. Highway 54, thence along U.S. Highway 54 to the Oklahoma-New Mexico State line. The purpose of this filing is to eliminate the gateways of Des Moines, Iowa, Martin City, Mo., Claremore, Okla., and points in Kansas within 15 miles of Martin City, Mo.

No. MC 114211 (Sub-No. E1153), filed July 3, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Grading, paving*, and *finishing machinery, equipment, parts, accessories*, and *attachments*, between Oregon, Ill., on the one hand, and, on the other, points in Washington, Oregon, California, Idaho, Montana, Wyoming, Nevada, Utah, Arizona, New Mexico, North Dakota, South Dakota; and to points in that part of Texas on and west of a line beginning at the Texas-Oklahoma State line extending along U.S. Highway 385 to junction U.S. Highway 290, thence along U.S. Highway 290 to junction Texas Highway 349, thence along Texas Highway 349 to junction U.S. Highway 90, thence along U.S. Highway 90 to Del Rio, Tex. The purpose of this filing is to eliminate the gateways of Canton, S. Dak., and points in Iowa.

No. MC 115826 (Sub-No. E23), filed June 4, 1974. Applicant: W. J. DIGBY, INC., P.O. Box 5088, Denver, Colo. 80217. Applicant's representative: Charles J.

Kimball, 2310 Colorado State Bank Bldg., Denver, Colo. 80202. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fresh lamb carcasses*, suspended or in racks, in vehicles equipped with mechanical refrigeration, from those points in California on, west, and north of a line beginning at the Pacific Ocean and extending along California Highway 55 to junction California Highway 91, thence along California Highway 91 to junction U.S. Highway 395, thence along U.S. Highway 395 to junction U.S. Highway 6, thence along U.S. Highway 6 to the California-Nevada State line, to the District of Columbia, Philadelphia, Pa., Albany and New York, N.Y., Boston, Mass., Waterbury, Conn., and Providence, R.I. The purpose of this filing is to eliminate the gateway of Nampa, Idaho.

No. MC 115826 (Sub-No. E41), filed June 4, 1974. Applicant: W. J. DIGBY, INC., P.O. Box 5088, Denver, Colo. 80202. Applicant's representative: Charles J. Kimball, 2310 Colorado State Bank Bldg., Denver, Colo. 80202. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods, frozen juice*, and *frozen juice concentrate*, in vehicles equipped with mechanical refrigeration, (1) from those points in California on, west, and north of a line beginning at the Pacific Ocean and extending along California Highway 55 to junction California Highway 91, thence along California Highway 91 to junction U.S. Highway 395, thence along U.S. Highway 395 to junction Interstate Highway 15, thence along Interstate Highway 15 to Barstow, Calif., thence along California Highway 58 to junction U.S. Highway 395, thence along U.S. Highway 395 to junction U.S. Highway 6, thence along U.S. Highway 6 to the California-Nevada State line, to those points in Kansas on, east, and north of a line beginning at the Kansas-Nebraska State line and extending along U.S. Highway 81 to junction U.S. Highway 40, thence along U.S. Highway 40 to Lawrence, Kans., thence along Kansas Highway 10 to junction Interstate Highway 35, thence along Interstate Highway 35 to the Kansas-Missouri State line, and those points in Missouri on, north, and east of a line beginning at the Kansas-Missouri State line and extending east along U.S. Highway 50 to junction U.S. Highway 63, thence along U.S. Highway 63 to Rolla, Mo., thence along U.S. Highway 66 to junction Missouri Highway 8, thence along Missouri Highway 8 to junction U.S. Highway 67, thence along U.S. Highway 67 to junction Missouri Highway 72, thence along Missouri Highway 72 to junction U.S. Highway 61, thence along U.S. Highway 61 to Sikeston, Mo., thence along U.S. Highway 62 to the Missouri-Illinois State line (Franklin, Idaho)*; and (2) from those points in California on and north of a line beginning at the Pacific Ocean and extending along California Highway 68 to junction California Highway 101, thence along California Highway 101 to junction California Highway 152, thence along California Highway 152 to junction Interstate Highway 5, thence along Interstate Highway 5 to junction California Highway 140, thence along California Highway 140 to junction California Highway 49, thence along California Highway 49 to junction California Highway 4, thence along California Highway 4 to the California-Nevada State line, to points in Missouri, Mississippi, and Kansas (except those in Morton, Stevens, Stanton, and Grant Counties, Kans.), and Memphis, Tenn. (Strevell, Idaho)*. The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 117344 (Sub-No. E2), filed May 17, 1974. Applicant: THE MAXWELL CO., 10380 Evendale Drive, Cincinnati, Ohio 45215. Applicant's representative: Thomas L. Maxwell (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* (except liquid hydrogen), in bulk, in tank vehicles, from Cincinnati, Ohio, to points in Illinois. Restriction: The service authorized herein is restricted against the transportation of Petro-chemicals, dry, to points in St. Louis, Mo.-East St. Louis, Ill., Commercial Zone as defined by the Commission. The purpose of this filing is to eliminate the gateway of Jackson County, Ind.

No. MC 117344 (Sub-No. 10), filed May 17, 1974. Applicant: THE MAXWELL CO., 10380 Evendale Drive, Cincinnati, Ohio 45215. Applicant's representative: Thomas L. Maxwell (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Sulphuric Acid*, in bulk, in tank vehicles, from Columbia Park (Hamilton County), Ohio, to points in Illinois (except points in the St. Louis, Mo.-East St. Louis, Ill., Commercial Zone as defined by the Commission), the Upper Peninsula of Michigan, those in the Lower Peninsula of Michigan, on and west of a line beginning at the Michigan-Indiana boundary and extending north along U.S. Route 131 to its junction with U.S. Route 31, thence north along U.S. Route 31 to Mackinaw City (except Grand Rapids, Michigan, and points in its Commercial Zone as defined by the Commission), and points in Wisconsin. The purpose of this filing is to eliminate the gateway of Jackson County, Ind.

No. MC 117344 (Sub-No. E64), filed May 21, 1974. Applicant: THE MAXWELL COMPANY, 10380 Evendale Drive, Cincinnati, Ohio 45215. Applicant's representative: Thomas L. Maxwell (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Dearborn County, Md., Boone County, Ky., and points in Kentucky on and east of U.S. Highway 25 within 100 miles of Cincinnati, Ohio to points in Wisconsin. The purpose of this filing is to eliminate the gateways of Cincinnati, Ohio and Jackson County, Ind.

No. MC 117344 (Sub-No. E84), filed June 2, 1974. Applicant: THE MAXWELL CO., 10380 Evendale Drive, Cincinnati, Ohio 45215. Applicant's representative: Thomas L. Maxwell (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Vegetable oils*, in bulk, in tank vehicles (1) from points in Indiana (except Indianapolis) on, south and west of a line beginning at the Indiana-Ohio State line and extending along U.S. Highway 224 to Huntington, thence along U.S. Highway 24 to Logansport, thence along U.S. Highway 35 to junction U.S. Highway 30, thence along U.S. Highway 30 to junction Interstate Highway 65, thence along Interstate Highway 65 to Gary, to points in Massachusetts, and (2) from points in Indiana north and east of the above-described line and on, south and west of a line beginning at the Indiana-Ohio State line and extending along U.S. Highway 30 to junction U.S. Highway 35, thence along U.S. Highway 35 to Lake Michigan to points in Massachusetts on and east of Interstate Highway 91. The purpose of this filing is to eliminate the gateways of Cincinnati and Columbus, Ohio.

No. MC 117344 (Sub-No. E85), filed May 22, 1974. Applicant: THE MAXWELL CO., 10380 Evendale Drive, Cincinnati, Ohio 45215. Applicant's representative: Stiverson & Alden, P.O. Box 5241, Columbus, Ohio 43212. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lacquers, paints, resins, stains, varnishes and plastics*, in bulk, in tank vehicles, from Dayton, Ohio, to points in Missouri on and south of a line beginning at the Missouri-Illinois State line and extending along Missouri Highway 51 to junction Missouri Highway 34, thence along Missouri Highway 34 to junction U.S. Highway 60, thence along U.S. Highway 60 to Springfield, thence along Missouri Highway 13 to Clinton, thence along Missouri Highway 7 to its junction with Interstate Highway 71, thence along Interstate Highway 71 to Kansas City, Mo. The purpose of this filing is to eliminate the gateway of the facilities of the Polymers & Chemical Division of W. R. Grace & Co., at Owensboro, Ky.

No. MC 121060 (Sub-No. E24), filed March 3, 1975. Applicant: ARROW TRUCK LINES, INC., P.O. Box 1416, Birmingham, Ala. 35207. Applicant's representative: William P. Jackson, Jr., 919 Eighteenth St. NW., Washington, D.C. 20006. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: *Roofing and roofing materials, gypsum, and gypsum products, composition boards, insulation materials, and urethane and urethane products* (except in bulk and intended for use in construction), (1) from the facilities of the Celotex Corporation at Memphis, Tenn., to points in the District of Columbia, New Jersey, Delaware, and points in Maryland on and east of U.S. Highway 15, and (2) from

the facilities of the Celotex Corporation at points in Henry County, Tenn., to the District of Columbia, Delaware, points in Maryland on and east of a line beginning at the Virginia-Maryland State line west of Washington, D.C., thence along Interstate Highway 495 to its junction with U.S. Highway 29, thence along U.S. Highway 29 to its junction with Interstate Highway 70N, thence along Interstate Highway 70N to its junction with Interstate Highway 695, thence along Interstate Highway 695 west of Baltimore to its junction with Interstate Highway 83, thence along Interstate Highway 83 to the Maryland-Pennsylvania State line, and points in New Jersey, on and east of a line beginning at the New Jersey-Pennsylvania State line, thence extending along U.S. Highway 202 to junction with New Jersey Highway 53, thence along New Jersey Highway 53 to its junction with Interstate Highway 80, thence along Interstate Highway 80 to its junction with New Jersey Highway 513, thence along New Jersey Highway 513 to its junction with New Jersey Highway 511, thence along New Jersey Highway 511 to the New Jersey-New York State line. The purpose of this filing is to eliminate the gateway of Wayne County, N.C.

No. MC 123685 (Sub-No. E23), filed May 15, 1974. Applicant: PEOPLES CARTAGE, INC., 8045 Navarre Road SW., Massillon, Ohio 44646. Applicant's representative: James W. Muldoon (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fertilizer, fertilizer ingredients, and pesticides*, in bulk, in dump vehicles, between those points in Ohio on and east and south of a line beginning at the Ohio-Pennsylvania State line and extending along Ohio Highway 82 to junction Ohio Highway 5, thence along Ohio Highway 5 to junction Interstate Highway 76, thence along Interstate Highway 76 to junction Ohio Highway 3, thence along Ohio Highway 3 to junction U.S. Highway 250, thence along U.S. Highway 250 to the Ohio-West Virginia State line, and on and east and north of a line beginning at Lake Erie and extending along Ohio Highway 76 to junction U.S. Highway 250, thence along U.S. Highway 250 to the Ohio-West Virginia State line, on the one hand, and, on the other, points in Michigan, Illinois, and Indiana. The purpose of this filing is to eliminate the gateway of Orrville, Ohio.

No. MC 136166 (Sub-No. E1), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles, from points in California (except Lassen, Modoc, and San Bernardino (east of Barstow) Counties. The purpose of this filing is to eliminate the gateways of Santa Clara and Long Beach, Calif.

No. MC 136166 (Sub-No. E2), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles, from Chicago, Ill., to points in California. The purpose of this filing is to eliminate the gateway of Salt Lake City, Utah.

No. MC 136166 (Sub-No. E3), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles, from Louisville, Ky., to points in California. The purpose of this filing is to eliminate the gateway of the site of the Thiokol Chemical Corporation plant near Corrine, Utah.

No. MC 136166 (Sub-No. E4), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid latex*, in bulk, in tank vehicles, from points in California (except Alpine, Butte, Del Norte, Glenn, Lake, Lassen, Modoc, Mono, Nevada, Placer, Plumas, Riverside, San Bernardino, Shasta, Sierra, Siskiyou, and Tehama Counties to points in Wisconsin. The purpose of this filing is to eliminate the gateway of Torrance, Calif.

No. MC 136166 (Sub-No. E5), filed May 10, 1974. Applicant: CFF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid weed killing chemicals*, in bulk, in tank vehicles, from points in that part of California located in and north in Inyo, Kern, and Santa Barbara Counties to Tampa, Fla. The purpose of this filing is to eliminate the gateway of Richmond, Calif.

No. MC 136166 (Sub-No. E6), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Phenol*, in bulk, in tank vehicles, from Riverview, Ohio, to points in Nevada (except Elko, Eureka, Lander, and White Pine Counties). The purpose of this filing is to eliminate the gateways of points in California.

No. MC 136166 (Sub-No. E8), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid chemicals*, in bulk, in tank vehicles, from Atlas Point, Del., to points in Nevada (except Elko and Lander Counties). The purpose of this filing is to eliminate the gateway of points in California.

No. MC 136166 (Sub-No. E9), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid latex*, in bulk, in tank vehicles, from points in California (except Alpine, Del Norte, Imperial, Inyo, Lassen, Modoc, Mono, Nevada, Placer, Plumas, Sierra, Siskiyou, and San Bernardino (east of Barstow) Counties) to points in Missouri. The purpose of this filing is to eliminate the gateway of Torrance, Calif.

No. MC 136166 (Sub-No. E10), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Materials used in the manufacture of plastics*, in bulk, in tank vehicles, from Longview, Wash., and points within five miles thereof to points in California. The purpose of this filing is to eliminate the gateway of Progress, Oreg.

No. MC 136166 (Sub-No. E11), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Liquid petroleum products*, in bulk, in tank vehicles, from points in that part of Washington west of the Cascade Mountains to points in Ada, Canyon, Gem, Payette, and Washington Counties, Idaho. The purpose of this filing is to eliminate the gateway of Portland, Oreg.

No. MC 136166 (Sub-No. E12), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Weed killing compounds, agricultural insecticides*, and *bichromate of soda*, in bulk, in tank vehicles, from Des Moines, Iowa, to points in Nevada, (except Elko, Eureka, Humboldt, Lander, Lincoln, and White Pine Counties). The purpose of this filing is to eliminate the gateways of points in California.

No. MC 136166 (Sub-No. E13), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Weed killing compounds, agricultural insecticides*, and *bichromate of soda*, in bulk, in tank vehicles, from Painesville, Ohio, to points in Nevada (except Elko, Eureka, Lander, Lincoln,

and White Pine Counties). The purpose of this filing is to eliminate the gateways of points in California.

No. MC 136166 (Sub-No. E14), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Weed killing chemicals*, liquid, in bulk, in tank vehicles, from the plant sites of storage facilities of Stauffer Chemical Company at Le Moyne, Ala., to points in California [except San Bernardino (east of Barstow) County]. The purpose of this filing is to eliminate the gateway of Los Angeles, Calif.

No. MC 136166 (Sub-No. E15), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Laurel, Mont., to points in Del Norte, Humboldt, and Mendocino Counties, Calif. The purpose of this filing is to eliminate the gateways of Boise, Idaho, Pasco, Wash., and points in that part of Oregon east of the Cascade Mountains.

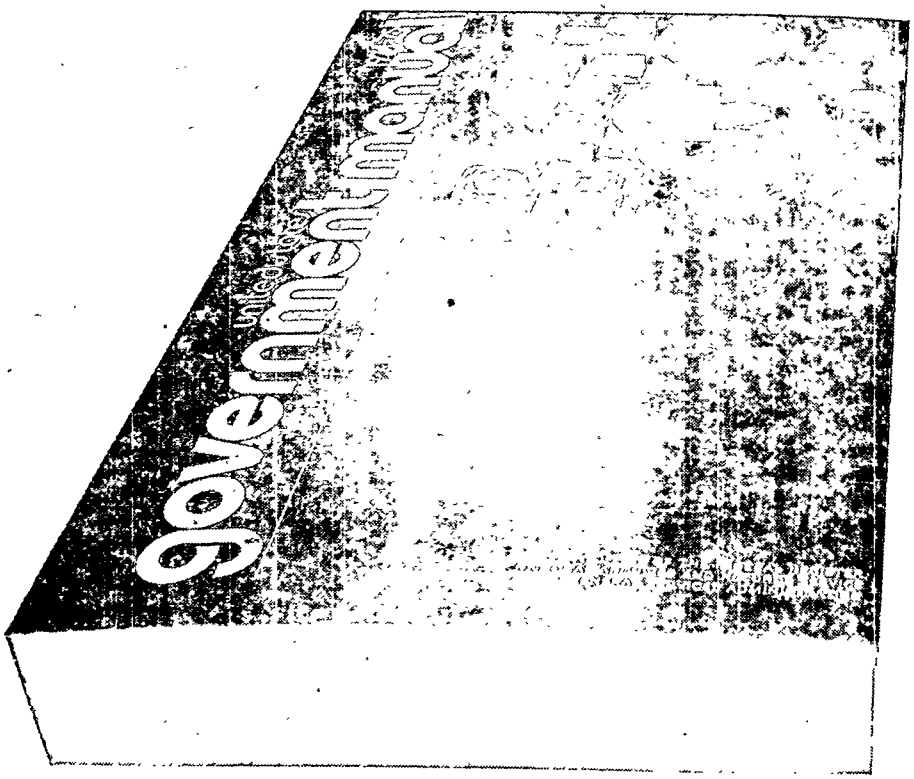
No. MC 136166 (Sub-No. E16), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Lovell, Casper, and Zube, Wyo., to points in Skamania, Yakima, Kittitas, Chelan, and Okanogan Counties, Wash. The purpose of this filing is to eliminate the gateway of Boise, Idaho.

No. MC 136166 (Sub-No. E17), filed May 10, 1974. Applicant: CF TANK LINES, INC., P.O. Box 3062, Portland, Oreg. 97208. Applicant's representative: E. V. Taylor (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products*, in bulk, in tank vehicles, from Lovell, Casper, and Zube, Wyo., to points in Jefferson, Deschutes, Klamath, and Lake Counties, Oreg. The purpose of this filing is to eliminate the gateways of Boise, Idaho, and Pasco, Wash.

By the Commission.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.75-8026 Filed 3-26-75;8:45 am]



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WASHINGTON, D.C.

Volume 40 ■ Number 60

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

ANIMAL DRUG PROCEDURE

Reorganization and Republication

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 8]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

ANIMAL DRUG PROCEDURE

Reorganization and Republication

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the eighth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

This body of regulations includes the animal drug procedural regulations formerly under Parts 3, 130, 131, 135, 144, 146, and 148, reorganized under five separate parts: 500, 505, 510, 511, and 514, which are divided into Subparts. The regulations consisting of new animal drug application approvals of drugs, not subject to certification, administered under various dosage forms under Parts 135a, 135b, 135c, 135d, and 135f have been reorganized and placed in Parts 520 through 529 and assigned numbers according to the basic drug. The drugs are arranged using a master numbering system that gives each drug the same number to the right of the decimal point in all parts. The certificable animal drugs have been incorporated into their particular categories according to their requirements for certification, tests and methods of assay and their conditions of marketing. Each drug is keyed to the bulk drug section established in the human drug recodification published in the FEDERAL REGISTER of May 30, 1974 (39 FR 18922), and carries a uniform last two digits throughout the various dosage forms. The animal drugs subject to certification include animal drug provisions from Parts 141a through 151c which are now Parts 540, 544, 546, and 548. Also included in this body of regulations are the animal feed and tolerances regulations formerly Parts 135g and 135e now Parts 556 and 558, respectively.

The following table shows the relationship of the CFR section numbers under the former Subchapters A and C to this redesignation reflected in Parts 500 through 558:

Old section	New section
3.25	510.110.
3.55	510.112.
3.68	558.4.
3.517	510.6.
130.201	510.120.
131.11	505.3.
131.20	505.20.
131.21	505.10.
135.1	510.3.
135.2	510.4.
135.3	511.1.
135.4a	514.1.
135.4b	514.2.
135.5	510.5.
135.6	510.7.
135.7	514.110.
135.8	514.100.
135.9	514.6.
135.10	514.7.
135.11	514.105.
135.12	514.111.
135.13a	514.8.
135.13b	514.9.
135.14a	510.300.
135.14b	510.301.
135.14c	510.302.
135.15	514.200.
135.16	514.201.
135.17	514.202.
135.18	514.203.
135.19	514.204.
135.20	514.220.
135.21	514.221.
135.22	514.222.
135.23	514.205.
135.24	514.206.
135.25	514.230.
135.26	514.231.
135.27	514.232.
135.28	514.115.
135.29	514.120.
135.30	514.121.
135.31	514.15.
135.32	514.235.
135.33	514.12.
135.33a	514.11.
135.34	514.116.
135.35	510.310.
135.36	510.200.
135.37	510.95.
135.101	510.410.
135.102	510.450.
135.103	510.105.
135.104	500.40.
135.105	500.35.
135.106	510.440.
135.107	500.55.
135.108	500.65.
135.109	558.15.
135.111	500.25.
135.112	558.5.
135.113	500.45.
135.114	500.52.
135.501	510.600.
135a.2	524.660a.
135a.3	555.310e(c).
135a.4	524.321.0
135a.5	524.120a.
135a.6	524.1200b.
135a.7	524.920.
135a.8	524.1204.
135a.9	555.310d(c).
135a.10	524.1982.
135a.11	524.1600b.
135a.12	524.1600a.
135a.13	524.1700.
135a.14	524.1742.
135a.15	555.310f(c).
135a.16	524.2481.
135a.17	524.1000.
135a.18	524.1484g.
135a.19	524.1580.
135a.20	524.1883.
135a.21	524.981e.
135a.22	524.1044.
135a.23	524.981d.
135a.24	524.1662b.
135a.25	524.1880.
135a.26	524.2620.
135a.27	524.1881a.
135a.28	524.1484a.
135a.29	555.310c(c).
135a.30	524.1484b.
135a.31	524.1484d.
135a.32	524.1484f.
135a.33	524.981c.
135a.34	524.1484c.
135a.35	524.402.
135a.37	524.2640.
135a.38	548.314b(c).
135a.39	524.1484e.
135a.40	524.960.
135a.41	524.2140.
135a.42	524.1662a.
135a.43	524.900.
135a.44	524.2542.
135a.45	548.314a(c).
135a.47	524.541.
135a.48	524.1881b.
135a.49	524.660b.
135a.50	524.981a.
135a.51	524.463.
135a.52	524.981b.
135a.56	524.520.
135a.57	524.1301.
135a.58	524.1443.
135b.2	522.2640.
135b.3	522.640
135b.4	522.1940.
135b.5	522.842.
135b.6	522.2350
135b.7	522.844.
135b.8	522.2340.
135b.9	522.2240.
135b.10	522.2200.
135b.11	522.1260.
135b.12	522.2680.
135b.13	522.161.
135b.14	522.961.
135b.15	522.2220.
135b.16	522.1563.
135b.17	522.1380.
135b.18	522.1204.
135b.19	522.1044.
135b.21	522.144.
135b.22	522.62.
135b.23	522.2120.
135b.24	540.280(c).
135b.25	540.274a(c).
135b.27	540.265b(c).
135b.28	522.1222.
135b.29	522.2480.
135b.30	522.480.
135b.32	522.960.
135b.34	522.1020.
135b.35	522.1884.
135b.36	522.1462.
135b.37	522.800.
135b.38	522.1182.
135b.39	522.2424.
135b.40	522.1484.
135b.41	540.207b(c).
135b.42	522.82.
135b.43	540.255c(c).
135b.44	522.1862.
135b.45	522.340.
135b.46	522.2002.
135b.47	522.1720.
135b.49	540.274b.
135b.50	522.1081.
135b.51	522.44
135b.52	522.1800.
135b.53	522.2100.
135b.54	522.2444a.
135b.55	522.1920.
135b.56	522.2022.
135b.57	522.380.
135b.58	522.2662.
135b.59	522.204.
135b.60	522.1962.
135b.61	522.940.
135b.62	522.163.
135b.63	522.1060.
135b.64	522.1680.
135b.65	522.1662a.
135b.66	522.1183.
135b.67	522.1620.
135b.69	522.883.
135b.70	522.723.
135b.71	522.740.
135b.72	522.23.
135b.73	522.863.
135b.74	522.1404.
135b.75	522.2063.
135b.77	555.210(c).
135b.79	522.2404.
135b.80	522.423.
135b.82	522.1881.
135b.83	522.540.
135b.84	522.1704.
135b.85	522.1362.
135b.86	522.564.
135b.88	522.281.
135b.89	522.1885.
135b.90	522.1143.
135b.91	522.1244.
135b.92	522.1880.
135b.93	522.1662b.
135b.94	522.784.
135b.95	522.2582.
135b.96	540.274c(c).
135b.97	522.1503.
135b.98	540.255a(c).
135b.99	522.2444a.
135b.100	522.1612.
135b.101	522.1820.
135b.104	540.207a(c).
135c.2	546.110c(c). and 546.110d-(c).
135c.3	520.100.
135c.4	520.2640.
135c.5	520.1660.
135c.6	520.680.
135c.7	520.2380a.
135c.8	520.2320.
135c.9	546.110c(c) and 546.113b-(c).
135c.10	520.2200.
135c.12	520.2002.
135c.13	520.2220a.
135c.14	520.2240.
135c.15	544.173a(c).
135c.16	520.2184.
135c.17	520.1422.
135c.18	520.1242.
135c.19	520.2520b.
135c.20	520.620.
135c.21	520.1100.
135c.22	520.1120a.
135c.23	520.1840.
135c.24	520.2122.
135c.25	520.2162.
135c.26	520.1540.
135c.27	520.222.
135c.28	520.2200.
135c.29	520.1962.
135c.30	520.62.
135c.31	540.129a and 540.129b.
135c.32	520.2123b.
135c.33	520.1204.
135c.35	548.110(c).
135c.36	548.114.
135c.37	548.112b(c).
135c.38	546.110f(c).
135c.39	520.2520a.
135c.40	520.2491.
135c.41	520.2300.
135c.42	520.2301.
135c.43	540.174a(c).
135c.44	544.170b(c).
135c.45	540.174b(c).
135c.46	520.2220b.
135c.47	540.107b(c).
135c.50	520.600.
135c.51	520.1380.
135c.52	520.622b.
135c.53	520.82a.
135c.54	520.1801.
135c.55	520.2480.
135c.56	520.580.
135c.57	520.1720a.
135c.58	520.2080.
135c.59	520.2045.
135c.60	520.2380b.
135c.61	520.440.
135c.62	520.704.
135c.63	555.110b(c).
135c.64	520.44.
135c.65	520.500.
135c.66	520.1780.
135c.67	520.182.
135c.69	520.1802.
135c.70	520.2022.
135c.71	520.1920.
135c.72	540.120c(c).
135c.73	540.119(c).
135c.74	520.2280.
135c.75	520.1720b.
135c.76	520.1760.
135c.77	520.260.
135c.78	520.240.
135c.79	520.540a.
135c.81	520.540b.
135c.82	520.763a.
135c.83	520.763b.
135c.84	520.2560.
135c.85	540.107 d(c).
135c.86	520.622a.
135c.87	520.82b.
135c.88	520.2604.
135c.89	520.863.
135c.92	520.1900.
135c.93	520.2362.
135c.94	520.1263b.
135c.97	520.23.
135c.98	520.1284.
135c.99	555.110c(c).
135c.100	520.1263a.
135c.101	520.1520.
135c.102	555.110a(c).
135c.103	520.1162.
135c.104	520.1320.
135c.105	520.423.
135c.107	540.107c(c).
135c.108	520.1362.
135c.110	540.105(c).
135c.111	520.2160a.
135c.112	520.2582.
135c.113	520.2100.
135c.114	544.110(c).
135c.115	520.784.
135c.116	520.120.
135c.117	520.823.
135c.118	540.181b(c).
135c.119	520.2043.
135c.120	520.1662.
135c.121	540.180d(c).
135c.122	540.180c(c).
135c.123	540.180a(c).
135c.124	540.180b(c).
135c.125	540.180e(c).
135c.127	520.1803.
135c.128	520.2123a.
135c.129	520.1120b.
135c.130	540.107a(c).
135c.131	540.173a(c).
135c.132	520.2160b.
135c.133	540.173b(c).
135c.134	520.2160.
135c.135	520.1341.
135c.136	520.300.
135c.137	540.107c(c).
135d.2	540.829(c).
135d.13	540.874d(c).
135d.14	540.874a(c).
135d.15	540.814a(c).
135d.16	540.814(c).
135d.17	540.874f(c).
135e.2	558.503.
135e.5	558.525.
135e.6	558.55.
135e.7	558.415.
135e.10	558.625.
135e.20	558.615.
135e.31	558.35.
135e.34	558.105.
135e.36	558.630.
135e.39	558.185.
135e.43	558.45.
135e.45	558.435.
135e.46	558.175.
135e.49	558.325.
135e.50	558.355.
135e.51	558.195.
135e.52	558.25.
135e.54	558.205.
135e.55	558.575.
135e.56	558.305.
135e.57	558.365.
135e.58	558.155.
135e.59	558.315.
135e.60	558.465.
135e.61	558.145.
135e.63	558.115.
135e.64	558.485.
135e.65	558.95.
135e.66	558.515.
135e.67	558.565.
135e.69	558.635.
135e.1000	558.10.
135f.2	529.253.0
135f.3	529.1041a.
135f.4	529.1041b.
135f.5	529.360.
135g.1	556.1.
135g.2	556.90.
135g.3	556.320.
135g.4	556.70
135g.5	556.570.
135g.6	556.480
135g.7	556.770.
135g.8	556.150.
135.g9	556.50.
135g.10	556.330.
135g.11	556.610.
135g.12	556.510.
135g.13	556.460.
135g.14	556.500.
135g.15	556.740.
135g.17	556.470.
135g.18	556.290.
135g.20	556.280.
135g.21	556.450.
135g.22	556.260.
135g.23	556.130.
135g.24	556.600.
135g.25	556.430.
135g.26	556.190.
135g.27	556.670.

Old section	New section
135g.28	556.540.
135g.29	556.710.
135g.30	556.240.
135g.31	556.140.
135g.32	556.590.
135g.33	556.60.
135g.34	556.230.
135g.35	556.650.
135g.36	556.290.
135g.37	556.520.
135g.38	556.250.
135g.39	556.730.
135g.40	556.530.
135g.41	556.390.
135g.42	556.550.
135g.43	556.340.
135g.44	556.210.
135g.45	556.220.
135g.47	556.120.
135g.48	556.270.
135g.49	556.370.
135g.52	556.625.
135g.53	556.708.
135g.54	556.110.
135g.55	556.660.
135g.56	556.380.
135g.57	556.640.
135g.58	556.700.
135g.59	556.680.
135g.60	556.30.
135g.61	556.410.
135g.62	556.160.
135g.63	556.350.
135g.64	556.760.
135g.65	556.360.
135g.67	556.400.
135g.68	556.420.
135g.69	556.310.
135g.70	556.170.
135g.71	556.20.
135g.72	556.720.
135g.73	556.690.
135g.75	556.180.
135g.76	556.490.
135g.77	556.630.
135g.79	556.440.
135g.80	556.300.
135g.81	556.100.
135g.82	556.560.
135g.83	556.40.
135g.84	556.380.
135g.85	556.580.
135g.89	556.750.
141a.8	540.380a(b).
141a.9	540.173b(b).
141a.19	540.281b(b).
141a.21	540.180a(b).
141a.22	536.500.
141a.23	540.281a(b).
141a.27	540.274c(b).
141a.29	540.274a(b).
141a.33	540.174a(b).
141a.35	535.501.
141a.36	536.502.
141a.37	536.503.
141a.38	540.274e(b).
141a.39	540.250(b).
141a.42	536.504.
141a.46	540.274d(b).
141a.49	536.505.
141a.54	540.255a(b).
141a.60	540.274f(b).
141a.62	540.255c(b).
141a.63	536.506.
141a.67	536.507.
141a.71	540.174b(b).
141a.74	540.260(b).
141a.82	540.173a(b).
141a.86	536.508.
141a.89	540.380b(b).
141a.90	540.881(b).
141a.93	540.874c(b).
141a.95	536.509.
141a.97	536.510.
141a.98	536.511.
141a.108	540.874b(b).
141a.109	536.512.
141b.107	544.373a(b).
141b.109	544.173a(b).
141b.111	544.274(b).
141b.113	544.173b(b).
141b.115	544.473(b).
141b.116	544.173c(b).
141b.117	536.513.
141b.118	544.211b(b).
141b.119	539.170b.
141b.120	544.173d(b).
141b.122	544.211a(b).
141b.124	544.170b(b).
141b.126	544.370b(b).
141b.128	544.173c(b).
141b.129	544.373c(b).
141b.132	544.973b(b).
141b.134	536.514.
141b.138	536.515.
141c.204	546.180a(b).
141c.205	546.110c(b).
141c.207	546.110d(b).
141c.217	546.180c(b).
141c.219	546.110a(b).
141c.223	536.516.
141c.228	546.110f(b).
141c.237	546.312a(b).
141c.241	546.110b(b).
141c.256	546.110g(b).
141c.264	539.210c.
141c.265	546.113a(b).
141c.267	539.210b.
141c.268	536.517.
141d.303	555.310c(b).
141e.403	548.212(b).
141e.416	539.310b.
141e.417	548.112d(b).
141e.422	548.310b.
141e.423	548.112a(b).
141e.425	548.110(b).
141e.426	548.112b(b).
141e.427	548.113(b).
141e.428	548.112c(b).
141e.429	536.518.
141e.431	548.111(b).
144.11	510.505.
144.25	510.510.
144.26	510.515.
146.2	514.50.
146.3	514.51.
146.4	514.150.
146.5	510.350.
146.6	514.155.
146.8	514.60.
146.9	514.160.
146.13	514.55.
146.15	514.210.
146.16	514.10.
146a.24	540.280(a).
146a.26	540..380a(a).
146a.27	540.173b(a).
146a.28	540.181a.
146a.34	540.153(a).
146a.39	540.174c(a).
146a.41	540.281a(a).
146a.43	540.253.
146a.45	540.274c(a).
146a.47	540.274a(a).
146a.49	540.163(a).
146a.51	540.174a(a).
146a.53	540.150a(a).
146a.57	540.274e(a).
146a.58	540.250(a).
146a.61	539.73.
146a.62	540.874c(a).
146a.65	540.265a.
146a.66	540.265b(a).
146a.67	540.274d(a).
146a.69	540.155(a).
146a.75	540.261.
146a.77	540.255a(a).
146a.80	540.259.
146a.84	540.274f(a).
146a.86	540.255c(a).
146a.88	540.180b.
146a.93	540.174b(a).
146a.95	540.160(a).
146a.96	540.260(a).
146a.98	540.166(a).
146a.100	540.255b.
146a.104	540.173a(a).
146a.111	540.380b(a).
146a.112	540.881(a).
146a.128	540.874b(a).
146a.129	540.874f.
146b.101	539.170c.
146b.102	544.373a(a).
146b.104	544.173a(a).
146b.105	544.370a.
146b.106	544.274(a).
146b.107	544.170a.
146b.108	544.173b(a).
146b.110	544.473(a)
146b.111	544.173c(a).
146b.113	544.211b(a).
146b.114	539.170a.
146b.115	544.173d(a).
146b.117	544.211a(a).
146b.119	544.170b(a).
146b.121	544.370b(a).
146b.123	544.173c(a).
146b.124	544.373b(a).
146b.127	544.973b(a).
146c.204	546.180a(a).
146c.205	546.110c(a).
146c.206	546.312b(a).
146c.207	546.110d(a).
146c.208	546.481(a).
146c.212	546.713(a).
146c.217	546.180c(a).
146c.219	546.110a(a).
146c.222	546.160f(a).
146c.228	546.110f(a).
146c.237	546.312a(a).
146c.241	546.110b(a).
146c.244	546.381a(a).
146c.246	546.381b(a).
146c.256	546.110g(a).
146c.264	539.210c.
146c.265	546.113a(a).
146c.267	539.210a.
146d.303	555.310c(a).
146d.304	555.310a.
146d.308	555.310b and 555.410.
146e.401	539.310c.
146e.402	548.313b.
146e.403	548.212(a).
146e.408	548.310a(a).
146e.416	539.310a.
146e.417	548.112d(a).
146e.423	548.112a(a).
146e.425	548.110(a).
146e.426	548.112b(a).
146e.427	548.113(a).
146e.428	548.112c(a).
146e.430	548.313a.
146e.431	548.111(a).
148.2	510.45.
148.3	510.55.
148.5	510.105.
149a.14	540.119.
149b.17	540.107b.
149b.19	540.207.
149b.21	540.107d.
149b.23	540.107e.
149b.24	540.105.
149b.26	540.107a.
149b.27	540.207a.
149b.28	540.107c.
149e.6	540.129b.
149e.7	540.129a.
149e.8	540.129c.
149e.10	540.829.
149j.1	540.114a.
149j.2	540.114.
149j.11	540.514a.
149j.12	540.514.
151c.12	555.110b.
151c.14	555.310g.
151c.16	555.310e.
151c.18	555.310d.
151c.19	555.210.
151c.20	555.110c.
151c.21	555.110a.

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 500 through 558 are set out below.

Dated: March 21, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

Therefore 21 CFR is amended by redesignating the animal drug regulations and the animal drug provisions in regulations under Part 3 of Subchapter A and Parts 130, 131, 135 through 135g and Parts 141a through 151c of Subchapter C—Drugs as Parts 500 through 558 of Subchapter E—Animal Drugs, Feeds, and Related Products, and republished to read as follows:

Part
500 General
505 Interpretive Statements Re: Warnings on Animal Drugs for Over-the-Counter Sale
510 New Animal Drugs
511 New Animal Drugs for Investigational Use
514 New Animal Drug Applications
520 Oral Dosage Form New Animal Drugs Not Subject to Certification
522 Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification
524 Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification
529 Certain Other Dosage Form New Animal Drugs Not Subject to Certification
536 Tests for Specific Antibiotic Dosage Forms
539 Bulk Antibiotic Drugs Subject to Certification
540 Penicillin Antibiotic Drugs for Animal Use
544 Certifiable Oligosaccharide Antibiotic Drugs for Animal Use
546 Tetracycline Antibiotic Drugs for Animal Use
548 Certifiable Peptide Antibiotic Drugs for Animal Use
555 Chloramphenicol Drugs for Animal Use
556 Tolerances for Residues of New Animal Drugs in Food
558 New Animal Drugs for Use in Animal Feeds

PART 500—GENERAL

Subpart A—[Reserved]

Subpart B—Specific Administrative Rulings and Decisions

Sec.
500.25 Anthelmintic drugs for use in animals.
500.35 Animal feeds contaminated with Salmonella microorganisms.
500.40 Use of poultry litter as animal feed.
500.45 Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed.

Subpart C—Animal Drug Labeling Requirements

500.52 Use of terms such as "tonic," "tone," "toner," or "conditioner" in the labeling of preparations intended for use in or on animals.
500.55 Exemption from certain drug-labeling requirements.

Subpart D—Requirements for Specific Animal Drugs

500.65 Epinephrine injection 1:1,000 in 10-milliliter containers for emergency treatment of anaphylactoid shock in cattle, horses, sheep, and swine.

AUTHORITY: Secs. 512, 701(a), 52 Stat. 1055; 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)).

Subpart A—[Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 500.25 Anthelmintic drugs for use in animals.

(a) The Commissioner of Food and Drugs has determined that, in order to assure that anthelmintic drugs, including animal feeds bearing or containing such drugs, which do not carry the prescription statement are labeled to provide adequate directions for their effective use, labeling of these anthelmintic drugs shall bear, in addition to other required information, a statement that a veterinarian should be consulted for assistance in the diagnosis, treatment, and control of parasitism.

(b) The label and any labeling furnishing or purporting to furnish directions for use, shall bear conspicuously the following statement: "Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism."

(c) For drugs covered by approved new animal drug applications, the labeling revisions required for compliance with this section may be placed into effect without prior approval as provided for in § 514.8 (d) and (e) of this chapter. For animal feeds bearing or containing anthelmintic drugs covered by approved applications, the labeling revisions required for compliance with this section may be placed into effect without the submission of supplemental applications as provided for in § 514.9 of this chapter.

(d) Labeling revisions required for compliance with this section shall be placed into effect by February 25, 1975, following which, any such drugs that are introduced into interstate commerce and not in compliance with this section will be subject to regulatory proceedings.

§ 500.35 Animal feeds contaminated with Salmonella microorganisms.

(a) Investigations by the Food and Drug Administration, the Center for Disease Control of the U.S. Public Health Service, the Animal Health Division of the Agricultural Research Service, U.S. Department of Agriculture, and by various State public health agencies have revealed that processed fish meal, poultry meal, meat meal, tankage, and other animal byproducts intended for use in animal feed may be contaminated with Salmonella bacteria, an organism pathogenic to man and animals. Contamination of these products my occur through inadequate heat treatment of the product during its processing or through recontamination of the heat-treated product during a time of improper storage or handling subsequent to processing.

(b) Articles used in food for animals are included within the definition of "food" in section 201(f) of the Federal Food, Drug, and Cosmetic Act. Further, Salmonella contamination of such animal feeds having the potentiality for producing infection and disease in animals must be regarded as an adulterant within the meaning of section 402(a) of the act. Therefore, the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of the following when intended for animal feed and encountered in interstate commerce and found upon examination to be contaminated with Salmonella microorganisms: Bone meal, blood meal, crab meal, feather meal, fish meal, fish solubles, meat scraps, poultry meat meal, tankage, or other similar animal byproducts, or blended mixtures of these.

§ 500.40 Use of poultry litter as animal feed.

(a) Poultry rations used today generally contain drugs used individually or in combination. The levels of drug use vary from very small quantities of antibiotic drugs for growth promotion to relatively large quantities of drugs for treatment of diseases. Consequently, poultry litter can be expected to contain drugs and antibiotic drugs or their metabolites. It is not practical to determine, or feasible to estimate, the nature and levels of the drugs and their metabolites in litter. Therefore, it is not possible to conclude that poultry litter is safe as a feed or as a component of feed for animals, nor is it possible to conclude that there will be no drug residues in the tissues and byproducts of animals fed poultry litter.

(b) Disease organisms may be transmitted from poultry to other animals through the use of poultry litter as animal feed. There are several diseases affecting poultry that can also affect cattle, hogs, and sheep as well as man. Thus such transmission of disease organisms from poultry to other animals and possibly to man constitutes a hazard to animals and to the public health.

(c) Therefore, the Food and Drug Administration has not sanctioned and does not sanction the use of poultry litter as a feed or as a component of feed for animals. Poultry litter subject to the jurisdiction of the Federal Food, Drug, and Cosmetic Act and offered for use as animal feed may be considered as adulterated within the meaning of section 402 (a) (1), (2) (C), and/or (3) of the act.

§ 500.45 Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption, (meat, milk, and eggs). Investigations by the Food and Drug Administration have revealed that heat exchange fluids for certain pasteurization equipment used in processing animal feed contain PCB's. Although heat exchange fluids in such equipment are considered to be in "closed systems", leakage has occurred that resulted in direct contamination of animal feed with PCB's and subsequently resulted in the transfer of PCB's to human food produced by animals consuming the contaminated feed. The use of PCB-containing coatings on the inner walls of silos has resulted in the contamination of silage which has in turn caused PCB residues in the milk of dairy cows consuming the contaminated silage. Since PCB's are toxic chemicals, the PCB contamination of food as a result of these and other incidents represent a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of animal feed.

(b) The following special provisions are necessary to preclude accidental PCB contamination of animal feed:

(1) Coatings or paints for use on the contact surfaces of feed storage areas may not contain PCB's or any other harmful or deleterious substances likely to contaminate feed.

(2) New equipment or machinery for handling or processing feed in or around an establishment producing animal feed shall not contain PCB's.

(3) On or before Sept. 4, 1973, the management of establishments producing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices, be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any PCB-containing lubricants for equipment or machinery used for handling or processing animal feed.

(iii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such materials could cause animal feed to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement should be used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; (*d*) and its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) For the purpose of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

(d) For the purpose of this section, the term "animal feed" includes all articles used for food or drink for animals other than man.

Subpart C—Animal Drug Labeling Requirements

§ 500.52 Use of terms such as "tonic", "tone", "toner" or "conditioner" in the labeling of preparations intended for use in or on animals.

(a) The use of terms such as "tonic", "tone", "toner", and similar terms in the

labeling of a product intended for use in or on animals implies that such product is capable of a therapeutic effect(s) and causes such a product to be a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act. The unqualified use of such terms in a product's labeling fails to provide adequate directions and indications for use of such product and causes it to be misbranded within the meaning of section 502(a) and (f)(1) of the act. The terms "tonic", "tone", "toner", and similar terms may be used in labeling only when appropriately qualified so as to fully inform the user regarding the intended use(s) of the product.

(b) The unqualified use of the term "conditioner" and similar terms in the labeling of a product intended for use in or on animals implies that such product is capable of a therapeutic effect(s) and causes such a product to be a drug within the meaning of section 201(g) of the act. The unqualified use of such terms in a product's labeling fails to provide adequate directions and indications for use of such product and causes it to be misbranded within the meaning of section 502(a) and (f)(1) of the act. The term "conditioner" and similar terms may be used in labeling only when appropriately qualified so as to fully inform the user regarding the intended use(s) of the product. A product labeled as a "conditioner" or with a similar term can be either a food or drug depending upon the manner in which the term is qualified in the labeling to reflect the product's intended use.

(c) An article so qualified as to be represented as a drug must be the subject of an approved new animal drug application unless the use of the article under the conditions set forth in its labeling is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs.

§ 500.55 Exemption from certain drug-labeling requirements.

(a) Section 201.105(c) of this chapter provides that in the case of certain drugs for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law, such information may be omitted from the dispensing package. Under this proviso, the Commissioner of Food and Drugs will offer an opinion, upon written request, stating reasonable grounds therefor on a proposal to omit such information from the dispensing package.

(b) The Commissioner of Food and Drugs has considered submitted material covering a number of drug products and has offered the opinion that the following drugs when intended for those veterinary uses for which they are now generally employed by the veterinary medical profession, should be exempt from the requirements of § 201.105(c) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

Atropine sulfate. As an injectable for cattle, goats, horses, pigs, and sheep, not in excess of 15 milligrams per dosage unit; as an injectable for cats and dogs, not in excess of 0.6 milligram per dosage unit.

Barbital sodium. For oral use in cats and dogs, not in excess of 300 milligrams per dosage unit.

Epinephrine injection, 1 : 1,000. For cats, dogs, cattle, goats, horses, pigs, and sheep (except as provided in § 500.65).

Morphine sulfate. As an injectable for dogs, not in excess of 15 milligrams per dosage unit.

Pentobarbital sodium. For oral use in cats, and dogs, not in excess of 100 milligrams per dosage unit.

Phenobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Procaine hydrochloride injection. Containing not in excess of 2 percent procaine hydrochloride, with or without epinephrine up to a concentration of 1:50,000. For use in cats, dogs, cattle, goats, horses, pigs, and sheep.

Thyroid. For oral use in dogs, not in excess of 60 milligrams per dosage unit.

Subpart D—Requirements for Specific Animal Drugs

§ 500.65 Epinephrine injection 1:1,000 in 10-milliliter containers for emergency treatment of anaphylactoid shock in cattle, horses, sheep, and swine.

(a) Anaphylactoid reactions in cattle, horses, sheep, and swine occur occasionally from the injection of antibiotics, bacterins, and vaccines. Adequate directions for use of these antibiotics, bacterins, and vaccines can generally be written for use by the laity and thus are available to livestock producers. Epinephrine injection is effective for the treatment of anaphylactoid reactions in animals and would be of value in saving lives of animals if it were readily available at the time of administration of the causative agents. In connection with this problem the Food and Drug Administration has obtained the views of the Advisory Committee on Veterinary Medicine, and other experts, and has concluded that adequate directions for over-the-counter sale of epinephrine injection 1:1,000 can be prepared.

(b) In view of the above, the Commissioner of Food and Drugs has concluded that it is in the public interest to make epinephrine injection 1:1,000 available for sale without a prescription provided that it is packaged in vials not exceeding 10 milliliters and its label bears, in addition to other required information, the following statements in a prominent and conspicuous manner: "For emergency use only in treating anaphylactoid shock. Usual Dosage: Cattle, horses, sheep, and swine—1 cubic centimeter per 100 pounds of body weight. Inject subcutaneously".

(c) The labeling must also bear a description of the symptoms of anaphylactoid shock including glassy eyes, increased salivation, grinding of the teeth, rapid breathing, muscular tremors, staggering gait, and collapse with death following. These symptoms may appear shortly after injection of a bacterin, vaccine, or antibiotic.

PART 505—INTERPRETIVE STATEMENTS RE: WARNINGS ON ANIMAL DRUGS FOR OVER-THE-COUNTER SALE

Subpart A—Definitions and Interpretations

Sec.
505.3 Warnings on animal drugs intended for administration to diseased animals.

Subpart B—Required Warning and Caution Statements

505.10 Animal drug warning and caution statements required by regulations.

Subpart C—Voluntary Warning and Caution Statements

505.20 Recommended animal drug warning and caution statements.

AUTHORITY: Secs. 502, 503, 506, 507, 701, 52 Stat. 1050, as amended, 1052, as amended, 1055–1056, as amended, 52 Stat. 854; 55 Stat. 851; 59 Stat. 463, as amended (21 U.S.C. 352, 353, 356, 357, 371).

Subpart A—Definitions and Interpretations

§ 505.3 Warnings on animal drugs intended for administration to diseased animals.

None of the warning or caution statements recommended for use in the labeling of drugs intended for administration to diseased animals shall be construed to suggest or imply that any product of a diseased animal is suitable for food use. (See section 402(a)(5) of the act.)

Subpart B—Required Warning and Caution Statements

§ 505.10 Animal drug warning and caution statements required by regulations.

ANIMAL FEED CONTAINING PENICILLIN, STREPTOMYCIN, DIHYDROSTREPTOMYCIN, CHLORTETRACYCLINE, TETRACYCLINE, CHLORAMPHENICOL, OR BACITRACIN, WITH OTHER DRUGS. (See § 510.515 of this chapter.)

A warning to the following effect is required when animal feeds containing any of the above-named antibiotics also contain the following drugs:

Arsanilic acid, sodium arsanilate, or 3-nitro-4-hydroxyphenol arsonic acid (3-nitro-4-hydroxyphenylarsonic acid) for poultry and swine. (See § 510.515 (a) and (b) of this chapter.)

Warning—Discontinue use 5 days before the treated animals are slaughtered for human consumption.

Chlortetracycline for leptospirosis of swine. (See § 510.515(b)(41) of this chapter.)

A warning to the following effect is required on preparations containing, per ton of feed, 400 grams of chlortetracycline:

Warning—Discontinue use 10 days before the treated animals are slaughtered for human consumption.

Hygromycin B for swine. (See § 510.515 (b) of this chapter.)

Warning—Discontinue use 48 hours before the treated swine are slaughtered for human consumption.

Nystatin for turkeys. (See § 510.515(b) of this chapter.)

Warning—If used in laying hens, eggs are to be used for hatching purposes only.

ANTIBIOTIC-CONTAINING PREPARATIONS FOR VETERINARY USE. (See Parts 540, 544, 546, 548 and 555 of this chapter.)

All drugs containing penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, tetracycline, chloramphenicol, or bacitracin or any of their derivatives, labeled solely for veterinary use and bearing directions for use by the laity, are required to bear a label statement to the effect "For veterinary use only."

BACITRACIN-CONTAINING OINTMENTS. (See Part 548 of this chapter.)

All bacitracin-containing ointments are required to bear the label statements:

For use only in the prevention of infection in minor cuts and abrasions. Use of the drug should be discontinued and a veterinarian consulted if signs of infection or irritation appear.

BACITRACIN-CONTAINING PREPARATIONS WITH VASOCONSTRICTOR; BACITRACIN OPHTHALMIC. (See § 548.310a(a) of this chapter.)

Warning—Not for injection.

BACITRACIN- (OR ZINC BACITRACIN-) NEOMYCIN-POLYMYXIN POWDER TOPICAL. (See § 548.313a of this chapter.)

This drug is required to bear the label statement: "Not sterile."

BACITRACIN- (OR ZINC BACITRACIN-) POLYMYXIN OINTMENT; BACITRACIN - POLYMYXIN - NEOMYCIN OINTMENT. (See §§ 448.510c(a) and 448.510e(a) of this chapter.)

These drugs are required to bear a label statement to the effect "For use only in the prevention of infection in minor cuts and abrasions. Use of the drug should be discontinued and a veterinarian consulted if signs of infection or irritation appear."

If they are in liquid form they also bear the statement: "Not for injection."

BACITRACIN OR FEED GRADE BACITRACIN POWDER ORAL VETERINARY; BACITRACIN METHYLENE DISALICYLATE AND STREPTOMYCIN SULFATE CAPSULES, POWDER, OR TABLETS ORAL VETERINARY. (See §§ 548.112d(a), 548.110(a), 548.112b(a), 548.113(a), 548.112c(a) of this chapter.)

These drugs are required to bear the label statement: "For oral veterinary use only."

CHLORAMPHENICOL OPHTHALMIC. (See § 553.310a of this chapter.)

Warning—Not for injection.

CHLORAMPHENICOL OTIC; CHLORAMPHENICOL TOPICAL. (See § 555.310e(c) of this chapter.)

Warning—For external use only.

CHLORTETRACYCLINE OR TETRACYCLINE - CONTAINING PREPARATIONS FOR VETERINARY USE ONLY. (See Part 546 of this chapter.)

All drugs containing chlortetracycline or tetracycline or their derivatives, labeled solely for veterinary use and bearing directions for use by the laity, are required to bear a label statement to the effect "For veterinary use only."

CHLORTETRACYCLINE- OR TETRACYCLINE - CONTAINING PREPARATIONS FOR OPHTHALMIC, OTIC, OR ORAL USE; CHLORTETRACYCLINE- OR TETRACYCLINE - CONTAINING PREPARATIONS WITH VASOCONSTRICTOR. (See §§ 546.180a(a), 546.180e(a), 546.312b(a), and 546.481(a) of this chapter.)

Warning—Not for injection.

CHLORTETRACYCINE ORAL VETERINARY (CRUDE); CHLORTETRACYCLINE SEED. (See §§ 546.110a(a) and 546.110b(a) of this chapter.)

These drugs are required to bear the label statement "For oral veterinary use only."

TETRACYCLINE HYDROCHLORIDE FOR INTRAMUSCULAR USE. (See § 446.281b(a) of this chapter.)

This drug is required to bear the label statement "For intramuscular use only."

BUFFERED CRYSTALLINE PENICILLIN. (See § 440.81(a) of this chapter.)

If represented for use as a treatment for mastitis, the statement: "Important—Milk from treated segments of udders should be discarded or used for purposes other than human consumption for at least 72 hours after the last treatment."

BUFFERED PENICILLIN POWDER, PENICILLIN POWDER WITH BUFFERED AQUEOUS DILUENT; DIBENZYLAMINE PENICILLIN AND POTASSIUM PENICILLIN POWDER, BUFFERED; PENICILLIN WITH VASOCONSTRICTOR. (See §§ 540.174a(a) and 540.160(a) of this chapter.)

Warning—Not for injection.

CRYSTALLINE PENICILLIN-STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) POLYMYXIN-OXYTETRACYCLINE-CARBOMYCIN POWDER VETERINARY. (See § 540.881(a) of this chapter.)

These drugs are required to bear the label statement "For udder instillations or cattle only."

DIETHYLSTILBESTROL FOR SHEEP. (See § 510.515(b)(38) of this chapter.)

Warning—Discontinue use 7 days before the treated animals are slaughtered for human consumption.

EPHEDRINE PENICILLIN TABLETS. (See § 540.163(a) of this chapter.)

Warning—Not for injection or oral use.

EPINEPHRINE INJECTION 1:1000 in 10-MILLILITER CONTAINERS FOR EMERGENCY TREATMENT OF ANAPHYLACTOID SHOCK IN CATTLE, HORSES, SHEEP, AND SWINE. (See § 500.65 of this chapter.)

The label for epinephrine injection 1 : 1000 packaged for over-the-counter sale for veterinary use must bear the following statements in a prominent and conspicuous manner: "For emergency use only in the treatment of anaphylactoid shock.

Usual dosage: Cattle, horses, sheep, and swine—1 cubic centimeter per 100 pounds of body weight. Inject subcutaneously."

The labeling must also bear a description of the symptoms of anaphylactoid shock including glassy eyes, increased salivation, grinding of the teeth, rapid breathing, muscular tremors, staggering gait, and collapse with death following. These symptoms may appear shortly after injection of a bacterin, vaccine, or antibotic.

PENICILLIN-CONTAINING PREPARATIONS FOR INTRAMUSCULAR USE ONLY. (See §§ 540.250(a), 540.253, 540.255c(a), 540.265a, 540.265b(a), 540.274a(a), 540.274f(a), 540.281a(a) of this chapter.)

All these preparations are required to bear the label statement "For intramuscular use only."

PENICILLIN-CONTAINING OINTMENTS. (See Part 540 of this chapter.)

If these preparations are labeled solely for udder instillations of cattle and are packaged in glass containers, they are required to bear the label statements: "Not for injection. For udder instillations of cattle only."

PENICILLIN FOR SURFACE APPLICATION.

If the drug is not sterile, the statements: "Not sterile—Not for injection—Not to be used in deep wounds or body cavities."

PENICILLIN-NEOMYCIN OINTMENT. (See § 540.874c(a) of this chapter.)

This drug is required to bear the label statement "For udder instillations of cattle only."

PROCAINE PENICILLIN AND STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) IN OIL; DIBENZYLAMINE PENICILLIN AND STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) IN OIL; PROCAINE PENICILLIN-STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) POLYMYXIN IN OIL (OR

OINTMENT). (See §§ 540.274e(a) and 540.260(a) of this chapter.)

These drugs are required to bear the label statements: "For udder instillations of cattle only" or "For subcutaneous injection in fowl only. Inject in the neck immediately behind the head."

PROCAINE PENICILLIN IN OIL; PROCAINE PENICILLIN AND STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) IN OIL; PENICILLIN-STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) NEOMYCIN IN OIL; BENZATHINE PENICILLIN G IN OIL; BENZATHINE PENCILLIN G-PROCAINE PENICILLIN G-STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) IN OIL. (See §§ 540.255b, 540.274c(a), and 540.274e(a) of this chapter.)

These drugs are required to bear the label statements:

"For udder instillations of cattle only" (if intended for such use): or

"For subcutaneous injection in fowl only. Inject in the neck immediately behind the head." (if packaged and labeled solely for subcutaneous injection in fowl).

STREPTOMYCIN FOR TOPICAL USE. (See § 544.370a of this chapter.)

Caution—Not for intravenous or systemic medication.

Subpart C—Voluntary Warning and Caution Statements

§ 505.20 Recommended animal drug warning and caution statements.

ACETYLAMINONITROTHIAZOLE FOR POULTRY.

Warning—Discontinue use at least 1 week before slaughtering birds for food to eliminate the drug from the food.

AMINONITROTHIAZOLE (2-AMINO-5-NITROTHIAZOLE) FOR POULTRY.

Warning—Discontinue use at least 1 week before slaughtering birds for food to eliminate the drug from the food.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS).

Caution—Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult veterinarian.

ANTHELMINTICS.

Caution—Consult veterinarian before using in severely debiliated animals.

ANTHELMINTICS: PHENOTHIAZINE.

Warning—Do not treat lactating dairy animals.

Caution—Consult veterinarian before using in severely debilitated animals. Individual animals are occasionally sensitive to phenothiazine.

ANTIHISTAMINICS FOR EXTERNAL USE.

Caution—If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult veterinarian.

ANTISEPTICS FOR EXTERNAL USE.

Caution—In case of deep or puncture wounds or serious burns consult veterinarian. If redness, irritation, or swelling persists or increases, discontinue use and consult veterinarian.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE.

Caution—Use only as directed. Avoid contact with the eyes and mucous membranes. Do not apply to large areas of broken skin. Do not use on cats.

CORTISONE, HYDROCORTISONE, PREDNISOLONE AND PREDNISONE PREPARATIONS FOR EXTERNAL USE.

Caution—Do not use where infection (pus) is present, since the drug may allow infection to spread. If redness, irritation, or swelling persists or increases, discontinue use and consult veterinarian.

COUNTERIRRITANTS AND RUBEFACIENTS.

Cautions—Do not apply to irritated skin or if excessive irritation develops. Avoid getting into eyes or on mucous membranes.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE.

Caution—Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to large areas of broken skin. Not recommended for use on cats.

DIARRHEA PREPARATIONS.

Caution—If symptoms persists after using this preparation for 2 or 3 days, consult veterinarian.

DIETHYLSTILBESTROL IN ANIMAL FEEDS.

Warning—Discontinue use at least 7 days before slaughtering animals for food to eliminate the drug from the food.

DISPENSERS PRESSURIZED BY GASEOUS PROPELLANT FOR DRUGS FOR EXTERNAL USE.

Caution—Keep away from eyes or other mucous membranes. Avoid inhaling.

This warning is not necessary for preparations especially designed for use on mucous membranes.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

DRESSINGS, PROTECTIVE SPRAY-ON TYPE.

Caution—In case of deep or puncture wounds or serious burns or if redness, irritation, or swelling persists or increases, consult veterinarian.

Keep away from eyes or other mucous membranes. Avoid inhaling.

See also Dispensers Pressurized by Gaseous Propellant * * * for additional warnings to be included for products under pressure.

ESTROGEN PELLETS IN CATTLE AND SHEEP.

Warning—Implant pellets in the _____ (name of the anatomical area) only. Any other location may result in violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

NICARBAZIN FOR POULTRY.

Warning—Do not feed to laying hens in production. Discontinue use at least 4 days before slaughtering birds for food to eliminate the drug from the food.

OPHTHALMIC PREPARATIONS.

Caution—If condition persists or increases discontinue use and consult veterinarian. Keep container tightly closed.

Solutions should also include the following statement: "Do not touch applicator tip to any surface, since this may contaminate solution."

SALMONELLOSIS TREATMENTS FOR POULTRY.

Important—Poultry that have survived salmonella outbreaks should not be kept for laying-house replacements or breeders, unless tests show that they are not carriers.

SULFONAMIDE PREPARATIONS (SYSTEMIC).

Caution—If symptoms persist after using this preparation for 2 or 3 days consult veterinarian.

SULFONAMIDES FOR EXTERNAL USE.

Caution—If redness, irritation, or swelling persists or increases, discontinue use and consult veterinarian.

If the preparation has not been sterilized, the following statement should also be used:

Caution—This preparation has not been sterilized. Do not use in body cavities or deep wounds.

PART 510—NEW ANIMAL DRUGS

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510.600 Names, addresses, and code numbers of sponsors of approved applications.

AUTHORITY: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371), unless otherwise noted.

Subpart A—General Provisions

§ 510.3 Definitions and interpretations.

As used in this part:

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended; 21 U.S.C. 321-392).

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Secretary" means the Secretary of Health, Education, and Welfare.

(d) "Commissioner" means the Commissioner of Food and Drugs.

(e) "Person" means individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

(3) Which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that:

(i) The requirement of certification of batches of such drug, as provided for in section 512(n) of the act, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved; and

(ii) That neither paragraph (g) (1) nor (2) of this section applies to such drug.

(h) The term "animal feed" means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) "Animals used only for laboratory research" and "laboratory research animals" mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) The term "sponsor" means the person responsible for an investigation of a new animal drug, including responsibility for compliance with applicable provisions of the act and regulations. The "sponsor" may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs.

(l) "Designated journal(s)" means journals listed in § 510.95 and § 310.9 of this chapter.

§ 510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 510.5 Certification of new animal drugs containing any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or derivative thereof.

(a) *New animal drugs subject to the provisions of section 512(n) of the act.* New animal drugs that contain or purport to contain any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or derivative thereof shall conform to:

(1) The specifications included in applicable monographs published pursuant to section 512(n) of the act, and

(2) The conditions of use specified in regulations published pursuant to section 512(i) of the act.

(b) *New animal drugs subject to the provisions of section 512(n) of the act and intended for use as components of animal feed.* Penicillin, streptomycin, chlortetracycline, bacitracin, feed grade bacitracin, feed grade manganese bacitracin, feed grade zinc bacitracin, and bacitracin methylene disalicylate intended for use solely in the manufacture

of one or more of the medicated animal feeds described in Part 558 of this chapter, and conspicuously so labeled, shall be exempt from the certification requirements of section 512(n) of the act if its manufacturer, packer, or distributor:

(1) Holds an approval for such a drug as published in accordance with section 512(i) of the act; and

(2) Holds an effective permit from the Commissioner issued under the provisions of § 433.13 of this chapter authorizing shipment for manufacturing use to such establishment.

(c) *Animal feeds subject to the provisions of section 512(m) of the act and bearing or containing a new animal drug subject to the provisions of section 512 (n).* An animal feed that bears or contains or purports to bear or contain penicillin, streptomycin, chlortetracycline, or bacitracin, or any derivative thereof, shall be exempted from the requirements of section 512(m) of the act in accordance with the conditions specified in applicable regulations published in Part 558 of this chapter.

§ 510.6 New animal drugs; transitional provisions re section 512 of the act.

(a) Section 512 of the Federal Food, Drug, and Cosmetic Act was enacted on June 13, 1968, to become effective August 1, 1969, by the Animal Drug Amendments of 1968 (Public Law 90-399).

(b) The provisions of the Animal Drug Amendments of 1968 require extensive revisions to existing regulations.

(c) Such regulations will be published at an early date in the FEDERAL REGISTER. An opportunity for comment by interested parties will be provided.

(d) Pending promulgation of the necessary regulations under section 512 of the act, the currently used Form FD 356-Rev. 1965, Form 5, and Form FD-1800 will be acceptable as a basis for approval of applications of new animal drugs and feeds containing new animal drugs under the provisions of section 512 provided that such applications include:

(1) A practicable method of analysis for determining the quantity, if any, of any substance in or on food resulting from the use of a new animal drug.

(2) The conditions and indications for use of the new animal drug, including any proposed tolerance or withdrawal period or other use restrictions for such drug required in order to assure that the proposed use of the drug will be safe, and if the new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements applicable to any animal feed in which the drug is to be approved).

(3) Applications submitted in the Form FD-1800 shall in lieu of the information required by section I include a reference to the regulation in Subpart C of Part 121 of this chapter upon which the application relies as a basis for approval of the application with respect to the use of a new animal drug in feed and the name and address of the supplier of the new animal drug.

(e) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug or a notice from the Food and Drug Administration to the effect that with respect to the use of such drug in animal feed, the consignee:

(1) Is the holder of an approved Form FD-1800; or

(2) Will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved Form FD-1800.

An unrevoked written notice that a new-drug application, supplemental new-drug application, antibiotic Form 10, or Form FD-1800 has been approved for such use of the drug in animal feed meets this requirement.

(f) The requirements of section 512 of the act shall apply with regard to approval, refusal to approve, and revocation of applications with respect to new animal drugs and feeds containing new animal drugs. All prior approvals of new-drug applications, supplemental new-drug applications, master files, Form FD-1800, and antibiotic Forms 5, 6, and 10, and food additive regulations for such drugs and feeds containing such drugs shall remain in effect until withdrawn or suspended under provisions of section 512 of the act.

(g) The regulations included in Subparts C and D of Part 121 of this chapter remain in effect until they have been incorporated as regulations under section 512(i) of the act or have been amended or revoked as provided in paragraph (f) of this section.

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Is the holder of an approved application under § 514.2 of this chapter; or

(2) Will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under § 514.2 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in Part 558 of this chapter.

§ 510.45 Packaging requirements for drugs for animal use.

The packaging requirements for antibiotic drugs for veterinary use are described under § 432.1 of this chapter, except that antibiotic drugs for veterinary use need not be packaged for dispensing in containers of colorless, transparent glass.

§ 510.55 Labeling requirements for antibiotic drugs for animal use.

If an antibiotic drug is subject to section 512(n) of the act and packaged for dispensing:

(a) It shall be labeled in accordance with the requirements prescribed by § 201.105 of this chapter and each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity in lieu of the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" (as provided in § 201.105(b)(1) of this chapter) unless such statement is required by regulations issued under section 512(i) of the act.

(b) Its labeling shall bear any additional information required for the drug by specific regulations.

(c) Each package shall bear on its outside wrapper or container and the immediate container an expiration date prescribed for the drug as provided in § 432.5(a)(3) of this chapter with the exception provided in § 432.5(c) of this chapter.

(d) If it is intended for udder instillation in cattle, it shall be exempt from the requirements of § 201.105(b)(5) of this chapter.

(Sec. 507, 59 Stat. 468 as amended (21 U.S.C. 357).)

§ 510.95 Designated journals.

The following journals, in addition to those listed in § 310.9 of this chapter, are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

All Pet's Magazine (Jersey City).
American Journal of Veterinary Research (Chicago).
Animal Health (Journal of the Animal Health Trust) (London).
Animal Nutrition & Health (Sausalito, Calif.).
Animal Production (Edinburgh).
Avian Diseases (Amherst).
British Poultry Science (Edinburgh).
Canadian Journal of Comparative Medicine and Veterinary Science (Gardenvale, Quebec).
Canadian Veterinary Journal (Guelph, Ontario).
Cornell Veterinarian (Ithaca).
Experimental Parasitology (New York).
The Feed Bag (Milwaukee).
Feedstuffs (Minneapolis).
Hoard's Dairyman (Fort Atkinson).
Journal of the American Veterinary Medical Association (Chicago).
Journal of Animal Science (Albany).
Journal of Dairy Science (Champaign).

Journal of Economic Entomology (Baltimore).
Journal of Small Animal Practice (London).
Modern Veterinary Practice (formerly North American Veterinarian) (Wheaton, Ill.).
National Hog Farmer (Grundy Center, Iowa).
New Zealand Veterinary Journal (Wellington).
Poultry Science (Guelph, Ontario).
Praktische Tierarzt (Postfach, Germany).
Research in Veterinary Science (Chicago).
Small Animal Clinician (Kansas City, Mo.).
Veterinaermedizin (Konstanz, Germany).
Veterinarian (London).
Veterinarian (International) (New York).
The Veterinary Bulletin (Farnham Royal, England).
Veterinary Medicine (Kansas City, Mo.).
Veterinary Record (Croydon, England).
Zentralblatt Fuer Veterinaermedizin Zentr. Veterinaermed (Berlin).

Subpart B—Specific Administrative Rulings and Decisions

§ 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 540 of this chapter provides for new animal drugs intended for intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(D) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the warning, "Milk that has been taken from animals during treatment and within _____ hours (_____ milkings) after the latest treatment must not be used for food," the blanks to be filled in with the number of hours (not to exceed 96) and milkings that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

§ 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement "Warning: Not for use in animals producing milk, since this use will result in contamination of the milk" or the statement "Warning: Milk that has been taken from animals during treatment and for __ hours (____ milkings) after the latest treatment must not be used for food", the first blank being filled in with the figure, which shall not be greater than 96, that the Commissioner has authorized the manufacturer of the drug to use, and the second figure shall be the first number divided by 12. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, he may exempt the drug from bearing either of the above warning statements.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

§ 510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, § 510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to establish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the date of publication of § 510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to transfer this resistance, and the development of sensitivity to antibiotics in humans, unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.

(d) Based on evaluation of information available, including the conclusions of the aforementioned ad hoc Committee, the Commissioner concludes that antibiotic preparations intended for use in food-producing animals, other than topical and ophthalmic preparations, are not generally recognized among qualified experts as having been shown to be safe for their intended use(s) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

(e) Therefore, all exemptions from the provisions of section 409 of the act for use of antibiotics in food-producing animals based on sanctions or approvals granted prior to enactment of the Food Additives Amendment of 1958 (Public Law 85-929; 72 Stat. 1784) will be revoked and the uses which are concluded to be safe will be covered by food additive regulations. On those products for which there are inadequate residue data, actions will be initiated to amend or revoke antibiotic regulations under the provisions of section 507 of the act, or to withdraw approval of new-drug applications under the provisions of section 505 of the act. Antibiotic preparations, other than those for topical and ophthalmic application in food-producing animals, which are not covered by food additive regulations will be subject to regulatory action within 180 days after publication of the forthcoming revocation order.

(f) Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations (except certifiable antibiotics), including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives. An Antibiotic Form 6 (see § 431.50 of this chapter) will be required for all medicated premixes containing certifiable antibiotics.

(Sec. 409, 505, 507, 52 Stat. 1052, as amended, 59 Stat. 463, as amended, 72 Stat. 1785 et seq., as amended; 21 U.S.C. 348, 355, 357)

§ 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Nonmedical Uses of Antibiotics, was formed by the Food and Drug Administration to study, and advise the Commissioner on, the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of the Assistant Commissioner for Public Affairs, 5600 Fishers Lane, Rockville, MD 20852.

(b) On the basis of the report of the Committee and other information, sponsors of drugs containing any antibiotic

intended for use in food-producing animals shall submit data for determining whether or not such antibiotics and their metabolites are present as residues in edible tissues, milk, and eggs from treated animals; however, in the case of a drug for which such data have already been submitted and for which a regulation has been promulgated under section 409 of the act, only such data as has been accumulated since the issuance of the regulation need be submitted.

(c) The required data shall be submitted within 180 days of the date of publication of this section in the FEDERAL REGISTER; except that in the case of data on intramammary infusion preparations, the data shall be submitted within 60 days of such publication. Data demonstrating the absence in milk of residues of intramammary infusion preparations when used as directed in their labeling are needed within the 60-day period because of the importance of milk in the human diet.

(d) Regulatory proceedings including revocation of prior sanctions, or actions to suspend or amend new drug or antibiotic approvals granted prior to passage of the Food Additives Amendment of 1958 (72 Stat. 1784), may be initiated with regard to the continued marketing of any antibiotic preparation on which the required information is not submitted within the period of time prescribed by paragraph (c) of this section.

(e) Questions relating to the acceptability of proposed research protocols and assay methods for determining the amount of antibiotic residues in food should be directed to the Director, Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

(Secs. 409, 505, 507, 52 Stat. 1052, as amended, 59 Stat. 463, as amended, 72 Stat. 1785; 21 U.S.C. 348, 355, 357)

§ 510.120 Suspension of approval of new-drug applications for certain diethylstilbestrol and diethylstilbestrol-containing drugs.

In the matter of suspension of approval of New-Drug Application Nos. 7175, 7310, 8254, 9105, 9506, 9532, 11121: [Mattox and Moore, Inc., Indianapolis, IN; Vineland Poultry Laboratories, Vineland, NJ; George N. Bell Co., Indianapolis, IN, respondents (FDC-D-49, 50, and 55)].

Following the public hearing held in the above-identified matter, beginning on April 25, 1960, and finally terminating on June 17, 1960, and issuance of tentative findings of fact, conclusions of law and facts, and tentative order, the Commissioner of Food and Drugs on December 15, 1961, issued final findings of fact, conclusions of law and facts and a final order. This final order concluded that all the products involved were unsafe within the meaning of section 505(e) of the Federal Food, Drug, and Cosmetic Act, in that the drug diethylstilbestrol is capable of producing and has produced cancer in animals and that this drug may be expected to produce, excite or stimulate the growth of certain cancers in human beings.

This final order was appealed to the U.S. District Court for the District of New Jersey, pursuant to the then effective provisions of section 505(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(h)). On August 20, 1964, this Court set aside this final order and remanded the case to the Food and Drug Administration with directions to reconsider the case in conformity with the opinion of the Court. (Goldhaft et al. t/a Vineland Poultry Laboratories v. George P. Larrick, et al.; Civil Action No. 122-62.)

Pursuant to the above-described opinion and order of the Court this case has been reconsidered.

Based on the substantial evidence of record, and pursuant to section 505(e) of the act (21 U.S.C. 355(e)) and Part 310 of Title 21 of the Code of Federal Regulations.

It is ordered, That:

1. New-Drug Application 7175, covering the drug "Tend-A-Wate," filed by Mattox & Moore, Inc., be, and is hereby suspended.
2. New-Drug Application 9532, covering the drugs "Tend-A-Wate 537," "Tend-A-Wate 539," and "Tend-A-Wate 545," filed by Mattox & Moore, Inc., be, and is hereby suspended.
3. New-Drug Application 7310, covering the drug "Tenderettes," filed by Vineland Poultry Laboratories, be, and is hereby suspended.
4. New-Drug Application 9105, covering the drug "Caponade," filed by Vineland Poultry Laboratories, be, and is hereby suspended.
5. New-Drug Application 11121, covering the drug "Stilboserts," filed by George N. Bell, Manufacturing Chemists, be, and is hereby suspended.
6. New-Drug Application 8254, covering the drug "No-Brood," filed by Mattox and Moore, Inc., be, and is hereby suspended.
7. New-Drug Application 9506, covering the drug "Anti-Brood," filed by Vineland Poultry Laboratories, be, and is hereby suspended.

(Secs. 505(e), 701(a), 52 Stat. 1053, 1055; 76 Stat. 782; (21 U.S.C. 355(e), 371(a)).)

Subpart C—Exportation of New Animal Drugs

§ 510.200 Export of new animal drug.

Before a new animal drug or an animal feed bearing or containing a new animal drug may be exported, it must comply with the regulations promulgated under section 512 of the act.

Subpart D—Records and Reports

§ 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

(a) On receiving notification that an application submitted pursuant to § 514.1 of this chapter for a new animal drug is approved, the applicant shall establish and maintain such records and make such reports as are specified in this section to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the application or whether any applicable regulation should be amended or repealed. The applicant shall maintain adequately organized and indexed files containing full reports of information pertinent to the safety or effectiveness of the new animal drug that have not previously been submitted as part of his application for the drug and which are received or otherwise obtained by him from any source, as follows:

(1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the new animal drug that is the subject of the application or any related drugs. An adequate summary and bibliography of reports in the scientific literature would ordinarily suffice. (The application must identify at the time of each report submission, each drug he considers related to the subject drug.)

(2) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the new animal drug, such as its behavior or properties in relation to microoganisms, including both the effects of the drug on microorganisms and the effect of microorganisms on the drug.

(3) For information required by this section, adequate identification of its source, when known, including the name and post office address of the person who furnishes such information.

(4) Copies of all mailing pieces and other labeling, and, if it is a prescription new animal drug, all advertising other than that contained in the application used in promoting the drug, and copies of the currently used package labeling that gives full information for use of the drug whether or not such labeling is contained in the application.

(5) Information concerning the quantity of the new animal drug distributed in a manner and from that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial, pricing, or sales data.

(6) Information concerning any previously unreported changes from the conditions described in an application conforming to the conditions of § 514.8 (a) (5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section, except routine assay and control records, appropriately identified with the new animal drug application(s) to which they relate, as follows:

(1) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(i) Information concerning a mixup in the new animal drug or its labeling with another article.

(ii) Information concerning any bacteriological or significant physical or other change or deterioration in the new animal drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records of reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effects, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical use, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug,

except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. "Unexpected" as used in this subdivision refers to conditions or developments not previously submitted as part of the new animal drug application, or conditions and developments occurring at a rate higher than that shown by information previously submitted as part of the application.

(ii) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activities.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the new animal drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling designed to contain samples of a drug shall be complete except for the omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraph (b) (1), (2), and (3) of this section, shall be submitted as follows unless otherwise ordered in a written communication from the Commissioner:

(i) At intervals within 6 months beginning with the date of approval of the new animal drug application during the first year following such date, and at yearly intervals thereafter.

(ii) Whenever an applicant is required to submit reports under the provisions of paragraph (b) (4) (i) of this section with respect to more than one approved application for preparations containing the same new animal drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as a part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the new animal drug applications for which the reports are submitted.

(iii) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.

(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports, containing the kinds of information described in this section shall be submitted.

(c) The applicant shall, upon request of any properly authorized officer or employee of the Department at reasonable times, permit such officers to have access to any copy and verify any records and reports established and maintained under the provisions of this section.

(d) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of this section, or that the applicant has refused to permit access to or copying of, or verification of such records or reports, the Commissioner shall give the applicant notice and opportunity for a hearing on the question of whether to withdraw the approval of the application, as provided in § 514.200 of this chapter.

(e) Upon written request of the applicant stating reasonable grounds therefor, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes is confidential.

(f) The "applicant" required to establish and maintain records and make reports required by this section includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the new animal drug application or any supplement to it; however, to avoid unnecessary duplication in the submission of reports, any such applicant's obligation to submit a report may be met by its submission on his behalf, designated as such, by another person responsible for reporting.

§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) to which they relate, to the Bureau of Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. "Unexpected" as used in this subparagraph refers to conditions or developments not previously submitted as part of the new animal drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

§ 510.302 Reporting forms.

(a) The information described in § 510.300 except that described in paragraph (b), (1), (2), and (3) of that section shall be submitted appropriately identified with the new animal drug application(s) to which they relate in duplicate on Form FD-2301 "Transmittal of Periodic Reports and Promotional Material for New Animal Drugs."

(b) All adverse experiences with new animal drugs as described in §§ 510.300 (b) (2) or 510.301(b) whether or not related to a required periodic report submitted on a Form FD-2301, shall be reported on Form FD-1932 "Adverse Drug Reaction" (except as provided in paragraph (c) of this section). Reports of adverse drug experiences may be submitted initially in the form of a written communication, but any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD-1932. A separate "Adverse Drug Reaction" form should be submitted for each patient where feasible.

(c) In lieu of Form FD-1932 the holder of an approved new animal drug application may submit (1) a computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form FD-1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.

(d) Forms FD-1932 and FD-2301, with instructions for their use, may be obtained from the Food and Drug Administration, Department of Health, Education, and Welfare, Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, MD 20852.

§ 510.310 Records and reports on new animal drugs and antibiotics for use in animals for which applications or certification Forms 5 and 6 became effective or were approved prior to June 20, 1963.

(a) Each applicant for whom a new animal drug application or supplement for a drug for use in animals became effective or was approved at any time prior to June 20, 1963, each person holding an approved Form 5 or 6 for an antibiotic drug for use in animals at any time prior to June 20, 1963, and each person who has been manufacturing and/or marketing a product deemed approved under §§ 510.510 and 510.515, shall submit in duplicate the following information for each dosage form within 90 days from the effective date of this section:

(1) Identification of the dosage form of the new animal drug by its established and proprietary names, if any, the formula showing quantitatively each ingredient of the drug to the extent disclosed on the label (a copy of the label will ordinarily fulfill this requirement), the route of administration, and the new animal drug or other identification or application number.

(2) Whether the new animal drug was marketed and whether it is currently marketed.

(3) If the new animal drug was marketed and marketing has been discontinued, the date and reason for discontinuing its marketing.

(b) Such reports shall be addressed to the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Veterinary Medicine (HFV–1), 5600 Fishers Lane, Rockville, MD 20852, and shall be distinctly marked "New Animal Drug (or Antibiotic) Report," together with the applicable new animal drug application number, antibiotic account number, or other identification on the envelope.

(c) Reports showing that a new animal drug was not marketed or has been discontinued may be followed by publication in the FEDERAL REGISTER of a notice of a proposal to withdraw approval of such application, on any of the grounds specified in section 512 of the act, giving any interested person who would be adversely affected by such an order an opportunity to respond and avail himself of a hearing prior to the issuance of such order. This will allow any person distributing a new animal drug that was covered by an application held by a person who did not market the drug or who has abandoned marketing of the drug an opportunity to show cause why approval of the application should not be withdrawn and why marketing of the drug should not be discontinued.

§ 510.350 Records of distribution of animal drugs subject to section 512(n) of the act.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

Subpart E—Requirements for Specific New Animal Drugs

§ 510.410 Corticosteroids for oral, injectable, and intramammary use in animals; warnings; labeling requirements.

(a) The Food and Drug Administration has received reports concerning side effects associated with the oral, injectable, and intramammary use of corticosteroid drugs in animals. The use of these drugs has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. These drugs, unless they are intended for intramammary use are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Commissioner of Food and Drugs has concluded that the labeling on or within the package from which the product is to be dispensed, and any other labeling furnishing or purporting to furnish information for the use of these preparations, should bear conspicuously;

(1) If subject to the labeling requirements of § 201.105 of this chapter the following warning statement:

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) If intended for intramammary use, the following warning statement:

Warning: Studies have demonstrated that corticosteroids may cause abortion or premature birth when given during the last third of pregnancy and also may lead to difficulty in giving birth, death of fetus, retained afterbirth and infection of the uterus. Therefore, to prevent these side effects, this preparation should not be administered during the last third of pregnancy.

The label revisions described above should be placed into effect at the earliest possible time and may be implemented without prior approval as provided for in § 514.8 (d) and (e) of this chapter.

(c) Approved new animal drug applications which have not been supplemented in accordance with paragraph (b) of this section within 60 days following the date of publication of this statement of policy in the FEDERAL REGISTER will be subject to provisions of section 512(e) of the Federal Food, Drug, and Cosmetic Act.

§ 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

§ 510.450 Sulfonamide-containing drugs for oral, injectable, intramammary, or intrauterine use in food-producing animals.

(a) The Commissioner of Food and Drugs announced in the FEDERAL REGISTER of October 23, 1970 (35 FR 16538) the need for additional information regarding the labeling and residues of sulfonamide-containing drugs as follows:

(1) New information available to the Commissioner of Food and Drugs has shown that, under certain circumstances where food-producing animals have been treated with oral or parenteral sulfonamide-containing drugs, sulfonamide residues may be detected in the edible products of such animals when they are slaughtered within 10 days of the last treatment.

(2) The presence of sulfonamide residues in food constitutes an adulteration within the meaning of section 402(a)(2)(D) of the act in the absence of a tolerance for such residues established pursuant to section 512(i) of the act.

(3) To assure that edible products from treated animals are safe for human consumption, the labeling of preparations which contain sulfonamide drugs intended for oral or parenteral use and which are not the subject of a regulation providing for such use shall bear:

(i) A statement that the use of the drug (other than use in chickens) must be discontinued 10 days before treated animals are slaughtered for food; or

(ii) A statement of withdrawal period which has been established based upon data submitted to the Commissioner and found satisfactory for the elimination of drug residues from edible products.

(4) It has been concluded that, because of poultry husbandry practices in

the production of chickens, withdrawal periods exceeding 5 days for drugs administered continuously, are not generally practical and cannot reasonably be expected to be followed. Therefore, it is concluded that such sulfonamide drugs are not to be used continuously in chickens unless a withdrawal period which does not exceed 5 days has been established in accordance with paragraph (a) (3) (ii) of this section.

(5) Labeling revisions required for compliance with this paragraph were to be made at the earliest possible time and, in any case by January 21, 1971. Any such products now on the market and not in compliance with this paragraph are subject to regulatory action.

(6) The labeling requirements of paragraph (a) (3) (i) of this secton were disclosure of any record in the NADA file adopted as an interim measure. Sponsors of sulfonamide-containing drugs subject to the provisions of this section were required to submit by October 22, 1971, adequate data to permit the establishment of appropriate withdrawal periods as required by paragraph (a) (3) (ii) of this section.

(b) Recently available studies indicate that the degree of thyroid response to exposure to sulfonamide drugs should be given greater significance in the evaluation of sulfonamide toxicity and in the determination of "no-effect" levels of the drugs in laboratory animals to support the establishment of tolerances for negligible residues of sulfonamides, in edible products from treated animals.

(c) The Commissioner has concluded that because of questions raised regarding sulfonamide toxicity there is a need to facilitate a determination of whether there are grounds to invoke section 512 (e) of the act regarding the continued use of these sulfonamide-containing drugs. Therefore, it has been concluded that sulfonamide-containing drugs for oral, injectable, intrauterine or intramammary use in food-producing animals are new animal drugs for which approved new animal drug applications are required. All persons or firms marketing such drugs which are not now the subject of an approved new animal drug application must submit a complete new animal drug application on or before January 20, 1975 for these drugs if marketing is to continue during the interim. Any such drug then on the market which is not the subject of an application submitted for such drug will be deemed adulterated within the meaning of section 501 (a) (5) of the act and subject to regulatory action. The submission of applications for sulfonamide-containing drugs pursuant to § 558.15 (38 FR 9811) which were required to be submitted by July 19, 1973 will be adequate to meet the requirements for submission of an application pursuant to this section.

(d) Under the provisions of section 512(l) of the act, by July 22, 1975, each sponsor of a new animal drug application for a sulfonamide-containing drug labeled for oral, injectable, intrauterine or intramammary use in food-producing animals shall submit, for each such drug, the results of 90-days subacute toxicity studies in one rodent and one non-rodent species. The studies shall include a determination of a "no-effect" level of the drug using thyroid response as one parameter. Protocols may be submitted to the Food and Drug Administration for review prior to the initiation of studies. If an evaluation of the results of these studies shows that existing methodology used to establish negligible tolerances for residues of the sulfonamide drugs in edible tissues is not of adequate sensitivity and specificity, improved methodology will be required. Any such drug then on the market which is not the subject of such submitted studies will be subject to the provisions of section 512 (e) (2) (A) of the act.

(e) New animal drug applications and the data required by this section pursuant to section 512(1) of the act shall be submitted to the Food and Drug Administration, Bureau of Veterinary Medicine, Division of New Animal Drugs, HFV-300, 5600 Fishers Lane, Rockville, MD 20852.

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

AUTHORITY: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).

§ 510.505 Antibiotic drugs subject to section 512(n) of the act for fish diseases.

Any antibiotic drug subject to the regulations in this chapter intended for use solely in the prevention or treatment of disease in fish and conspicuously so labeled shall be exempt from the requirements of sections 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if the fish so treated are not intended for human consumption.

§ 510.510 Antibiotic drugs for use in medicated animal feed (antibiotic medicated feed premixes).

Antibiotic drug premixes subject to section 512(n) of the act shall be exempt from the certification requirements under the conditions specified in § 510.5(b).

§ 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, streptomycin in combination with penicillin chlortetracycline, bacitracin, feed grade bacitracin, feed grade manganese bacitracin, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients, are approved for use if they comply with the requirements of Part 558 of this chapter and any one of the following paragraphs of this section:

(a) It is intended for use solely as an animal feeding supplement, it is conspicuously so labeled, and it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(4) Furazolidone: 0.00083 percent.

(5) Furazolidone 0.00083 percent, with or without nitrofurazone 0.0056 percent, and/or 3-nitro-4-hydroxyphenylarsonic acid not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed in which the limit of 3-nitro-4-hydroxyphenylarsonic acid shall be not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in the conditions set forth in any one of the following subparagraphs of this paragraph:

(1) It is intended for use solely in the prevention of coccidiosis outbreaks in poultry flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Sulfaquinoxaline: Not less than 0.0125 percent and not more than 0.025 percent.

(ii) [Reserved]

(iii) Nitrofurazone: 0.0056 percent.

(iv) N¹-acetyl-N¹-(4-nitrophenyl) sulfanilamide 0.03 percent and 3-nitro-4-hydroxyphenylarsonic acid 0.005 percent.

(v) Furazolidone 0.00083 percent, nitrofurazone 0.0056 percent, with or without 3-nitro-4-hydroxyphenylarsonic acid not less than 0.0025 percent and not more than 0.005 percent.

(2) It is intended for use solely in the control of coccidiosis outbreaks in poultry flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Sulfaquinoxaline: Not less than 0.033 percent and not more than 0.10 percent.

(ii) [Reserved]

(iii) Nitrofurazone: 0.0056 percent.

(3) It is intended for use solely in the prevention of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as herein after indicated:

(i) 2-Amino-5-nitrothiazole: 0.05 percent.

(ii) 4-Nitrophenylarsonic acid: 0.025 percent.

(4) It is intended for use solely in the control of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains 2-amino-5-nitrothiazole in a quantity, by weight of feed, of 0.10 percent.

(5) It is intended for use solely as an anthelmintic for poultry or swine, its labeling bears adequate directions and warnings for such use, and it contains

one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Di-*N*-butyl tin dilaurate 0.07 percent, nicotine 0.03 percent, and phenothiazine 0.29 percent.

(ii) Nicotine 0.067 percent, phenothiazine 0.60 percent, and 2,2'-dihydroxy-5,5'-dichlorodiphenylmethane 0.28 percent.

(iii) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent, and nicotine, not less than 0.03 percent and not more than 0.07 percent.

(iv) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent.

(v) Nicotine, not less than 0.03 percent and not more than 0.07 percent.

(vi) Sodium fluoride 0.3 percent and sodium sulfate 2.0 percent.

(vii) [Reserved]

(viii) [Reserved]

(ix) Sodium fluoride, not less than 0.5 percent and not more than 1.0 percent.

(x) Piperazine dihydrochloride, not less than 0.18 percent and not more than 0.72 percent (piperazine base 0.1 percent to 0.4 percent).

(xi) Piperazine phosphate monohydrate, not less than 0.23 percent and not more than 0.92 percent (piperazine base 0.1 percent to 0.4 percent).

(xii) Piperazine sulfate, not less than 0.21 percent and not more than 0.85 percent (piperazine base 0.1 percent to 0.4 percent).

(xiii) Piperazine monohydrochloride, not less than 0.13 percent and not more than 0.52 percent (piperazine base 0.1 percent to 0.4 percent).

(xiv) Di-*N*-butyl tin dilaurate 0.07 percent, piperazine sulfate 0.12 percent and phenothiazine 0.29 percent.

(6) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection) and hexamitiasis in poultry, bacterial swine enteritis, and/or bacterial calf diarrhea; its labeling bears adequate directions and warnings for such use, and it contains, per ton of feed, not less than 50 grams of chlortetracycline or oxytetracycline or a combination of such drugs; or, if it is intended solely for use as an aid in the prevention of bacterial swine enteritis, it contains, per ton of feed, not less than 45 grams nor more than 90 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin. If it contains not less than 100 grams of chlortetracycline or oxytetracycline or a combination of such drugs per ton of feed, it may also be represented for use as an aid in the prevention of synovitis in poultry. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(7) (i) It is intended for use solely as a treatment for complicated, chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever), and hexamitiasis in poultry, and/or bacterial swine enteritis; its labeling contains adequate directions and warnings for such use; and it contains, per ton of feed, not less than 100 grams of chlortetracycline or oxytetracycline or a combination of such drugs or not less than 90 grams nor more than 180 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin. If it contains not less than 200 grams of chlortetracycline or oxytetracycline or a combination of such drugs per ton of feed, it may also be represented for use as an aid in the control of synovitis in poultry. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it is intended for use solely in poultry, it may contain 0.1 percent of para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid; or if it is intended for continuation of coccidiosis prevention it shall contain, in the amount specified, one of the ingredients prescribed by paragraph (b)(1) of this section. If it is intended for use solely in the treatment of the diseases of chickens described in this subparagraph, it contains, per ton of feed, not less than 100 grams and not more than 200 grams of chlortetracycline and it contains not less than 0.4 percent and not more than 0.8 percent of dietary calcium, then representations may be made in its labeling to the effect that the reduced amount of calcium aids in increasing the concentrations of the antibiotic in the blood of treated birds; the labeling of such medicated feed shall include that required by § 121.208 of this chapter. If it is intended for use solely as a treatment for bacterial swine enteritis, it may contain, per ton of feed, not less than 90 grams nor more than 270 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin, provided that its labeling bears a warning that the feed is not to be used for more than 14 days.

(ii) It is also intended for use in the prevention and control of coccidiosis in chickens caused by *E. tenella* and *E. necatrix*; its labeling bears adequate directions and warnings for such use (including the directions and warnings required by paragraph (b)(7)(i) of this section), and it contains, per ton of feed, 200 grams of chlortetracycline and 0.8 percent of dietary calcium.

(iii) It is also intended for use in the treatment of coccidiosis in chickens caused by *E. tenella* and *E. necatrix*; its labeling bears adequate directions and warnings for such use (including the directions and warnings required by paragraph (b)(7)(i) of this section); and it contains, per ton of feed, 200 grams of chlortetracycline and 0.4 percent to 0.55 percent of dietary calcium.

(8) It is intended for use solely in the prevention of coccidiosis and hexamitasis outbreaks in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains di-*N*-butyl tin dilaurate in a quantity, by weight of feed, of 0.0375 percent.

(9) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use, and it contains, per ton of feed, the equivalent of not less than 50 grams and not more than 100 grams of bacitracin, or not less than 50 grams and not more than 100 grams of penicillin, or not less than 50 grams and not more than 100 grams of penicillin and bacitracin in a combination containing not less than 50 percent nor more than 75 percent of bacitracin. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(10) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infections sinusitis, and blue comb nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of either 100 grams of penicillin, or not less than 100 grams and not more than 500 grams of bacitracin (as bacitracin or zinc bacitracin), or not less than 100 grams and not more than 200 grams of bacitracin (as bacitracin methylene disalicylate), or not less than 100 grams and not more than 500 grams of penicillin and bacitracin (as bacitracin or zinc bacitracin) in a combination containing not less than 50 percent nor more than 75 percent of bacitracin but in no case containing more than 125 grams of penicillin, or not less than 100 grams and not more than 200 grams of penicillin and bacitracin (a bacitracin methylene disalicylate) in a combination containing not less than 25 percent of penicillin nor less than 50 percent of bacitracin; except that, if it is intended for the treatment of bacterial swine enteristis, it contains, per ton of feed, either 100 grams of bacitracin (as bacitracin, zinc bacitracin, or bacitracin methylene disalicylate), or 100 grams of a combination of penicillin and bacitracin (as bacitracin, zinc bacitracin, or bacitracin methylene disalicylate), containing not less than 50 percent nor more than 75 percent of bacitracin. When intended for the uses specified in this subparagraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section; *Provided, however,* That the level of antibiotic or antibiotic combination present is not greater than the minimum amount specified therefor in this subparagraph.

(11) It is intended for use solely as a treatment for bacterial swine enteritis caused by *Salmonella choleraesuis*, its labeling bears adequate directions and warnings for such use, and it contains nitrofurazone in a quantity, by weight of feed, of 0.056 percent.

(12) It is intended for use solely in the prevention of coccidiosis, chronic respiratory disease (air-sac infection) and hexamitiasis in poultry; its labeling bears adequate directions and warnings

for such use; and it contains, in the amount specified, one of the ingredients prescribed by paragraph (b) (1) of this section and not less than 50 grams of chlortetracycline per ton of feed. When intended for such uses it may also contain oxytetracycline in a quantity not less than 50 grams per ton of feed.

(13) It is intended for use solely in the prevention or treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid.

(14) It is intended solely as an aid in the prevention and control of losses due to low-grade bacterial enteritis in mink; its labeling bears adequate directions and warnings for such use; and it contains not less than 5.7 grams of chlortetracycline, 1.0 gram of bacitracin, and 0.75 gram of penicillin (with or without oxytetracycline) per ton of feed.

(15) It is intended for use solely as an aid in the prevention or treatment or to lessen the morbidity in poultry in outbreaks of fowl typhoid, pullorum, the paratyphoids, infectious arthritis due to a filterable agent, histomoniasis (blackhead), hexamitiasis, quail disease (ulcerated enteritis), paracolon infection, avian infectious hepatitis, and coccidiosis, its labeling bears adequate directions and warnings for such use; and it contains the following quantities of furazolidone, by weight of feed, for the conditions indicated:

(i) For the prevention of fowl typhoid, pullorum, and the paratyphoids in birds older than 2 weeks: 0.0055 percent.

(ii) For the prevention of the diseases listed in paragraph (b) (15) (i) of this section in birds younger than 2 weeks, and for the treatment of these same conditions in birds regardless of age: 0.011 percent.

(iii) For the prevention of histomoniasis (blackhead), paracolon infection, and infectious arthritis due to a filterable agent, and for the prevention and treatment of hexamitiasis and quail disease (ulcerative enteritis): 0.011 percent.

(iv) For the treatment of histomoniasis (blackhead), paracolon infection, and avian infectious hepatitis of chickens, and to lessen the morbidity in outbreaks of infectious arthritis due to a filterable agent: 0.022 percent.

(v) For the prevention of coccidiosis in chickens: 0.0055 percent.

(vi) For the control of coccidiosis in chickens: 0.011 percent.

(16) (i) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection); its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline or oxytetracycline or a combination of these two drugs per ton of feed. When intended for such use, it may also contain the equivalent of not less than 50 grams of bacitracin per ton of feed.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in paragraph (b) (15) of this section; it contains one of the ingredients in the amount and under the conditions set forth in paragraph (b) (16) (i) of this section; and it contains furazolidone in the amount specified in paragraph (b) (15) of this section.

(17) (i) It is intended for use solely as an aid in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever) in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 100 grams of chlortetracycline or oxytetracycline or a combination of these two drugs per ton of feed. When intended for such use, it may also contain the equivalent of not less than 100 grams of bacitracin per ton of feed.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in paragraph (b) (15) of this section; it contained one of the ingredients in the amount and under the conditions set forth in paragraph (b) (17) (i) of this section; and it contains furazolidone in the amount specified in paragraph (b) (15) of this section.

(18) (i) It is intended for use solely in the prevention of outbreaks of coccidiosis in poultry flocks, and it contains nicarbazin (4,4'-dinitrocarbanilide complex with 2-hydroxy-4,6-dimethylpyrimidine) in a quantity, by weight of feed, of not less than 0.01 percent and not more than 0.02 percent, or 2,4-diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine in a quantity, by weight of feed, of 0.00075 percent and sulfaquinoxaline in a quantity, by weight of feed, or 0.0075 percent; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug, unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in paragraph (b) (6) and (7) and/or (9) and (10) or (16) and (17) of this section, it contains one of the ingredients in the amount and under the conditions set forth in paragraph (b) (18) (i) of this section, and it contains the ingredients in the amounts specified in paragraph (b) (6) and (7) and/or (9) and (10) or (16) and (17) of this section, except that the coccidiostat shall be only one of those specified in paragraph (b) (18) (i) of this section.

(iii) It is intended for use in the diseases specified in paragraph (b) (18) (i), (ii), and (iv) of this section, it contains ingredients in the amounts and under the conditions specified in those subdivisions, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

(iv) It is also intended for use as an adjunct in reducing the tapeworm and large roundworm burden of chickens so treated, it contains 2,2'-dihydroxy-3,3',5,5'-tetrachlorodiphenyl sulfide (bithionol), and 4,6-diamino-1-(4-methylmercaptophenyl) - 1,2 - dihydro - 2,2 - dimethyl - 1,3,5 - triazine hydrochloride (methiotriazamine), in the amounts and under the conditions set forth in paragraph (b) (18) (i) of this section.

(19) [Reserved]

(20) It is intended as an aid in stimulating growth, the prevention of coccidiosis, large roundworms and tapeworms in chickens and turkeys and the prevention of hexamitiasis in turkeys, and it contains in a quantity by weight of feed acetyl (*p*-nitrophenyl) sulfanilamide 0.03 percent, dibutyltin dilaurate 0.02 percent, dinitrodiphenylsulfonylethylenediamine 0.02 percent, and 3-nitro-4-hydroxyphenylarsonic acid 0.005 percent.

(21) It is a medicated chicken feed containing penicillin and dienestrol diacetate with or without amprolium in the amounts and for the purposes indicated in § 121.266 of this chapter, and its labeling gives adequate directions and warnings for such use.

(22) (i) It is intended for use solely in the control of outbreaks of coccidiosis in poultry flocks and it contains in a quantity, by weight of feed, not less than 0.003 percent and not more than 0.006 percent of 2,4-diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine and not less than 0.01 percent and not more than 0.02 percent of sulfaquinoxaline, and there has been submitted to the Commissioner, in triplicate, the information required for Form FD-1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(ii) It is intended for use in the disease specified in paragraph (b) (20) (i) of this section, it contains the ingredients in the amounts and under the conditions specified in that paragraph, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

(23) It is intended for use solely as an aid in the reduction of losses due to enterotoxemia in sheep; its labeling bears adequate directions and warnings for such use; and it contains not less than 20 grams of chlortetracycline per ton of feed.

(24) It is intended for use in the maintenance of weight gains of swine in the presence of atrophic rhinitis or as an aid in reducing the incidence of cervical abscesses in swine; its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline per ton of feed.

(25) It is a medicated cattle feed containing chlortetracycline in the amounts and for the purposes indicated in § 121.208 of this chapter, and its labeling bears adequate directions and warnings for such use.

(26) (i) It is intended for use solely for accelerating weight gains in beef cattle, and it contains a quantity of diethylstilbestrol adequate to provide not more than 10 milligrams per head per day when fed in accordance with the directions for use that accompany the feed, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form F–1800 and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 514.9 of this chapter.

(ii) It is also intended for the prevention or treatment of the diseases specified in paragraph (b) (25) of this section, It contains diethylstilbestrol in the amount and under the conditions set forth in subdivision (i) of this subparagraph, and it contains the antibiotic in the amount specified in paragraph (c) (25) of this section.

(27) It is intended for use as an aid in maintaining or increasing egg production, hatchability of eggs, prevention of early mortality of chicks when due to organisms that are sensitive to chlortetracycline, and for improving feed efficiency as related to egg production; its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline per ton of feed, except that if it is intended for use in the presence of disease outbreaks it shall contain not less than 100 grams of chlortetracycline per ton of feed.

(28) It is a medicated feed for beef cattle containing bacitracin methylene disalicylate with or without diethylstilbestrol in the amounts and for the purposes specified in § 121.252 of this chapter and its labeling bears adequate directions and warnings for such use.

(29) It is intended for use solely as an aid in reducing the incidence of bacterial diarrhea in laboratory mice; its labeling bears adequate directions and warnings for such use; and it contains not less than 100 grams of chlortetracycline per ton of feed.

(30) It is intended for use as an aid in maintaining or increasing egg production of chickens, hatchability of eggs, prevention of early mortality of chicks when due to organisms that are sensitive to streptomycin and penicillin, and for improving feed efficiency of chickens or turkeys; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, not less than 22.5 grams and not more than 50 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin, except that if it is intended for use in the presence of disease as an aid in maintaining or increasing hatch ability of eggs or for the prevention of early mortality of chicks, it contains 90 grams per ton of feed of penicillin and streptomycin in a combination containing 16.7 percent penicillin.

(31) [Reserved]

(32) (i) It is intended for use as an aid in the control of infestation of large roundworms (*Ascaris suis*), nodular worm (*Oesophagostemum dentatum*), and whipworm (*Trichuris suis*) in swine; its labeling bears adequate directions and warnings for such use, including a warning that its use must be discontinued 48 hours before the treated swine are slaughtered for human consumption. If it is a complete feed it contains 6,000 units (6 milligrams) of hygromycin B (produced by the growth of *Streptomyces hygroscopicus*) per pound, or if it is a hygromycin B feed supplement or premix it contains not more than 8,000,000 units (8 grams) of hygromycin B per pound. It contains less than 50 grams of antibiotics per ton of finished feed. If it is a hygromycin B feed supplement or premix and it contains more than 8,000,000 units of hygromycin B per pound, it shall be exempt from certification only if there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter. When intended for the uses specified in this paragraph (b) (32), it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in such paragraph, its labeling must bear a warning that it must be discontinued 5 days (in lieu of 48 hours as required in this subparagraph) before the treated swine are slaughtered for human consumption.

(ii) It is also intended for the prevention or treatment of bacterial swine enteritis as specified in paragraph (b) (9) and (10) of this section; it contains hygromycin B in the amounts and under the conditions set forth in paragraph (b) (32) (i) of this section; and it contains the drugs in the amount specified in paragraph (b) (9) and (10) of this section. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear the warning specified in paragraph (b) (32) (i) of this section.

(iii) It is also intended for the prevention and treatment of bacterial swine enteritis, it contains hygromycin B in the amounts and under the conditions set forth in paragraph (b) (32) (i) of this section, and it contains penicillin and streptomycin in the amounts specified in paragraph (b) (6) and (7) of this section. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear the warning specified in paragraph (b) (32) (i) of this section.

(iv) It is also intended for the prevention and treatment of bacterial swine enteritis, for the maintenance of weight gains of swine in the presence of atrophic rhinitis and for reducing the incidence of cervical abcesses in swine, it contains hygromycin B in the amounts and under the conditions set forth in paragraph (b) (32) (i) of this section, and it contains, per pound of feed, 0.025 gram (50 grams per ton), of the chlortetracycline; except that if it is intended for use in the treatment of bacterial swine enteritis it shall contain, per pound of feed, 0.05 gram (100 grams per ton) of chlortetracycline.

(33) It is intended for use as an aid in reducing the incidence and severity of bloat in cattle on legume pastures; it contains a quantity of procaine penicillin that, when used as directed in the labeling, is sufficient to furnish each treated bovine animal not less than 75,000 units as a single daily dose; and, if the drug supplement used to prepare the medicated feed contains more than 2 percent moisture, its manufacturer has submitted to the Commissioner information adequate to prove its stability for 6 months under customary conditions of purchase and use.

(34) It is intended for use as an aid in the reduction of bacterial diarrhea in dairy cattle or as an aid in reduction of losses due to respiratory infection (infectious rhinotracheitis—shipping fever complex) or as an aid in the prevention of foot rot in cattle; its labeling bears adequate directions and warnings for such uses; and it contains the following quantities of chlortetracycline, by weight of feed, for the conditions indicated:

(i) For the prevention of foot rot and as an aid in the reduction of bacterial diarrhea in diary cattle: 0.1 milligram per pound of body weight per day.

(ii) As an aid in reduction of losses due to respiratory infection (infectious rhinotracheitis—shipping fever complex) in dairy cattle: 0.1 milligram per pound of body weight per day, except that if it is intended for use for more than 30 days it may contain chlortetracycline, in a quantity by weight of feed to provide 70 milligrams per head per day.

(35) It is a medicated chicken feed containing antibiotics, sulfanitran (acetyl-(*p*-nitrophenyl)-sulfanilamide), and 3,5-dinitrobenzamide, with or without 3-nitro-4-hydroxyphenylarsonic acid in the amounts and for the purposes indicated in § 121.264 of this chapter; or containing antibiotics, sulfanitran (acetyl-(*p*-nitrophenyl) - sulfanilamide), and aklomide (2-chloro-4-nitrobenzamide), in the amounts and for the purposes indicated in §§ 121.264 and 121.269 of this chapter; its labeling bears adequate directions and warnings for such use; and

there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling of potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(36) [Reserved]

(37) [Reserved]

(38) It is intended for use solely for accelerating weight gains in sheep; its labeling bears adequate directions and warnings for such use, including a warning that its use must be discontinued 7 days before the treated animals are slaughtered for human consumption; it contains a quantity of diethylstilbestrol adequate to provide not more than 2 milligrams per head per day when fed in accordance with the directions for use that accompany the feed; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800 and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 514.9 of this chapter.

(39) It is intended for use solely as an aid in the prevention or treatment of fowl typhoid, paratyphoid, and pullorum disease and as an aid in stimulating growth in poultry flocks; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 48 hours before the treated animals are slaughtered for human consumption; and it contains 3,5-dinitrobenzamide in a quantity, by weight of feed, of not less than 0.075 percent and not more than 0.15 percent; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter. When intended for the uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear a warning that it must be discontinued 5 days (in lieu of 48 hours as required in this paragraph (b)(39) before the treated chickens or turkeys are slaughtered for human consumption.

(40) It is intended as an aid in maintaining or increasing egg production, hatchability of eggs, reduction of the effects of stress, prevention of early mortality of chicks, and reduction of the effects of diseases when due to organisms that are sensitive to bacitracin or to a mixture of bacitracin and penicillin, for maintaining appetite and for improving feed efficiency as related to egg production; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of 50 grams of bacitracin or a mixture of 37.5 grams of bacitracin and 12.5 grams of penicillin when fed during the first 4 to 6 weeks of egg production, and not less than the equivalent of 10 grams of bacitracin or a mixture of 7.5 grams of bacitracin and 2.5 grams of penicillin when fed during the remainder of the laying period; except that if it is intended for use to increase egg hatchability or prevention of early mortality of chicks or for use in the presence of disease outbreaks or during periods of stress, it shall contain, per ton of feed, the equivalent of 100 grams of bacitracin or a mixture of 75 grams of bacitracin and 25 grams of penicillin, and except that if it is a starter ration for chicks for the purpose of preventing early mortality of chicks due to susceptible organisms, it may contain, per ton of feed, 100 grams to 500 grams of a combination of penicillin and bacitracin (as bacitracin or zinc bacitracin) containing not less than 50 percent and not more than 75 percent of bacitracin, but in no case more than 125 grams of penicillin.

(41) (i) It is intended for use as an aid in reducing the spread of leptospirosis in swine; it contains 200 grams of chlortetracycline per ton of feed; and its labeling bears information that it is to be administered continuously.

(ii) It is intended for use solely as an aid in reducing the shedding of leptospirae in swine and as an aid in reducing abortion rate and mortality of newborn pigs in the presence of leptospirosis; it contains 400 grams of chlortetracycline per ton of feed; and its labeling bears information that it is to be administered to the animals for 14 days.

(42) It is a medicated chicken and turkey feed containing certifiable antibiotics and nystatin in the amounts and for the purposes indicated in § 121.220 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(43) It is intended for use solely as an aid in reducing the incidence of vibrionic abortion in breeding sheep; its labeling bears adequate directions and warnings for such use, including information that it is to be administered continuously during pregnancy; and it contains chlortetracycline in a quantity that, when administered as directed in its labeling, will provide a total daily dose of 80 milligrams per animal.

(44) It is a medicated chicken or turkey feed containing antibiotics and amprolium, with or without arsanilic acid, in the amounts and for the purposes indicated in § 121.210 of this chapter, and its labeling bears adequate directions and warnings for such use: *Provided, however,* That such medicated complete feed has been prepared from a concentrated amprolium-antibiotic medicated feed that contained not more than 0.05 percent amprolium. If the complete medicated feed is prepared from a product of amprolium that contains more than 0.05 percent of the drug, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter. Both concentrates and complete poultry feed containing amprolium must comply with all the requirements of § 121.210 of this chapter, including labeling.

(45) It is a medicated chicken or turkey feed containing antibiotics and zoalene, with or without arsanilic acid, or 3-nitro-4-hydroxyphenylarsonic acid, in the amounts and for the purposes indicated in § 121.207 of this chapter; *Provided, however,* That such medicated complete feed has been prepared from a concentrated zoalene-antibiotic medicated feed that contained not more than 0.0375 percent zoalene. If the complete medicated feed is prepared from a product of zoalene that contains more than 0.0375 percent zoalene, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the the change is made in conformance with other provisions of § 314.8 of this chapter. Both concentrates and complete poultry feed containing zoalene must comply with all the requirements of

§ 121.207 of this chapter, including labeling.

(46) It is a mink feed containing chlortetracycline, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(47) It is a pheasant feed containing bacitracin, zinc bacitracin, or bacitracin methylene disalicylate and penicillin, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(48) It is a quail feed containing bacitracin and penicillin, in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(49) It is a medicated chicken or turkey feed containing antibiotics and reserpine in the amounts and for the purposes indicated in § 121.205 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions § 314.8 of this chapter.

(50) It is a medicated chicken feed containing antibiotics and hygromycin B in the amounts and for the purposes indicated in § 121.213 of this chapter, and its labeling bears adequate directions and warnings for such use: *Provided, however,* That such medicated complete feed has been prepared from a feed additive concentrate that contains not more than 32 grams of hygromycin B per ton. If the medicated feed is prepared from a feed additive concentrate containing more than 32 grams of hygromycin B per ton, it is exempt from certification only under the condition that there has been submitted to the Commissioner in triplicate, adequate information of the kind required for Form FD–1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approval supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(51) It is a medicated beef cattle, chicken, or turkey feed containing bacitracin, bacitracin methylene disalicylate or zinc bacitracin or a combination of one of these with penicillin, in the amounts and for the purposes indicated in §§ 121.232, 121.233, and 121.252 of this chapter, and its labeling bears adequate directions and warnings for such use.

(52) It is a cattle feed containing zinc bacitracin, with or without diethylstilbestrol, in the amounts and for the purposes indicated in § 121.225 or § 121.241 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That if such feed contains diethylstilbestrol it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800 and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 514.9 of this chapter.

(53) It is a medicated feed for turkeys and contains chlortetracycline hydrochloride and dietary calcium in the amounts and for the purposes indicated in § 121.208(d), Table 1, Item 12, of this chapter; and its labeling bears adequate directions and warnings for such use.

(54) It is a medicated feed for growing broiler and replacement chickens; it contains amprolium, ethopabate (methyl-4-acetamido-2-ethoxy benzoate), and antibiotics, with or without arsanilic acid or 3-nitro-4-hydroxyphenylarsonic acid, in the amounts and for the purposes indicated in § 121.210 of this chapter; and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such medicated complete feed has been prepared from a concentrated medicated feed that contained not more than 0.05 percent amprolium and not more than 0.0016 percent ethopabate. If the medicated feed is prepared from a product that contains more than 0.05 percent amprolium and more than 0.0016 percent ethopabate, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter. Both concentrates and finished poultry feed containing amprolium and ethopabate must comply with all the requirements of § 121.210 of this chapter, including labeling.

(55) It is a medicated swine feed containing a combination of chlortetracycline, penicillin, and sulfamethazine, or sulfathiazole in the amounts and for the purposes indicated in § 121.208 or § 558.115 of this chapter, and its labeling bears adequate directions and warnings for such use.

(56) It is a medicated feed for chickens containing a combination of procaine penicillin and tylosin phosphate in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That such medicated complete feed has been prepared from a concentrated medicated feed that contained not more than 200 grams of tylosin phosphate per ton. If the medicated feed is prepared from a concentrated medicated feed containing more than 200 grams of tylosin phosphate per ton, it is exempt from certification only under the condition that there has been submitted to the Commissioner in triplicate, adequate information of the kind required for Form FD–1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(57) It is a horse feed containing chlortetracycline in the amounts and for the purposes indicated in § 121.225 of this chapter, and its labeling bears adequate directions and warnings for such use.

(58) [Reserved]

(59) It is a medicated feed for chickens containing penicillin, tylosin phosphate, and either amprolium, or zoalene, or hygromycin B, or hygromycin B and zoalene, or hygromycin B and amprolium in the amounts and for the purposes indicated in § 121.207, § 121.210, or § 121.213 of this chapter, and its labeling bears adequate directions and warnings for such use: *Provided, however,* That such medicated complete feed has been prepared from a concentrated penicillin-tylosin phosphate-amprolium, or penicillin-tylosin phosphate-zoalene, or penicillin-tylosin phosphate-hygromycin B or penicillin-tylosin phosphate-zoalene-hygromycin B, or penicillin-tylosin phosphate-hygromycin B-amprolium medicated feed containing per ton of feed, not more than 200 grams of tylosin and either not more than 0.05 percent amprolium or not more than 0.0375 percent zoalene, or not more than 32 grams per ton of hygromycin B, or not more than 0.0375 percent zoalene and not more than 32 grams per ton of hygromycin B, or not more than 0.05 percent amprolium and not more than 32 grams per ton of hygromycin B. If the medicated feed is prepared from a product that contains more than any of the specified quantities, it is exempt from certification only under the condition that there has been submitted to the Commissioner, in triplicate adequate information of the kind required for Form FD–1800—Revised under § 314.1(c)(3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in

conformance with other provisions of § 314.8 of this chapter.

(60) It is a medicated chicken feed containing antibiotics and nihydrazone in the amounts and for the purposes indicated in § 121.237 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(61) It is a medicated chicken feed containing antibiotics and buquinolate in the amounts and for the purposes indicated in § 121.291 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(62) It is a medicated cattle feed containing antibiotics and sulfamethazine in the amounts and for the purposes indicated in § 121.208 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(63) It is a medicated feed containing antibiotics, clopidol, and 3-nitro-4-hydroxyphenylarsonic acid in the amounts and for the purposes indicated in §§ 121.262 and 121.325 of this chapter; its labeling bears adequate directions and warnings for such use; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD-1800—Revised under § 314.1(c) (3) of this chapter and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning for any act changing the labeling of potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 314.8 of this chapter.

(64) It is a medicated feed containing decoquinate and antibiotics and it is used in accordance with § 558.195 of this chapter.

Subpart G—Sponsors of Approved Applications

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical code. The code numbers identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The code numbers will appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section.

(c) The names, addresses, and drug listing numbers of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address:	*Drug listing No.*
Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., 19 North Railroad St., Myerstown, PA 17067	011825
Agricultural Processing Corp., 225 Alabama St., P.O. Box 245, Salem, VA 24153	011904
Agricultural & Veterinary Products Division, Abbott Laboratories, Abbott Park, North Chicago, IL 60064	043731
Albers Milling Co., Carnation Bldg., 5045 Wilshire Blvd., Los Angeles, CA 90036	017826
Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015	011485
Allied Chemical Corp., Agricultural Division, 40 Rector St., New York, NY 10006	011462
Alton Premium Feed Co., Alton, IA 51003	018356
American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540	010042
American Scientific Laboratories, A Division of Schering Corp., Bloomfield, NJ 07003	000138
Anthony Veterinary Products Co., 11634 McBean Drive, El Monte, CA 91732	000864
Armour Pharmaceutical Co., P.O. Box 3113, Omaha, NE 68103	000053
Ayerst Laboratories, Division of American Home Products Corp., 685 Third Ave., New York, NY 10017	000046
Babineaux's Veterinary Products, Inc., 6425 Airline Highway, Metairie, LA 70003	021188
Balfour Guthrie & Co., Ltd., 315 North H St., Fresno, CA 93701	043728
Bayvet Corp., P.O. Box 390, Shawnee Mission, KS 66201	000859
Beecham-Massengill Pharmaceuticals, Division of Beecham, Inc., Bristol, TN 37620	000029
Blair Milling & Elevator Co., Inc., 1000 Main St., Atchison, KS 66002	018597
Bristol Laboratories, Division of Bristol-Myers Co., P.O. Box 657, Syracuse, NY 13201	000015
Burns Biotec Laboratories Division, Chromalloy Pharmaceuticals, Inc., 7711 Oakport St., Oakland, CA 94621	000845
Cadco, Inc., P.O. Box 3599, 10100 Douglas Ave., Des Moines, IA 50322	011490
Caribe Chemical Co., Inc., 576 Fifth Ave., New York, NY 10036	000345
Carson Chemicals, Inc., New Castle, IN 47362	011769
Central Soya Co., Inc., McMillan Feed Division, 1300 Fort Wayne Bank Building, Fort Wayne, IN 46802	012286
Ciba Pharmaceutical Co., 556 Morris Ave., Summit, NJ 07901	000028
Commercial Solvents Corp., 1331 South First St., Terre Haute, IN 47808	012769
The A. O. Cooper Co., Humbolt, NE 68376	043426
Cooper U.S.A., Inc., P.O. Box 12338, Research Triangle Park, NC 27709	011492
John D. Copanos & Co., Inc., Baltimore, MD 21225	010271
Cutter Laboratories, Inc., Fourth and Parker St., Berkeley, CA 94710	000161
D-M-Pharmaceuticals, Inc., 1146 Taft St., Rockville, MD 20850	000693
Danbury Pharmacal, Inc., 131 Wests St., Danbury, CT 06810	000591
Dawes Laboratories, Inc., 450 State St., Chicago Heights, IL 60411	024264
Dean's Specialty Supply Co., 310 Second Ave. SW., Waseca, MN 56093	024817
Diagnostic Data, Inc., 518 Logue Ave., Mountain View, CA 94040	024991
Diamond Laboratories, Inc., P.O. Box 863, Des Moines, IA 50304	013947
Diamond Shamrock Chemical Co., 60 Park Pl., Newark, NJ 07101	025001
Doboy Feeds, Domain Industries, Inc., 215 North Knowles Ave., New Richmond, WI 54017	025796
The Dow Chemical Co., P.O. Box 1706, Midland, MI 48640	025700
Eaton Laboratories, Division of Morton-Norwich Products, Inc., P.O. Box 191, Norwich, NY 13815	000035
Elanco Products Co., A Division of Eli Lilly & Co., 740 South Alabama St., Indianapolis, IN 46206	000986
Endo Laboratories, Ind., 1000 Stewart Ave., Garden City, NY 11530	000056
Evsco Pharmaceutical Corp., 3345 Royal Ave., Oceanside, NY 11572	017030
Farmer's Union Grain Terminal Association, Feed Division, P.O. Box 1447, Sioux Falls, SD 57101	017162
Farmers Feed & Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772	043744
The Farnam Companies, Inc., 8701 North 29th St., Omaha, NE 68112	017135
Fasco Mills Co., Box 70, Route 34 East, Mendota, IL 61342	030804
Feed Fortifiers, Inc., Manson, IA 50563	017255
Feed Products, Inc., 1000 West 47th Ave., Denver, CO 80211	013959
Feed Specialties Co., 1877 NE. 58th Ave., Des Moines, IA 50313	017274
Forbes Laboratories, 402 West Lakeside St., Madison, WI 53715	032420

Firm name and address:	Drug listing No.
Formica Laboratories, 124 East Fifth St., Little Rock, AR 72115	043734
Fort Dodge Laboratories, Fort Dodge, IA 50501	000856
Fromm Laboratories, Inc., Grafton, WI 53024	020112
FS Services, Inc., 1701 Towanda Ave., Bloomington, IL 61701	020275
Gland-O-Lac Co., 1818 Leavenworth St., Omaha, NE 68102	043735
Glogau & Co., Inc., 4614 West Lake St., Melrose Park, IL 60160	010469
H. Clay Glover Co., Inc., 1001 Franklin Ave., Garden City, NY 11530	010471
Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334	021780
Gooch Feed Mill Corp., 540 South St., Lincoln, NE 68501	021798
Grain Processing Corp., Muscatine, IA 52761	022591
G. C. Hanford Manufacturing Co., P.O. Box 1055, Syracuse, NY 13201	010515
Hart-Delta, Inc., 5055 Choctaw Drive, Baton Rouge, LA 70805	015563
Heinold Elevator Co., Inc., Kouts, IN 46347	043727
Henwood Feed Additives, Inc., 211 Western Rd., Box 577, Lewisburg, OH 45338	026186
Hess & Clark, Division of Rhodia, Inc., Ashland, OH 44805	011801
Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035	000514
Hoechst-Roussel Pharmaceuticals, Inc., Route 202-206, Somerville, NJ 08876	000039
Hoffmann-La Roche, Inc., Nutley, NJ 07110	000004
Hubbard Milling Co., 424 North Front St., Mankato, MN 56001	012190
International Nutrition, Inc., 6664 "L" St., Omaha, NE 68117	043733
Jensen-Salsbery Laboratories, Division of Richardson-Merrell, Inc., Kansas City, MO 64141	017220
KASCO-EFCO Laboratories, Inc., P.O. Box 730, Hicksville, NY 11802	010616
Land O'Lakes, Inc., Agricultural Services, 2827 Eighth Avenue South, Fort Dodge IA 50501	034500
Dr. LeGear, Inc., 4161 Beck Ave., St. Louis, MO 63116	011950
Mattox & Moore, Inc., 1503 East Riverside Drive, Indianapolis, IN 46207	027863
Maurry Biological Co., Inc., 6109 South Western Ave., Los Angeles, CA 90047	010719
McClellan Laboratories, Inc., 19600 Sixth Ave., Lakeview, CA 92353	043738
McKesson Laboratories, Bridgeport, CT 06602	000022
McNeil Laboratories, Inc., Camp Hill Rd., Fort Washington, PA 19034	000045
Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065	000006
M & M Livestock Products Co., Eagle Grove, IA 50533	026282
Moorman Manufacturing Co., Quincy, IL 62301	021930
Myers-Carter Laboratories, Inc., 5160 West Bethany Home Rd., Glendale, AZ 85301	000381
National Laboratories Corp., 1721 Baltimore Ave., Kansas City, MO 64108	011811
Nixon and Co., Kiewitt Plaza, Omaha, NE 88501	043729
Norden Laboratories, Inc., Lincoln, NE 68501	011519
Norwich Agricultural Products, A Division of Morton-Norwich Products, Inc., Norwich, NY 13815	000947
Parke, Davis & Co., Joseph Campau Avenue at the River, Detroit, MI 48232	000071
S. B. Penick & Co., 100 Church St., New York, NY 10008	000794
Penwalt Corp., P.O. Box 1297, Takoma, WA 98401	000018
Peter Hand Foundation, 2 East Madison St., Waukegan, IL 60085	043737
Pfizer, Inc., 235 East 42d St., New York, NY 10017	000069
Philips Roxane, Inc., 2621 North Belt Highway, St. Joseph, MO 64502	000010
Pitman-Moore, Inc., Washington Crossing, NJ 08560	011716
Premier Malt Products, Inc., Milwaukee, WI 53201	032707
Protein Blenders, Inc., Box 631, Highway 218 South, Iowa City, IA 52240	033999
The Purdue Frederick Co., 50 Washington St., Norwalk, CT 06856	000034
Quail-Tech Products, Inc., 318 Lake Hazeltine Drive, Chaska, MN 55318	016968
Rachelle Laboratories, Inc., 700 Henry Ford Ave., P.O. Box 2029, Long Beach, CA 90801	000196
Ralston-Purina Co., Checkerboard Square, St. Louis, MO 63199	017800
Richlyn Laboratories, Inc., Castor and Kensington Aves., Philadelphia, PA 19124	000115
A. H. Robins Co., Research Laboratories, 1211 Sherwood Ave., Richmond, VA 23220	000031
Salsbury Laboratories, Charles City, IA 50616	017210
Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033	000085
G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680	000014
Shell Chemical Co., Division of Shell Oil Co., Agricultural Division, 2401 Crow Canyon Rd., San Ramon, CA 94583	011461
Simonsen Mill-Rendering Plant, Inc., Quimby, IA 51049	034418
Smith Kline Animal Health Products, Division of SmithKline Corp., 1500 Spring Garden St., Philadelphia, PA 19101	000007
Square Deal Fortification Co., Kouts, IN 46347	036108
E.R. Squibb & Sons, Inc., P.O. Box 4000, Princeton, NJ 08540	000003
Stauffer Chemical Co., 1200 South 47th St., Richmond, CA 94804	017032
Sterling Drug Inc., 90 Park Ave., New York, NY 10016	000934
Summit Hill Laboratories, P.O. Box 1, Avalon, NJ 08202	037990
Syntex Laboratories, Inc., 3401 Hillview Drive, Palo Alto, CA 94304	000033
Tevcon Ind., Inc., 8904 J St., Omaha, NE 68127	011757
Thuron Industries, Inc., 12200 Denton Drive, Dallas, TX 75234	011536
The Upjohn Co., Kalamazoo, MI 49001	000009
Vita Plus Corp., 1508 W. Badger Rd., P.O. Box 926, Madison, WI 53701	033071
V.P.O., Inc., 4444 S. 76th St., Omaha, NE 68127	043743
Walnut Grove Products, Division of W. R. Grace & Co., 201 Linn St., Atlantic, IA 50022	034139
West Chemical Products, Inc., 42-16 West St., Long Island City, NY 11101	011538
Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601	043732
Western Serum Co., P.O. Box 7025, Phoenix, AZ 85011	011398
Whitmoyer Laboratories, 19 North Railroad St., Myerstown, PA 19067	011794
Winthrop Laboratories, Division Sterling Drug, Inc., 90 Park Ave., New York, N.Y. 10016	000024
Wittney & Co., 4655 Colorado Blvd., Denver, CO 80216	012481
Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101	000008
Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247	035369
Young's Inc., Roaring Spring, PA 16673	035393
Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647	000172
Zip Feed Mills, 304 East Eighth St., Sioux Falls, SD 57102	017434

(2) NUMERICAL LISTING OF SPONSORS

Drug Listing No.:	Firm name and address
000003	E. R. Squibb & Sons, Inc., P.O. Box 4000, Princeton, NJ 08540.
000004	Hoffmann-La Roche, Inc., Nutley, NJ 07110.
000006	Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065.
000007	Smith Kline Animal Health Products, Division of SmithKline Corp., 1500 Spring Garden St., Philadelphia, PA 19101.
000008	Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101.
000009	The Upjohn Co., Kalamazoo, MI 49001.
000010	Philips Roxane, Inc., 2621 North Belt Highway, St. Joseph, MO 64502.
000014	G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680.
000015	Bristol Laboratories, Division of Bristol-Myers Co., P.O. Box 657, Syracuse, NY 13201.
000018	Penwalt Corp., P.O. Box 1297, Takoma, WA 98401.
000022	McKesson Laboratories, Bridgeport, CT 06602.
000024	Winthrop Laboratories, Division Sterling Drug, Inc., 90 Park Ave., New York, NY 10016.
000028	Ciba Pharmaceutical Co., 556 Morris Ave., Summit, NJ 07901.
000029	Beecham-Massengill Pharmaceuticals, Division of Beecham, Inc., Bristol, TN 37620.
000031	A. H. Robins, Research Laboratories, 1211 Sherwood Ave., Richmond, VA 23220.
000033	Syntex Laboratories, Inc., 3401 Hillview Dr., Palo Alto, CA 94304.
000034	The Purdue Frederick Co., 50 Washington St., Norwalk, CT 06856.

Drug Listing No.:	Firm name and address
000035	Eaton Laboratories, Division of Morton-Norwich Products, Inc., P.O. Box 191, Norwich, NY 13815.
000039	Hoechst-Roussel Pharmaceuticals, Inc., Route 202–206, Somerville, NJ 08876.
000045	McNeil Laboratories, Inc., Camp Hill Rd., Fort Washington, PA 19034.
000046	Ayerst Laboratories, Division of American Home Products Corp., 685 Third Ave., New York, NY 10017.
000053	Armour Pharmaceutical Co., P.O. Box 3113, Omaha, NE 68103.
000056	Endo Laboratories, Inc., 1000 Stewart Ave., Garden City, NY 11530.
000069	Pfizer, Inc., 235 East 42d St., New York, NY 10017.
000071	Parke, Davis & Co., Joseph Campau Avenue at the River, Detroit, MI 48232.
000085	Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.
000115	Richlyn Laboratories, Inc., Castor and Kensington Aves., Philadelphia, PA 19124.
000138	American Scientific Laboratories, A Division of Schering Corp., Bloomfield, NJ 07003.
000161	Cutter Laboratories, Inc., Fourth and Parker St., Berkeley, CA 94710.
000172	Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647.
000196	Rachelle Laboratories, Inc., 700 Henry Ford Ave., P.O. Box 2029, Long Beach, CA 90801.
000345	Caribe Chemical Co., Inc., 576 Fifth Ave., New York, NY 10036.
000381	Myers-Carter Laboratories, Inc., 5160 West Bethany Home Rd., Glendale, AZ 85301.
000514	Dow B. Hickam, Inc. Pharmaceuticals, P.O. Box 35413, Houston, TX 77035.
000591	Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810.
000693	D-M-Pharmaceuticals, Inc., 1146 Taft St., Rockville, MD 20850.
000794	S. B. Penick & Co., 100 Church St., New York, NY 10008.
000845	Burns Biotec Laboratories, Inc., Subsidiary of Chromalloy American Corp., 7711 Oakport St., Oakland, CA 94621.
000856	Fort Dodge Laboratories, Fort Dodge, IA 50501.
000859	Bayvet Corp., P.O. Box 390, Shawnee Mission, KS 66201.
000864	Anthony Veterinary Products Co., 11634 McBean Dr., El Monte, CA 91732.
000934	Sterling Drug Inc., 90 Park Ave., New York, NY 10016.
000947	Norwich Agricultural Products, A Division of Morton-Norwich Products, Inc., Norwich, NY 13815.
000986	Elanco Products Co., A Division of Eli Lilly & Co., 740 South Alabama St., Indianapolis, IN 46206.
010042	American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540.
010271	John D. Copanos & Co., Inc., Baltimore, MD 21225.
010469	Glogau & Co., Inc., 4614 West Lake St., Melrose Park, IL 60160.
010471	H. Clay Glover Co., Inc., 1001 Franklin Ave., Garden City, NY 11530.
010515	G. C. Hanford Manufacturing Co., P.O. Box 1055, Syracuse, NY 13201.
010616	KASCO-EFCO Laboratories, Inc., P.O. Box 730, Hicksville, NY 11802.
010719	Maury Biological Co., Inc., 6109 South Western Ave., Los Angeles, CA 90047.
011398	Western Serum Co., P.O. Box 7025, Phoenix, AZ 85011.
011461	Shell Chemical Co., Division of Shell Oil Co., Agricultural Division, 2401 Crow Canyon Rd., San Ramon, CA 94583.
011462	Allied Chemical Corp., Agricultural Division, 40 Rector St., New York, NY 10006.
011485	Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015.
011490	Cadco, Inc., P.O. Box 3499, 10100 Douglas Ave., Des Moines, IA 50322.
011492	Cooper U.S.A., Inc., P.O. Box 12338, Research Triangle Park, NC 27709.
011519	Norden Laboratories, Inc., Lincoln, NE 68501.
011536	Thuron Industries, Inc., 12200 Denton Drive, Dallas, TX 75234.
011538	West Chemical Products, Inc., 42–16 West St., Long Island City, NY 11101.
011716	Pitman-Moore, Inc., Washington Crossing, NJ 08560.
011757	Tevcon Ind., Inc., 3904 J St., Omaha, NE 68127.
011769	Carson Chemicals, Inc., New Castle, IN 47362.
011794	Whitmoyer Laboratories, 19 North Railroad St., Myerstown, PA 19067.
011801	Hess & Clark, Division of Rhodia, Inc., Ashland, OH 44805.
011806	[Reserved]
011811	National Laboratories Corp., 1721 Baltimore Ave., Kansas City, MO 64108.
011825	Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., 19 North Railroad St., Myerstown, PA 17067.
011904	Agricultural Processing Corp., 225 Alabama St., P.O. Box 845, Salem, VA 24153.
011950	Dr. LeGear, Inc., 4161 Beck Ave., St. Louis, MO 63116.
012190	Hubbard Milling Co., 424 North Front St., Mankato, MN 56001.
012286	Central Soya Co., Inc., McMillan Feed Division, 1300 Fort Wayne Bank Building, Fort Wayne, IN 46802.
012481	Wittney & Co., 4655 Colorado Blvd., Denver, CO 80216.
012769	Commercial Solvents Corp., 1331 South First St., Terre Haute, IN 47808.
013947	Diamond Laboratories, Inc., P.O. Box 863, Des Moines, IA 50304.
013959	Feed Products, Inc., 1000 West 47th Ave., Denver, CO 80211.
015563	Hart-Delta, Inc., 5055 Choctaw Dr., Baton Rouge, LA 70805.
016968	Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318.
017030	Evsco Pharmaceutical Corp., 3345 Royal Ave., Oceanside, NY 11572.
017032	Stauffer Chemical Co., 1200 South 47th St., Richmond, CA 94804.
017135	The Farnam Companies, Inc., 8701 North 29th St., Omaha, NE 68112.
017162	Farmer's Union Grain Terminal Association, Feed Division, P.O. Box 1447, Sioux Falls, SD 57101.
017210	Salsbury Laboratories, Charles City, IA 50616.
017220	Jensen-Salsbery Laboratories, Division of Richardson-Merrell, Inc., Kansas City, MO 64141.
017255	Feed Fortifiers, Inc., Manson, IA 50563.
017274	Feed Specialties Co., 1877 Northeast 58th Ave., Des Moines, IA 50313.
017434	Zip Feed Mills, 304 East Eighth St., Sioux Falls, SD 57102.
017800	Ralston-Purina Co., Checkerboard Sq., St. Louis, MO 63199.
017826	Albers Milling Co., Carnation Bldg., 5045 Wilshire Blvd., Los Angeles, CA 90036.
018356	Alton Premium Feed Co., Alton, IA 51003.
018597	Blair Milling & Elevator Co., Inc., 1000 Main St., Atchison, KS 66002.
020275	FS Services, Inc., 1701 Towanda Ave., Bloomington, IL 61701.
020112	Fromm Laboratories, Inc., Grafton, WI 53024.
021188	Babineaux's Veterinary Products, Inc., 6425 Airline Highway, Metairie, LA 70003.
021780	Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334.
021798	Gooch Feed Mill Corp., 540 South St., Lincoln, NE 68501.
021930	Moorman Manufacturing Co., Quincy, IL 62301.
022591	Grain Processing Corp., Muscatine, IA 52761.
024264	Dawes Laboratories, Inc., 450 State St., Chicago Heights, IL 60411.
024817	Dean's Specialty Supply Co., 310 Second Ave., SW., Waseca, MN 56093.
024991	Diagnostic Data, Inc., 518 Logue Ave., Mountain View, CA 94040.
025001	Diamond Shamrock Chemical Co., 60 Park Pl., Newark, NJ 07101.
025700	The Dow Chemical Co., P.O. Box 1706, Midland, MI 48640.
025796	Doboy Feeds, Domain Industries, Inc., 215 North Knowles Ave., New Richmond, WI 54017.
026186	Henwood Feed Additives, Inc., 211 Western Rd., Box 577, Lewisburg, OH 45338.
026282	M & M Livestock Products Co., Eagle Grove, IA 50533.
027863	Mattox & Moore, Inc., 1503 East Riverside Dr., Indianapolis, IN 46207.
030804	Fasco Mills Co., Box 70, Route 34 East, Mendota, IL 61342.

Drug Listing No.	Firm name and address
032420	Forbes Laboratories, 402 West Lakeside St., Madison, WI 53715.
032707	Premier Malt Products, Inc., Milwaukee, WI 53201.
033071	Vita Plus Corp., 1508 West Badger Rd., P.O. Box 926, Madison, WI 53701.
033999	Protein Blenders, Inc., Box 631, Highway 218 South, Iowa City, IA 52240.
034139	Walnut Grove Products, Division of W.R. Grace & Co., 201 Linn St., Atlantic, IA 50022.
034418	Simonsen Mill-Rendering Plant, Inc., Quimby, IA 51049.
034500	Land O'Lakes, Inc., Agricultural Services, 2827 Eighth Avenue South, Fort Dodge, IA 50501.
035369	Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247.
035393	Young's, Inc., Roaring Spring, PA 16673.
036108	Square Deal Fortification Co., Kouts, IN 46347.
037990	Summit Hill Laboratories, P.O. Box 1, Avalon, NJ 08202.
043426	The A. O. Cooper Co., Humboldt, NE 68376.
043727	Heinold Elevator Co., Inc., Kouts, IN 46347.
043728	Balfour Guthrie & Co., Ltd., 315 North H St., Fresno, CA 93701.
043729	Nixon and Co., Kiewitt Plaza, Omaha, NE 88501.
043731	Agricultural & Veterinary Products Division, Abbott Laboratories, Abbott Park, North Chicago, IL 60064.
043732	Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601.
043733	International Nutrition, Inc., 6664 L St., Omaha, NE 68117.
043734	Formica Laboratories, 124 East Fifth St., Little Rock, AR 72115.
043735	Gland-O-Lac Co., 1818 Leavenworth St., Omaha, NE 68102.
043737	Peter Hand Foundation, 2 East Madison St., Waukegan, IL 33142.
043738	McClellan Laboratories, Inc., 19600 Sixth Ave., Lakeview, CA 92353.
043743	V.P.O., Inc., 4444 South 76th St., Omaha, NE 68127.
043744	Farmers Feed & Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772.

Part 511—New Animal Drugs for Investigational Use

AUTHORITY: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351; (21 U.S.C. 360b, 371 (a)), unless otherwise noted.

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

(a) *New animal drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the act if it is labeled as follows:

Caution. Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(2) The person distributing or causing the distribution of new animal drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new animal drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new animal drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new animal drug or drugs, which discs are intended for use in determining susceptibility of microorganisms to the new animal drug or drugs.

(b) *New animal drugs for clinical investigation in animals.* A shipment or other delivery of a new animal drug or an animal feed containing a new animal drug intended for clinical investigational use in animals shall be exempt from section 512 (a) and (m) of the act if all the following conditions are met:

(1) The label shall bear the statements:

Caution. Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear the caution statements required by paragraphs (a) or (b) of this section, the statements may be included on the carton label and other labeling on or within the package from which the new animal drug is to be dispensed.

(2) The person or firm distributing or causing the distribution of the new animal drug or animal feed containing a new animal drug shall use due diligence to assure that the new animal drug or animal feed containing a new animal drug will actually be used for tests in animals and is not used in humans.

(3) The person who introduced such shipment or who delivered the new animal drug or animal feed containing a new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the investigator to whom the new animal drug or animal feed containing a new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, such records shall be made available for inspection and copying.

(4) Prior to shipment of the new animal drug for clinical tests in animals, the sponsor of the investigation shall submit in triplicate to the Food and Drug Administration a "Notice of Claimed Investigational Exemption for a New Animal Drug" including a signed statement containing the following information:

(i) The identity of the new animal drug.

(ii) All labeling and other pertinent information to be supplied to the investigators.

(iii) The name and address of each clinical investigator.

(iv) The approximate number of animals to be treated (or if not available, the amount of new animal drug to be shipped).

(v) If the new animal drug is given to food-producing animals, the statement shall contain the following additional information:

(*a*) A commitment that the edible products from such animals shall not be used for food without prior authorization in accordance with the provisions prescribed in this section.

(*b*) Approximate dates of the beginning and end of the experiment or series of experiments.

(*c*) The maximum daily dose(s) to be administered to a given species, the size of animal, maximum duration of administration, method(s) of administration, and proposed withdrawal time, if any.

(5) Authorization for use of edible products derived from a treated food-producing animal may be granted under the provisions of this section and when the following specified conditions are met, except that in the case of an animal administered any unlicensed experimental veterinary biological product regulated under the viruses, serums, toxins statute (21 U.S.C., Chapter V, sec. 151 et seq.) the product shall be exempt from the requirements of this section when U.S. Department of Agriculture approval has been obtained as provided in 9 CFR 103.2. Conditional authorization may be granted in advance of identification of the name(s) and address(es) of the clinical investigator(s) as required by paragraph (b)(4)(iii) of this section. Information required for authorization shall include, in addition to all other requirements of this section, the following:

(i) Data to show that consumption of food derived from animals treated at the maximum levels with the minimum withdrawal periods, if any, specified in ac-

cordance with paragraph (b)(4)(v)(c) of this section, will not be inconsistent with the public health; or

(ii) Data to show that food derived from animals treated at the maximum levels and with the minimum withdrawal periods, if any, specified in accordance with paragraph (b)(4)(v)(c) of this section, does not contain drug residues or metabolites.

(iii) The name and location of the packing plant where the animals will be processed, except that this requirement may be waived, on request, by the terms of the authorization.

Authorizations granted under this subparagraph do not exempt investigational animals and their products from compliance with other applicable inspection requirements.

(6) On written request of the Food and Drug Administration, the sponsor shall submit any additional information reported to or otherwise received by him with respect to the investigation deemed necessary to facilitate a determination whether there are grounds in the interest of public health for terminating the exemption.

(7) The sponsor shall assure himself that the new animal drug is shipped only to investigators who:

(i) Are qualified by scientific training and/experience to evaluate the safety and/or effectiveness of the new animal drug.

(ii) Shall maintain complete records of the investigations, including complete records of the receipt and disposition of each shipment or delivery of the new animal drug under investigation. Copies of all records of the investigation shall be retained by the investigator for 2 years after the termination of the investigation or approval of a new animal drug application.

(iii) Shall furnish adequate and timely reports of the investigation to the sponsor.

(8) The sponsor:

(i) Shall retain all reports received from investigators for 2 years after the termination of the investigation or approval of a new animal drug application and make such reports available to a duly authorized employee of the Department for inspection at all reasonable times.

(ii) Shall provide for current monitoring of the investigation by a person qualified by scientific training and experience to evaluate information obtained from the investigation, and shall promptly investigate and report to the Food and Drug Administration and to all investigators any findings associated with use of the new animal drug that may suggest significant hazards pertinent to the safety of the new animal drug.

(iii) Shall not unduly prolong distribution of the new animal drug for investigational use.

(iv) Shall not, nor shall any person acting for or on behalf of the sponsor, represent that the new animal drug is safe or effective for the purposes for which it is under investigation. This requirement is not intended to restrict the full exchange of scientific information.

(v) Shall not commercially distribute nor test-market the new animal drug until a new animal drug application is approved pursuant to section 512(c) of the act.

(9) If the shipment or other delivery of the new animal drug is imported or offered for importation into the United States for clinical investigational use in animals, it shall also meet the following conditions:

(i) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has, prior to such shipments and deliveries, informed the Food and Drug Administration of his intention to import the new animal drug as sponsor in compliance with the conditions prescribed in this subdivision; or

(ii) The new animal drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct laboratory or clinical investigations and is intended solely for use in such institutions and which institution has submitted a statement as sponsor of the investigation.

(10) When requested by the agency, the sponsor shall submit an environmental impact analysis report pursuant to § 6.1 of this chapter.

(c) *Withdrawal of eligibility to receive investigational-use new animal drugs.* (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations or has submitted false information either to the sponsor of the investigation or in any required report, the Director of the Bureau of Veterinary Medicine will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Bureau of Veterinary Medicine, the Commissioner will provide the investigator an opportunity for an informal hearing on the question of whether the investigator is entitled to receive investigational-use new animal drugs, if the hearing is requested within 10 days after receipt of notification that the explanation is not acceptable.

(2) If, after evaluating all available information including any explanation and assurance presented by the investigator, the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation and has failed to furnish adequate assurance that the conditions of the exemption will be met, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational-use new animal drugs with a statement of the basis for such determination.

(3) Each "Notice of Claimed Investigational Exemption for a New Animal Drug" and each approved new animal drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use new animal drugs will be examined to determine whether he has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any new animal drug application.

(4) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he will notify the sponsor and provide him with an opportunity for a conference in accordance with paragraph (d) of this section. If an imminent hazard to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the Commissioner, on request, will afford the sponsor an opportunity for an informal hearing on the question of whether the exemption should be reinstated.

(5) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are such that a new animal drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 512(e) of the act.

(6) An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use new animal drugs when the Commissioner determines that he has presented adequate assurance that he will employ such new animal drugs solely in compliance with the exempting regulations in this section for investigational-use new animal drugs.

(d) *Termination of exemption.* If the Commissioner finds that:

(1) The sponsor of the investigation has failed to comply with any of the conditions for the exemption established under this section, or

(2) The continuance of the investigation is unsafe or otherwise contrary to the public interest or the drug is being or has been used for purposes other than bona fide scientific investigation, he shall notify the sponsor and invite his immediate correction. A conference will will be arranged if requested. If the conditions of the exemption are not immediately met, the Commissioner shall notify the sponsor of the termination of the exemption and the sponsor shall recall or have destroyed the unused supplies of the new animal drug.

(e) *Statements and requests.* "Notice(s) of Claimed Investigational Exemption for a New Animal Drug" and requests for authorization to use investigational animals and their products for food should be addressed to the Department of Health, Education, and Welfare,

Food and Drug Administration, Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, MD 20852.

PART 514—NEW ANIMAL DRUG APPLICATIONS

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AUTHORITY: Secs. 512 (i), (n), 701(a), 52 Stat. 1055; 82 Stat. 343-351 (21 U.S.C. 360b (i), (n)), unless otherwise noted.

Subpart A—General Provisions

§ 514.1 Applications.

(a) Applications to be filed under section 512(b) of the act shall be submitted in the form described in paragraph (b) of this section. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part. Translations of literature printed in a foreign language shall be accompanied by copies of the original publication. The application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of, and must be countersigned by, an authorized attorney, agent, or official residing or maintaining a place of business within the United States. Pertinent information may be incorporated in, and will be considered as part of, an application on the basis of specific reference to such information, including information submitted under the provisions of § 511.1 of this chapter, in the files of the Food and Drug Administration; however, the reference must be specific in identifying the information. Any reference to information furnished by a person other than the applicant may not be considered unless its use is authorized in a written statement signed by the person who submitted it.

(b) Applications for new animal drugs shall be submitted in triplicate and assembled in the manner prescribed by paragraph (b)(15) of this section, and shall include the following information:

(1) *Identification.* Whether the submission is an original or supplemental application; the name and the address of the applicant; the date of the application; the trade name(s) (if one has been proposed) and chemical name(s) of the new animal drug. Upon receipt, the application will be assigned a number NADA ------, which shall be used for all correspondence with respect to the application.

(2) *Table of contents and summary.* The application shall be organized in a cohesive fashion, shall contain a table of contents which identifies the data and other material submitted, and shall contain a well-organized summary and evaluation of the data in the following form:

(i) Chemistry:

(a) Chemical structural formula or description for any new animal drug substance.

(b) Relationship to other chemically or pharmacologically related drugs.

(c) Description of dosage form and quantitative composition.

(ii) Scientific rationale and purpose the new animal drug is to serve:

(a) Clinical purpose.

(b) Highlights of laboratory studies: The reasons why certain types of studies were done or omitted as related to the proposed conditions of use and to information already known about this class of compounds. Emphasize any unusual or particularly significant pharmacological effects or toxicological findings.

(c) Highlights of clinical studies: The rationale of the clinical study plan showing why types of studies were done, amended, or omitted as related to laboratory studies and prior clinical experience.

(d) Conclusions: A short statement of conclusions combining the major points of effectiveness and safety as they relate to the use of the new animal drug.

(3) *Labeling.* Three copies of each piece of all labeling to be used for the article (total of 9).

(i) All labeling should be identified to show its position on, or the manner in which it is to accompany the market package.

(ii) Labeling for nonprescription new animal drugs should include adequate directions for use by the layman under all conditions of use for which the new animal drug is intended, recommended, or suggested in any of the labeling or advertising sponsored by the applicant.

(iii) Labeling for prescription veterinary drugs should bear adequate information for use under which veterinarians can use the new animal drug safely and for the purposes for which it is intended, including those purposes for which it is to be advertised or represented, in accord with § 201.105 of this chapter.

(iv) All labeling for prescription or nonprescription new animal drugs shall be submitted with any necessary use restrictions prominently and conspicuously displayed.

(v) Labeling for new animal drugs intended for use in the manufacture of medicated feeds shall include:

(a) Specimens of labeling to be used for such new animal drug with adequate directions for the manufacture and use of finished feeds for all conditions for which the new animal drug is intended, recommended, or suggested in any of the labeling, including advertising, sponsored by the applicant.

(b) Specimens of all labeling representative of those proposed to be used for finished feeds manufactured from the new animal drug.

(vi) Draft labeling may be submitted for preliminary consideration of an application. Final printed labeling will ordinarily be required prior to approval of an application. Proposed advertising for veterinary prescription drugs may be submitted for comment or approval.

(4) *Components and composition.* A complete list of all articles used for production of the new animal drug including a full list of the composition of each article:

(i) A full list of the articles used as components of the new animal drug. This list should include all substances used in the synthesis, extraction, or other method of preparation of any new animal drug and in the preparation of the finished dosage form, regardless of whether they undergo chemical change or are removed in the process. Each component should be identified by its established name, if any, or complete chemical name, using structural formulas when necessary for specific identification. If any proprietary name is used, it should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed component may be specified.

(ii) A full statement of the composition of the new animal drug. The statement shall set forth the name and amount of each ingredient, whether active or not, contained in a stated quantity of the new animal drug in the form in which it is to be distributed (for example, amount per tablet or milliliter) and a batch formula representative of that to be employed for the manfacture of the finished dosage form. All components should be included in the batch formula regardless of whether they appear in the finished product. Any calculated excess of an ingredient over the label declaration should be designated as such and percent excess shown. Reasonable variation may be specified.

(iii) If it is a new animal drug produced by fermentation:

(*a*) Source and type of microorganism used to produce the new animal drug.

(*b*) Composition of media used to produce the new animal drug.

(c) Type of precursor used, if any, to guide or enhance production of the antibiotic during fermentation.

(*d*) Name and composition of preservative, if any, used in the broth.

(*e*) A complete description of the extraction and purification processes including the names and compositions of the solvents, precipitants, ion exchange resins, emulsifiers, and all other agents used.

(*f*) If the new animal drug is produced by a catalytic hydrogenation process (such as tetracycline from chlortetracycline), a complete description of each chemical reaction with graphic formulas used to produce the new animal drug, including the names of the catalyst used, how it is removed, and how the new animal drug is extracted and purified.

(5) *Manufacturing methods, facilities, and controls.* A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new animal drug. This description should include full information with respect to any new animal drug in sufficient detail to permit evaluation of the adequacy of the described methods of manufacture, processing, and packing, and the described facilities and controls to determine and preserve the identity, strength, quality, and purity of the new animal drug, and the following:

(i) If the applicant does not himself perform all the manufacturing, processing, packaging, labeling, and control operations for any new animal drug, he shall: Identify each person who will perform any part of such operations and designate the part; and provide a signed statement from each such person fully describing, directly or by reference, the methods, facilities, and controls he will use in his part of the operation. The statement shall include a commitment that no changes will be made without prior approval by the Food and Drug Administration, unless permitted under § 514.8.

(ii) A description of the qualifications, including educational background and experience, of the technical and professional personnel who are responsible for assuring that the new animal drug has the identity, strength, quality, and purity it purports or is represented to possess, and a statement of their responsibilities.

(iii) A description of the physical facilities including building and equipment used in manufacturing, processing, packaging, labeling, storage, and control operations.

(iv) The methods used in the synthesis, extraction, isolation, or purification of any new animal drug. When the specifications and controls applied to such new animal drugs are inadequate in themselves to determine its identity, strength, quality, and purity, the methods should be described in sufficient detail, including quantities used, times, temperature, pH, solvents, etc., to determine these characteristics. Alternative methods or variations in methods within reasonable limits that do not affect such characteristics of the new animal drug may be specified. A flow sheet and indicated equations should be submitted when needed to explain the process.

(v) Precautions to insure proper identity, strength, quality, and purity of the raw materials, whether active or not, including:

(*a*) The specifications for acceptance and methods of testing for each lot of raw material.

(*b*) A statement as to whether or not each lot of raw materials is given a serial number to identify it, and the use made of such numbers in subsequent plant operations.

(vi) The instructions used in the manufacturing, processing, packaging, and labeling of each dosage form of the new animal drug, including:

(*a*) The method of preparation of the master formula records and individual batch records and the manner in which these records are used.

(*b*) The number of individuals checking weight or volume of each individual ingredient entering into each batch of the new animal drug.

(c) A statement as to whether or not the total weight or volume of each batch is determined at any stage of the manufacturing process subsequent to making up a batch according to the formula card and, if so, at what stage and by whom it is done.

(*d*) The precautions used in checking the actual package yield produced from a batch of the new animal drug with the theoretical yield. This should include a description of the accounting for such items as discards, breakage, etc., and the criteria used in accepting or rejecting batches of drugs in the event of an unexplained discrepancy.

(*e*) The precautions used to assure that each lot of the new animal drug is packaged with the proper label and labeling, including provisions for labeling storage and inventory control.

(*f*) Any special precautions used in the operations.

(vii) The analytical controls used during the various stages of the manufacturing, processing, packaging, and labeling of the new animal drug, including a detailed description of the collection of samples and the analytical procedures to which they are subjected. The analytical procedures should be capable of determining the active components within a reasonable degree of accuracy and of assuring the identity of such components.

(*a*) A description of practicable methods of analysis of adequate sensitivity to determine the amount of the new animal drug in its final dosage form including finished feeds and in drinking water should also be included. Methods should be included for any premix or other intermediate mix for such drugs. Where two or more active ingredients are included, methods should be quantitative and specific for each active ingredient.

(*b*) If the article is one that is represented to be sterile, the same information with regard to the manufacturing, processing, packaging, and the collection of samples of the drug should be given for sterility controls. Include the standards used for acceptance of each lot of the finished drug.

(viii) An explanation of the exact significance of any batch control numbers used in the manufacturing, processing, packaging, and labeling of the new animal drug, including such control numbers that may appear on the label of the finished article. State whether these numbers enable determination of the complete manufacturing history of the product. Describe any methods used to permit determination of the distribution of any batch if its recall is required.

(ix) Adequate information with respect to the characteristics of and the test methods employed for the container, closure, or other component parts of the drug package to assure their suitability for the intended use.

(x) A complete description of, and data derived from, studies of the stability of the new animal drug, including information showing the suitability of the analytical methods used. Describe any additional stability studies underway or planned. Stability data should be submitted for any new animal drug, for the finished dosage form of the new animal drug in the container in which it is to be marketed, including any proposed multiple-dose container, and, if it is to

be put into solution at the time of dispensing, for the solution prepared as directed. If the data indicate that an expiration date is needed to preserve the identity, strength, quality, and purity of the new animal drug until it is used, the applicant shall propose such expiration date. If no expiration date is proposed the applicant must justify its absence.

(xi) Additional procedures employed which are designed to prevent contamination and otherwise assure proper control of the product. An application may be refused unless it includes adequate information showing that the methods used in, and the facilities and controls used for, the manufacturing, processing, and packaging of the new animal drug are adequate to preserve its identity, strength, quality, and purity in conformity with good manufacturing practice and identifies each establishment, showing the location of the plant conducting these operations.

(6) *Samples.* Samples of the new animal drug and articles used as components and information concerning them may be requested by the Bureau of Veterinary Medicine as follows:

(i) Each sample shall consist of four identical, separately packaged subdivisions, each containing at least three times the amount required to perform the laboratory test procedures described in the application to determine compliance with its control specifications for identity and assays. Each of the samples submitted shall be appropriately packaged and labeled to preserve its characteristics, to identify the material and the quantity in each subdivision of the sample, and to identify each subdivision with the name of the applicant and the new animal drug application to which it relates. Included are:

(*a*) A sample or samples of any reference standard and blank used in the procedures described in the application for assaying each new animal drug and other assayed components of the finished new animal drug.

(*b*) A representative sample or samples of each strength of the finished dosage form proposed in the application and employed in the clinical investigations and a representative sample or samples of each new animal drug from the batch(es) employed in the production of such dosage form.

(*c*) A representative sample or samples of finished market packages of each strength of the dosage form of the new animal drug prepared for initial marketing and, if any such sample is not from a representative commercial-scale production batch, such a sample from a representative commercial-scale production batch, and a representative sample or samples of each new animal drug from the batch(es) employed in the production of such dosage form, provided that in the case of new animal drugs marketed in large packages the sample should contain only three times a sufficient quantity of the new animal drug to allow for performing the control tests for drug identity and assays.

(ii) The following information shall be included for the samples when requested:

(*a*) For each sample submitted, full information regarding its identity and the origin of any new animal drug contained therein (including a statement whether it was produced on a laboratory, pilot-plant, or full-production scale) and detailed results of all laboratory tests made to determine the identity, strength, quality, and purity of the batch represented by the sample, including assays.

(*b*) For any reference standard submitted, a complete description of its preparation and the results of all laboratory tests on it. If the test methods used differed from those described in the application, full details of the methods employed in obtaining the reporting results.

(7) *Analytical methods for residues.* Applications for new animal drugs shall include a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food because of its use, and the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe. When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food, assay methodology is not required.

(i) The kind of information required by this subdivision may include: Complete experimental protocols for determining drug residue levels in the edible products, and the length of time required for residues to be eliminated from such products following the drug's use; residue studies conducted under appropriate (consistent with the proposed usage) conditions of dosage, time, and route of administration to show levels, if any, of the drug and/or its metabolites in test animals during and upon cessation of treatment and at intervals thereafter in order to establish a disappearance curve; if the drug is to be used in combination with other drugs, possible effects of interaction demonstrated by the appropriate disappearance curve or depletion patterns after drug withdrawal under appropriate (consistent with the proposed usage) conditions of dosage, time, and route of administration; if the drug is given in the feed or water, appropriate consumption records of the medicated feed or water and appropriate performance data in the treated animal; if the drug is to be used in more than one species, drug residue studies or appropriate metabolic studies conducted for each species that is food-producing. To provide these data, a sufficient number of birds or animals should be used at each sample interval. Appropriate use of labeled compounds (e.g. radioactive tracers), may be utilized to establish metabolism and depletion curves. Drug residue levels ordinarily should be determined in muscle, liver, kidney, and fat and where applicable, in skin, milk, and eggs (yolk and egg white). As a part of the metabolic studies, levels of the drug or metabolite should be determined in blood where feasible. Samples may be combined where necessary. Where residues are suspected or known to be present in litter from treated animals, it may be necessary to include data with respect to such residues becoming components of other agricultural commodities because of use of litter from treated animals.

(ii) If such new animal drug is one which has been shown to induce cancer when ingested by man or animal or after other tests which are appropriate for the evaluation of the safety of such drug and the Secretary is requested to find that, under the conditions of use specified in the proposed labeling and reasonably certain to be followed in practice, such drug will not adversely affect the animals for which it is intended and that no residue of such drug will be found in any edible portion of such animals after slaughter or in any food yielded by or derived from the animal, methods of analysis shall be submitted in such form as to be suitable for publication in the FEDERAL REGISTER.

(8) *Evidence to establish safety and effectiveness.* (i) An application may be refused unless it contains full reports of adequate tests by all methods reasonably applicable to show whether or not the new animal drug is safe and effective for use as suggested in the proposed labeling.

(ii) An application may be refused unless it includes substantial evidence, consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the new animal drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

(iii) An application may be refused unless it contains detailed reports of the investigations, including studies made on laboratory animals, in which the purpose, methods, and results obtained are clearly set forth of acute, subacute, and chronic toxicity, and unless it contains appropriate clinical laboratory results related to safety and efficacy. Such information should include identification of the person who conducted each investigation, a statement of where the investigations were conducted, and where the raw data are available in the application.

(iv) All information pertinent to an evaluation of the safety and effectiveness of the new animal drug received or otherwise obtained by the applicant from any source, including information derived from other investigations or commercial marketing (for example, outside the United States), or reports in the scientific literature, both favorable and unfavorable, involving the new animal drug

that is the subject of the application and related new animal drugs shall be submitted. An adequate summary may be acceptable in lieu of a reprint of a published report that only supports other data submitted. Include any evaluation of the safety or effectiveness of the new animal drug that has been made by the applicant's veterinary or medical department, expert committee, or consultants.

(v) If the new animal drug is a combination of previously investigated or marketed new animal drugs, an adequate summary of preexisting information from preclinical and clinical investigation and experience with its components, including all reports received or otherwise obtained by the applicant suggesting side effects, contraindications, and ineffectiveness in use of such components, shall be submitted. Such summary should include an adequate bibliography of publications about the components and may incorporate by reference information concerning such components previously submitted to the Food and Drug Administration by the applicant; with written authorization, information may also be incorporated from the material that another applicant has on file with the Food and Drug Administration. Each ingredient designated as active in any new animal drug combination must make a contribution to the effect in the manner claimed or suggested in the labeling, and, if in the absence of express labeling claims of advantages for the combination such a product purports to be better than either component alone, it must be established that the new animal drug has that purported effectiveness.

(vi) An application shall include a complete list of the names and post office addresses of all investigators who received the new animal drug. This may be incorporated in whole or in part by reference to information submitted under the provisions of § 511.1 of this chapter.

(vii) Explain any omission of reports from any investigator to whom the investigational new animal drug has been made available. The unexplained omission of any reports of investigations made with the new animal drug by the applicant or submitted to him by an investigator or the unexplained omission of any pertinent reports of investigations or clinical experience received or otherwise obtained by the applicant from published literature or other sources that would bias an evaluation of the safety of the new animal drug or its effectiveness in use, constitutes grounds for the refusal or withdrawal of the approval of an application.

(9) *New animal drugs subject to section 512(n) of the act.* If the application is for a new animal drug subject to the certification provisions of section 512(n) of the act and the drug is included in regulations promulgated under section 507 of the act, the applicant may be exempted from the submission of some of the information required by paragraph (b)(8) of this section if the application includes data adequate to prove that the new animal drug is comparable to the new animal drug for which certification has been previously provided.

(10) *Supplemental applications.* If it is a supplemental application, full information shall be submitted on each proposed change concerning any statement made in the approved application.

(11) *Applicant's commitment.* It is understood that the labeling and advertising for the new animal drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application and if the article is a prescription new animal drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the new animal drug will also contain, in the same language and emphasis, information for its use including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant hazards, contraindications, side effects, and precautions contained in the labeling which is part of this application. It is understood that all representations in this application apply to the drug produced until changes are made in conformity with § 514.8.

(12) *Additional commitments.* (i) New animal drugs as defined in § 510.3 of this chapter, intended for use in the manufacture of animal feeds in any State will be shipped only to persons who may receive such drugs in accordance with § 510.7 of this chapter.

(ii) The methods, facilities, and controls described under item 5 of this application conform to the current good manufacturing practice regulations in Subchapter C of this chapter.

(13) [Reserved]

(14) *Environmental impact analysis report.* The applicant is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the utlimate use or consumption of the new animal drug pursuant to § 6.1 of this chapter.

(15) *Assembling and binding the application.* Assemble and bind three copies of the original application as follows:

(i) Obtain folders from the Food and Drug Administration. Bureau of Veterinary Medicine. 5600 Fishers Lane. Rockville, MD 20852, for binding triplicate copies of the new animal drug application. Approximately 2 inches of material may be bound in each folder.

(ii) Bind the original or ribbon copy of the application in a blue folder. This will be copy No. 1 and should be a complete copy.

(iii) Bind an identical copy in a red folder. copy No. 2, and an identical copy in a yellow folder. copy No. 3.

(iv) Identify each front cover with the name of the applicant and the name of the new animal drug.

(v) Use separate pages or sets of pages for each numbered heading consistent with paragraph (b) (1) through (12) of this section. Number the pages of the new animal drug application. Each copy should bear the same page numbering.

(vi) The labeling should be distributed in the three copies of the application as follows: One set of labeling in copy No. 1, one set in copy No. 2, and one set in copy No. 3.

(vii) Submit separate applications for each different dosage form of the drug proposed. Repeating in each application basic information pertinent to all dosage forms is unnecessary if reference is made to the application containing such information. Include in each application information applicable to the specific dosage form, such as labeling, composition, stability data, and method of manufacture.

(viii) Forward amendments, supplements, reports, and other correspondence submitted after the original application in these folders and this format if they contain sufficient material. The front cover of these submissions should be identified with the name of the applicant, the name of the new animal drug, and the new animal drug application number, if known.

(c) When a new animal drug application is submitted for a new animal drug which has a stimulant, depressant, or hallucinogenic effect on the central nervous system, if it appears that the drug has a potential for abuse, the Commissioner shall forward that information to the Attorney General of the United States.

§ 514.2 Applications for animal feeds bearing or containing new animal drugs.

Applications for animal feeds bearing or containing new animal drugs shall be submitted in triplicate on the Form FD-1800 6-68. Applications will be completed following the instructions printed on this form and will contain:

(a) A full statement of the composition of the animal feed. This requirement may be fulfilled by the declaration of the composition on the labeling submitted with the application.

(b) A statement that the proposed use of the animal feed described conforms to the applicable regulation published in accordance with section 512(i) of the act.

(c) A fully completed application Form FD-1800 signed by an authorized representative of the firm.

(d) One copy of the final printed labeling attached to each copy of the FD-1800.

§ 514.6 Amended applications.

The applicant may submit an amendment to an application that is pending, including changes that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, and controls to preserve them, in which case the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

§ 514.7 Withdrawal of applications without prejudice.

The sponsor may withdraw his pending application from consideration as a new animal drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The original application will be retained by the Food and Drug Administration although it is considered withdrawn. The applicant shall be furnished a copy at cost on request.

§ 514.8 Supplemental new animal drug applications.

(a) (1) After a new animal drug application is approved, a supplemental new animal drug application may propose changes. A supplemental application may omit statements made in the approved application concerning which no change is proposed. Each supplemental application shall include up-to-date reports of any of the kinds of information required by § 510.300(a) of this chapter that has not previously been submitted. A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 6.1 of this chapter.

(2) A supplemental new animal drug application shall be submitted for any change beyond the variations provided for in the application, including changes in the scale of production such as from pilot-plant to production batch, that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the new animal drug, or the adequacy of the manufacturing methods, facilities, or controls to preserve them.

(3) If it is a prescription drug, any mailing or promotional piece used after the drug is placed on the market is labeling requiring a supplemental application, unless:

(i) The parts of the labeling furnishing directions, warnings, and information for use of the drug are the same in language and emphasis as labeling approved or permitted; and

(ii) Any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(4) The supplemental application shall be submitted as follows—A communication proposing a change in a new animal drug application should provide for any one of the following kinds of changes:

(i) Revision in labeling, such as updating information pertaining to effects, dosages, and side effects and contraindications, which includes information headed "side effects," "warnings," precautions," and "contraindications."

(ii) Addition of claim.

(iii) Revision in manufacturing or control procedures; for example, changes in components, composition, method of manufacture, analytical control procedures, package or tablet size, etc.

(iv) Change in manufacturing facilities.

(v) Provision for outside firm to participate in the preparation, distribution, or packaging of a new animal drug (new distributor, packer, supplier, manufacturer, etc.); one firm per submission.

Any number of changes may be submitted at any one time; but if they fall into different categories as listed in paragraph (a) (4) (i) through (v) of this section, the proposed changes should be covered by separate communications. Where, however, a change necessitates an overlap in categories, it should be submitted in a single communication. For example, a change in tablet potency would require other changes such as in components, composition, and labeling and should be submitted in a single communication.

(5) The following kinds of changes may be placed into effect without the approval of a supplemental application, if such change is fully described in the next periodic report required under § 510.300(b) (4) of this chapter or, when such a report is not required, in a written communication to the Food and Drug Administration within 60 days of the effective date of the change (this does not apply to a change proposed because of any mixup or any bacteriological or significant chemical, physical, or other change or deterioration in the drug or any failure of one or more distributed batches of the drug to meet its specifications):

(i) A different container size for solid oral dosage forms where container and closure are of the same materials as those provided for in the approved application.

(ii) Change in personnel not involving new facilities.

(iii) Change in equipment that does not alter the method of manufacture of a new animal drug.

(iv) Change from one commercial batch size to another without any change in manufacturing procedure.

(v) Change to more stringent specification without altering the method described in the approved application.

(vi) Inclusion of additional specifications and methods without deletion of those described in the approved application.

(vii) Alteration of specifications or methods for inactive ingredients to bring them into compliance with new or revised specifications or methods in an official compendium.

(viii) Initiation of a product identification coding system.

(ix) Addition to labeling of a reasonable expiration date where none was previously used, with related conditions of drug storage when appropriate, except when evidence shows that a significant deterioration of the drug under marketing conditions has occurred which necessitates the immediate submission of a report under § 510.300(b)(1) of this chapter. The report or written communication describing such change in labeling should include stability data justifying the expiration date and recommended conditions of storage.

(x) Change from paper labels to direct printing on glass or other kinds of immediate containers without a change in text.

(6) Approval of a supplemental new animal drug application, will not be required to provide for an additional distributor to distribute a drug which is the subject of an approved new animal drug application if the conditions described below are met prior to putting such a change into effect. An order may issue refusing approval if any condition is not met or if any of the reasons for refusing or withdrawing approval, as stated in section 512 (d) and (e) of the act or § 514.110 applies. For the purposes of maintaining records and making reports under the requirements of § 510.300 of this chapter, a distributor provided for under this section shall be considered an "applicant" within the meaning of § 510.300(b) of this chapter. Said conditions are:

(i) A supplemental application is furnished to the Food and Drug Administration to provide for a designated distributor.

(ii) There are no changes from the conditions of the approved application except for a different and suitable proprietary name of the new animal drug (if one is used) and the name and address of the distributor as used on the label and labeling. The name of the distributor shall be accompanied by an appropriate qualifying phrase such as "manufactured for" or "distributed by."

(iii) A distributor's statement is furnished to the Food and Drug Administration identifying the category of his operations (for example, wholesaler, retailer) and stating: That he will distribute the new animal drug only under the labeling provided for in the new animal drug application; that any other labeling or advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling provided for in the application; and, if the drug is a prescription article, that he is regularly and lawfully engaged in the distribution or dispensing of presciption drugs.

(iv) Nine copies of the printed labels and other labeling to be used by the distributor are submitted, identified with the new animal drug application number.

(b) When necessary for the safety or effectiveness of the drug, a supplemental new animal drug application shall specify a period of time within which the proposed change will be made.

(c) If a material change is made in the components' composition, manufacturing methods, facilities, or controls, or in the labeling or advertising, from the representations in an approved application for a new animal drug (except changes conforming to the conditions set forth in paragraph (a) (5) and (6) and/or paragraphs (d), (e), (f), and (g) of this section), and the drug is marketed before a supplement is approved

for such change, approval of the application may be suspended or withdrawn as provided in section 512(e) of the act.

(d) Changes of the following kinds proposed in supplemental new animal drug applications should be placed into effect at the earliest possible time:

(1) The addition to package labeling, promotional labeling, and prescription drug advertising of additional warning, contraindication, side effect, and precaution information.

(2) The deletion from package labeling, promotional labeling, and drug advertising of false, misleading, or unsupported indications for use or claims for effectiveness.

(3) Changes in the methods, facilities, or controls used for the manufacture, processing, packing, or holding of the new animal drug (other than utilization of establishments not covered by the approval that is in effect) that give increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess.

(e) The Food and Drug Administration will take no action against a new animal drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental new animal drug application if all the following conditions are met:

(1) The supplemental new animal drug application providing a full explanation of the basis for the changes has been submitted, plainly marked on the mailing cover and on the supplement, "Special new animal drug application supplement—changes being effected."

(2) The applicant specifically informs the Food and Drug Administration of the date on which such changes are being effected and submits to the Administration nine printed copies of any revised labeling to be placed in use, identified with the new animal drug application number.

(3) All promotional labeling and all drug advertising are promptly revised consistent with the changes made in the labeling on or within the new animal drug package.

(f) When a supplemental new animal drug application proposes changes only of the kinds described in paragraph (d) of this section, and the applicant informs the Food and Drug Administration that the changes are being put into effect, such notification will be regarded as an agreement by the applicant to an extension of the time for formal action on the application.

(g) In addition to changes as permitted by paragraphs (d) and (e) of this section, an applicant may place into effect changes proposed in a supplement to a new animal drug application that became effective prior to October 10, 1962, upon written notification from the Food and Drug Administration that such action is permitted, without approval of the supplemental application, pending the completion of the review of the effectiveness of such drug by the National Academy of Sciences-National Research Council and a determination as to whether there are grounds for refusing approval under section 512(d) of the act or for invoking section 512(e) of the act. The Food and Drug Administration will take no action against a new animal drug or an applicant solely because changes that have been permitted in a written communication are placed into effect by the applicant prior to his receipt of a written notice of approval of the supplemental new animal drug application.

(h) Except as provided in paragraphs (e) and (g) of this section, no provision of this section shall limit the authority of the Secretary or of the Commissioner to suspend or withdraw approval of a new animal drug application in accord with the provisions of section 512(e) of the act or to initiate any other regulatory proceedings with respect to a drug or applicant under provisions of the act.

(i) Changes from the conditions of an approved new animal drug application in accord with the provisions of paragraphs (d), (e), and (g) of this section are permitted on the basis of a temporary deferral of final action on the supplemental application under the provisions of section 512 (c), (d), or (e) of the act.

(j) When an applicant receives written notification from the Food and Drug Administration, under the provisions of paragraph (g) of this section, that he may place into effect changes proposed in a supplemental application without approval of the supplemental application, he may within 30 days submit a written request that the Food and Drug Administration process the supplemental application. In such case, the change shall not be put into effect until approved. Within 180 days of the receipt of such written request, the Food and Drug Administration will approve the supplemental application or furnish notice of an opportunity for a hearing under the provisions of section 512(d) or (e), or both, of the act on a proposal to refuse approval of the supplemental application or to withdraw approval of the application and supplements thereto.

(k) A supplement to an application that became effective prior to October 10, 1962, may include a written statement to the effect that a temporary deferral of final action under the provisions of paragraph (d), (e), or (g) of this section is unacceptable to the applicant and that the applicant requests action as provided in section 512(c) of the act. Final action on such supplemental applications will be expedited in accord with applicable provisions of section 512 of the act and regulations in this Subchapter E. In such cases, if the applicant places into effect any of the proposed changes prior to his receipt of a written notice of approval of the supplemental new animal drug application, such action may be regarded by the Food and Drug Administration as a basis for invoking the provisions of section 512(e)(1)(D) of the act; that is, the applicant may be furnished notice of an opportunity for a hearing on a proposal to withdraw approval of the application on the ground that the application contains an untrue statement of a material fact related to the changes from the conditions approved in the application.

§ 514.9 Supplemental applications for animal feeds bearing or containing new animal drugs.

(a) After an application for an animal feed bearing or containing a new animal drug has been approved, a supplemental application may propose changes.

(b) A supplemental application shall be submitted for any change which deviates from the conditions under which the application was originally approved.

(c) Each supplemental application shall be accompanied by a fully completed Form FD–1800 in triplicate including an explanation of the changes proposed.

(d) A supplemental application proposing substantial changes which may affect the quality of the human environment shall be accompanied by an environmental impact analysis report pursuant to § 6.1 of this chapter.

§ 514.10 Confidentiality of data and information in an investigational new animal drug notice and a new animal drug application file for an antibiotic drug.

(a) The rules established in §§ 514.12 and 514.11 of this chapter with regard to the confidentiality of an investigational new animal drug notice and a new animal drug application file shall apply to such notices and files for antibiotic drugs for new animal drug use.

(b) All records showing the Food and Drug Administration's testing of and action on a particular lot of a certifiable antibiotic drug for veterinary use are immediately available for public disclosure.

§ 514.11 Confidentiality of data and information in a new animal drug application file.

(a) For purposes of this section the "NADA file" includes all data and information submitted with or incorporated by reference in the NADA, INAD's incorporated into the NADA, supplemental NADA's, reports under §§ 510.300 and 510.301 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NADA file shall be handled in accordance with the provisions of this section.

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before an approval has been published in the FEDERAL REGISTER, unless it has previously been publicly disclosed or acknowledged.

(c) If the existence of an NADA file has not been publicly disclosed or acknowledged, no data or information in the NADA file is available for public disclosure.

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before an approval has been published in the FEDERAL REGISTER, no data or information contained in the file is available for public disclosure before such approval is published, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an approval has been published in the FEDERAL REGISTER, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in § 4.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NADA file. Such summaries do not constitute the full reports of investigations under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:

(i) For an NADA approved prior to July 1, 1975, internal agency records that describe such data and information, e.g., a summary of basis for approval or internal reviews of the data and information, after deletion of:

(*a*) Names and any information that would identify the investigators.

(*b*) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an NADA approved on or after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the approval is published in the FEDERAL REGISTER.

(*a*) The Bureau of Veterinary Medicine may at an appropriate time prior to approval of the NADA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, revised by the Bureau.

(*b*) The Bureau of Veterinary Medicine may prepare its own summary of such data and information.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 4.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of Part 4 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time that any one of the following events occurs:

(1) The NADA has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.

(3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NADA file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

§ 514.12 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an INAD notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in § 514.11.

§ 514.15 Untrue statements in applications.

Among the reasons why an application for a new animal drug or animal feed bearing or containing a new animal drug may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the product from the conditions of such use stated in the application;

(2) Articles used as components of the product from those listed in the application;

(3) Composition of the product from that stated in the application;

(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) If it is a supplement to an approved application and does not explain omissions in whole or in part from the original application or any amendment or supplement to it or from any record or report required under the provisions of section 512 of the act and § 510.300 or § 510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

§ 514.50 Requests for certification, check tests and assays, and working standards for animal drugs subject to section 512(n) of the act; information and samples required.

(a) A request for certification of a batch shall be addressed to the Commissioner and shall be in a form specified by him. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States. The agent will be held accountable for all outstanding certification fees incurred by the foreign manufacturer he represents, and, in signing the request for certification, the agent agrees to be financially responsible for any certification debts so incurred.

(b)(1) The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and

purity of each batch of such drug, including descriptions of:

(i) The methods and processes used in the manufacture of the drug;

(ii) The tests and assays of the drug made during the manufacture of the batch and after it is packaged; and

(iii) The laboratory facilities used in such controls.

(2) Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by specimens of all labeling to be used for such drug.

(c) A person who requests certification or check tests and assays of a batch shall submit with his request the following information and samples:

(1) The batch mark of the drug.

(2) The quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements or standards prescribed therefor, if any, by specific regulations or official compendium or otherwise approved by the Commissioner.

(3) The size of the batch, including the number of containers of each size in the batch.

(4) The date of the latest assay of the batch.

(5) The results of the latest tests and assays made by or for him on the batch as required for the drug by specific regulations.

(6) The batch mark(s) of the antibiotic(s) used in making the batch.

(7) Unless previously submitted, the results and dates of the latest tests and assays made by or for him on the antibiotic(s) used in making the batch as required by specific regulations.

(8) The number of accurately representative samples that are required for the batch by specific regulations:

(i) In the case of drugs such as dry powders, solutions, ointments, and suspensions, the sample shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal. In no case, however, shall more than 5,000 immediate containers have been packaged during each such interval of sampling, except for a sample collected for sterility testing.

(ii) In the case of drugs such as tablets or other such unit dosage forms, the sample shall be collected by taking single tablets at such intervals throughout the entire time of tableting the batch that the quantities tableted during the intervals are approximately equal. In no case, however, shall more than 5,000 tablets have been tableted during each interval of sampling, except for a sample collected for time of disintegration. If the person who packages the tablets into dispensing-size containers is not the manufacturer, such sample shall be collected throughout the entire time of packaging the batch into such containers.

(iii) In the case of drugs packaged for repacking or for use in the manufacture of another drug, the sample must be representative of the batch. Such samples may be taken from a composite composed of portions taken from a representative number of bulk containers, the composite consisting of no more than 10 times the amount required for conducting the required tests and assays. Such samples are not required if they have been previously submitted.

(iv) In the case of a sterile drug packaged in combination with containers of a sterile diluent, the sample shall be collected by taking 20 immediate containers of the diluent collected at regular intervals throughout each filling operation, except that if the diluent is sterilized after filling into containers, the representative sample shall consist of 20 immediate containers collected from each sterilizer load and each container shall be taken from a different part of each such sterilizer load. In the case of sterile drugs packaged in combination with sterile droppers, the sample shall be collected by taking 20 droppers from each sterilizer load and each stopper shall be taken from a different part of such sterilizer load.

(9) In the case of an initial request for certification, each ingredient used in making the batch other than ingredients required by specific regulations: 1 package of each containing approximately 5 grams. Results and dates of the latest tests and assays made by or for him on such ingredients shall precede or accompany the submission.

(10) The results and dates of tests and assays made by or for him on the nonantibiotic active ingredients in the batch.

(11) If such batch or any part thereof is to be packaged with a sterile diluent or sterile dropper, such request shall also be accompanied by a statement that such diluent or dropper is sterile and conforms to the requirements prescribed therefor by specific regulations.

(d) Each sample submitted pursuant to the regulations in this chapter shall be addressed to the Commissioner. Its package shall be clearly identified as to its contents and shall bear the name and post-office address of the person submitting it.

(e) In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this chapter, the person who requests certification of a batch shall submit such further information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of § 431.10 of this chapter for the issuance of a certificate.

(f) Upon the request of any person, stating reasonable grounds therefor, the Commissioner shall furnish such person with a portion of the working standards.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)).

§ 514.51 Certification of animal drugs subject to section 512(n) of the act.

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this chapter have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) The batch complies with the regulations in this chapter and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this chapter;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by § 437.11 of this chapter, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to the regulations in this chapter, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) All statements, samples, and other information and materials submitted in connection with a request for certification shall be considered to be part of such request.

(d) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this chapter shall be determined by the tests and methods of assay prescribed for such drug by regulations issued under this chapter.

(e) The regulations in this chapter, prescribing tests and methods of assay for antibiotic and antibiotic-containing drugs, shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

(1) A request for certification contains any untrue statement of a material fact; or

(2) A certification has been obtained through fraud, or through misrepresentation or concealment of a material fact.

(f) Except as specifically provided by the regulations in this chapter, no provision of any regulation shall be construed as exempting any certifiable antibiotic drug from any applicable provision of the act or any regulation thereunder.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)).

§ 514.55 Forms for certification or exemption of antibiotic drugs for animal use subject to section 512(n) of the act.

The following forms which must be supplied in connection with certain certification or exemption procedures for antibiotic drugs for veterinary use may

be obtained from the Certification Services Staff (HFD–145), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20852:

Form	
1	Application for exemption for storage.
2	Application for exemption for processing.
3	Application for exemption for labeling.
4	Application for exemption for manufacturing use.
7	Request for check tests and assays or certification of a batch of _____ (the blank to be filled in with the name of the antibiotic drug).
8	Application for exemption for repacking.
9	Request for supplemental certification of a batch of an antibiotic drug.
1800	Application for exemption for antibiotics mixed in animal feeds, Form FD-1800—Revised must be used when applications for medicated feeds rely for evidence of safety and effectiveness on a regulation published pursuant to section 512(i) of the act.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)).

§ 514.60 Fees for certification of animal drugs subject to section 512(n) of the act.

(a) The fees for certification services for veterinary drugs are described in the applicable provisions of § 431.53 of this chapter.

(b) The fees for the services rendered with respect to each application for an exemption from certification under the regulations in § 510.515(b) of this chapter, and for each amendment thereto, shall be:

(1) $10.00 for each medicated feed formula containing one or more new-drug substances described in an initial application.

(2) $10.00 for changes in one or more new-drug substances contained in a medicated feed formula described in an amendment to such application.

The fee prescribed by this paragraph shall accompany each application and each amendment to such application unless such fee is covered by an advance deposit maintained in accordance with § 431.53(d) of this chapter.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)).

Subpart B—Administrative Actions on Applications

§ 514.100 Evaluation and comment on applications.

(a) After the filed application has been evaluated, the applicant will be furnished written comment on any apparent deficiencies in the application.

(b) When the description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug appears adequate on its face, but it is not feasible to reach a conclusion as to the safety and effectiveness of the new animal drug solely from consideration of this description, the applicant may be notified that an establishment inspection is required to verify their adequacy.

(c) A request for samples of a new animal drug or any edible tissues and byproducts of animals treated with such a drug, shall specify the quantity deemed adequate to permit tests of analytical methods to determine their adequacy for regulatory purposes. The request should be made as early in the 180-day period as possible to assure timely completion. The date used for computing the 180-day limit for the purposes of section 512(c) of the act shall be moved forward 1 day for each day after the mailing date of the request until all of the requested samples are received. If the samples are not received within 90 days after the request, the application will be considered withdrawn without prejudice.

(d) The information contained in an application may be insufficient to determine whether a new animal drug is safe or effective in use if it fails to include (among other things) a statement showing whether such drug is to be limited to prescription sale and exempt under section 502(f) of the act from the requirement that its labeling bear adequate directions for lay use. If such drug is to be exempt, the information may also be insufficient if:

(1) The specimen labeling proposed fails to bear adequate information for professional use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer such drug can use the drug for the purposes for which it is intended, including all purposes for which it is to be advertised, or represented, in accordance with § 201.105 of this chapter, and information concerning hazards, contraindications, side effects, and precautions relevant with respect to any uses for which such drug is to be prescribed.

(2) The application fails to show that the labeling and advertising of such drug will offer the drug for use only under those conditions for which it is offered in the labeling that is part of the application.

(3) The application fails to show that all labeling that furnishes or purports to furnish information for professional use of such drug will contain, in the same language and emphasis, the information for use including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, which is contained in the labeling that is part of the application in accordance with § 201.105 of this chapter.

(e) The information contained in an application will be considered insufficient to determine whether a new animal drug is safe and effective for use when there is a refusal or failure upon written notice to furnish inspectors authorized by the Food and Drug Administration an adequate opportunity to inspect the facilities, controls, and records pertinent to the application.

(f) On the basis of preliminary consideration of an application or supplemental application containing typewritten or other draft labeling in lieu of final printed labeling, an applicant may be informed that such application is approvable when satisfactory final printed labeling identical in content to such draft copy is submitted.

(g) When an application has been found incomplete on the basis of a need for the kind of information described in § 514.6, such application shall be considered withdrawn without prejudice to future filing on the date of issuance of the letter citing the inadequacies contained in the application, unless within 30 days the sponsor chooses to avail himself of the opportunity for hearing as prescribed by § 514.111.

§ 514.105 Approval of applications.

(a) Within 180 days after an application has been filed pursuant to § 514.1, if the Commissioner determines that none of the grounds for denying approval specified in section 512(d) of the act applies:

(1) He shall forward for publication in the FEDERAL REGISTER a regulation prescribing the conditions under which the new animal drug may be used, including the name and address of the applicant; the conditions and indications for use covered by the application; any tolerance, withdrawal period, or other use restrictions; any tolerance required for the new animal drug substance or its metabolites in edible products of food-producing animals; and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed; and such other information the Commissioner deems necessary to assure safe and effective use.

(2) He shall notify the applicant by sending him a copy of the proposed publication as described in paragraph (a)(1) of this section.

(b) Within 90 days after an application filed pursuant to § 514.2 if the Commissioner determines that none of the grounds for denying approval specified in section 512(m)(3) of the act applies, he shall notify the applicant that it is approvable by signing and mailing to the sponsor the original copy of the FD–1800.

§ 514.110 Reasons for refusing to file applications.

(a) The date of receipt of an application for a new animal drug shall be the date on which the application shall be deemed to be filed.

(b) An application for a new animal drug shall not be considered acceptable for filing for any of the following reasons:

(1) It does not contain complete and accurate English translations of any pertinent part in a foreign language.

(2) Fewer than three copies are submitted.

(3) It is incomplete on its face in that it is not properly organized and indexed.

(4) On its face the information concerning required matter is so inadequate that the application is clearly not approvable.

(5) The new animal drug is to be manufactured, prepared, propagated, compounded, or processed in whole or in part in any State in an establishment that has not been registered or exempted from registration under the provisions of section 510 of the act.

(6) The sponsor does not reside or maintain a place of business within the United States and the application has not been countersigned by an attorney, agent, or other representative of the applicant, which representative resides in the United States and has been duly authorized to act on behalf of the applicant and to receive communications on all matters pertaining to the application.

(7) The new animal drug is a drug subject to licensing under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.). Such applications will be referred to the U.S. Department of Agriculture for action.

(c) If an application is determined not to be acceptable for filing, the applicant shall be notified within 30 days of receipt of the application and shall be given the reasons therefore.

(d) If the applicant disputes the findings that his application is not acceptable for filing, he may make written request that the application be filed over protest, in which case it will be filed as of the day originally received.

§ 514.111 Refusal to approve an application.

(a) The Commissioner shall, within 180 days after the filing of the application, inform the applicant in writing of his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to a new animal drug, that:

(1) The reports of investigations required to be submitted pursuant to section 512(b) of the act do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or

(2) The results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; or

(3) The methods used in and the facilities and controls used for, the manufacture, processing, and packing of such drugs are inadequate to preserve its identity, strength, quality, and purity; or

(4) There is insufficient information to determine whether such drug is safe for use under such conditions. In making this determination the Commissioner shall consider, among other relevant factors:

(i) The probable consumption of such drug and of any substances formed in or on food because of the use of such drug;

(ii) The accumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substances;

(iii) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data; and

(iv) Whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice; or

(5) There is a lack of substantial evidence based upon adequate and well-controlled investigations that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. An adequate and well-controlled investigation must satisfy the following criteria:

(i) A clear statement of the objective of the study is provided.

(ii) The method of selection of the animals to be studied and those to serve as controls provides for:

(*a*) Adequate confirmation of the disease or clinical state present, including criteria of diagnosis and any appropriate confirmatory laboratory tests.

(*b*) Assignment of the animals and control groups to test under conditions which exclude or minimize bias.

(iii) An outline and explanation of the methods of quantitation and observation of the parameters studied in the subjects.

(iv) A description of the steps taken to document comparability of variables such as species, age, sex, duration, and severity of disease, management practices, and use of drugs other than those being studied.

(v) A description of the methods of recording and analyzing the animal response variables studied and the means of excluding bias or minimizing bias in the observations.

(vi) A precise statement of the nature of the control group against which the effects of the new treatment modality can be compared. Three types of controlled comparisons are possible:

(*a*) Placebo control: The new animal drug entity may be compared quantitatively with an inactive placebo control. The level of blinding may affect the validity of the observation and comparisons.

(*b*) Active drug control: The new animal drug entity may be compared quantitatively with another drug or modality known to be effective.

(*c*) Historical control: In some circumstances involving diseases with high and predictable mortality or with signs and symptoms of predictable duration or severity, the results of use of a new animal drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease in comparable animals with no treatment or with treatment with an established effective therapeutic regimen.

(vii) A summary of statistical methods used in analysis of the data derived from the subjects.

Provided, however, That any of the above criteria in this paragraph (a)(5) of this section may be waived in whole or in part, either prior to the investigation or in the evaluation of a completed study, by the Director of the Bureau of Veterinary Medicine with respect to a specific clinical investigation. A petition for such a waiver may be filed by any person who would be adversely affected by application of the criteria to a particular clinical investigation. The petition should show that some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be or have been followed, the results of which will or have yielded data that can and should be accepted as substantial evidence of the drug's effectiveness. A petition for a waiver shall set forth clearly and concisely the specific provision or provisions in the criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be or have been employed, what results have been obtained, and the basis on which it can be or has been concluded that the clinical investigation will or has yielded substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(viii) Standardized test drug: For such an investigation to be considered adequate for consideration for approval of a new animal drug, the test drug must be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

(6) Failure to include an appropriate proposed tolerance for residues in edible products derived from animals or a withdrawal period or other restrictions for use of such drug if any tolerance or withdrawal period or other restrictions for use are required in order to assure that the edible products derived from animals treated with such drug will be safe.

(7) Based on a fair evaluation of all material facts, the labeling is false or misleading in any particular; or

(8) Such drug induces cancer when ingested by man or animal or, after appropriate tests for evaluation of the

safety of such drug, induces cancer in man or animal, except that this subparagraph shall not apply with respect to such drug if the Commissioner finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice:

(i) Such drug will not adversely affect the animal for which it is intended; and

(ii) No residue of such drug will be found (by methods of examination prescribed or approved by the Commissioner by regulations) in any edible portion of such animal after slaughter or in any food yielded by, or derived from the living animals.

(9) The applicant fails to submit an environmental impact analysis, report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the new animal drug pursuant to § 6.1 of this chapter.

(b) The Commissioner shall within 90 days after the filing of the application inform the applicant in writing of his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to an animal feed bearing or containing a new animal drug that:

(1) There is not in effect a regulation established pursuant to section 512(i) of the act (identified in such application) on the basis of which such application may be approved; or

(2) Such animal feed (including the proposed use of any new animal drug therein or thereon) does not conform to an applicable regulation published pursuant to section 512(i) of the act (identified in such application), or that the purposes or conditions or indications of use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable purposes and conditions or indications for use (including warnings) published pursuant to section 512(i) of the act or such labeling omits or fails to conform to other applicable information published pursuant to such section; or

(3) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(4) Based on a fair evaluation of all the material facts, such labeling is false or misleading in any particular.

(c) The Commissioner, as provided in § 514.200 of this chapter, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

§ 514.115 Withdrawal of approval of applications.

(a) The Secretary may suspend approval of an application approved pursuant to section 512(c) or (m)(2) of the act and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such new animal drug or animal feed is intended.

(b) The Commissioner shall notify in writing the person holding an application approved pursuant to section 512(c) or (m)(2) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application, or such changes are those for which written authorization or approval is not required as provided for in § 514.8. The supplemental application shall be treated in the same manner as the original application.

(3) That in the case of an application for use of a new animal drug approved or deemed approved pursuant to section 512(c) of the act:

(i) Experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(ii) New evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that section 512(d)(1)(H) of the act applies to such drug; or

(iii) On the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

(c) The Commissioner may notify in writing the person holding an application approved pursuant to section 512(c) or (m)(2) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under section 512(i)(1) or (m)(5)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by section 512(i)(2) or (m)(5)(B) of the act; or

(2) That on the basis of new information before him evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for the manufacture, processing, and packing of such drug or animal feed are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug or animal feed, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(d) Approval of an application pursuant to section 512(c) or (m)(2) of the act will be withdrawn on the basis of a request for its withdrawal submitted in writing by a person holding an approved new animal drug application on the grounds that the drug subject to such application is no longer being marketed and information is included in support of this finding, provided none of the conditions cited in paragraphs (a), (b), and (c) of this section pertain to the subject drug. A written request for such withdrawal shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Withdrawal of approval of an application under the provisions of this paragraph shall be without prejudice.

(e) On the basis of the withdrawal of approval of an application for a new animal drug approved pursuant to section 512(c) of the act, the regulation published pursuant to section 512(i) of the act covering the conditions of use of such drug as provided for in the application shall be revoked. An application providing for the manufacture of animal feeds bearing or containing such drug and approved pursuant to section 512(m)(2) of the act shall be deemed as withdrawn upon publication in the FEDERAL REGISTER of the order revoking the corresponding regulation.

§ 514.116 Notice of withdrawal of approval of application.

When an approval of an application submitted pursuant to section 512 of the act is withdrawn by the Commissioner, he will give appropriate public notice of such

action by publication in the FEDERAL REGISTER.

§ 514.120 Revocation of order refusing to approve an application or suspending or withdrawing approval of an application.

The Commissioner, upon his own initiative or upon request of an applicant stating reasonable grounds therefor and if he finds that the facts so require, may issue an order approving an application that previously has had its approval refused, suspended, or withdrawn.

§ 514.121 Service of notices and orders.

All notices and orders under this Subchapter E and section 512 of the act pertaining to new animal drug applications shall be served:

(a) In person by any officer or employee of the Department designated by the Commissioner; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at his last known address in the records of the Food and Drug Administration.

§ 514.150 Conditions on the effectiveness of certificates for animal drugs subject to section 512(n) of the act.

(a) A certificate shall not become effective:

(1) If it is obtained through fraud or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless it complies with the packaging requirements, if any, prescribed by the regulations in this chapter which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this chapter; or

(4) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this chapter.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this chapter;

(2) With respect to any immediate container when it or its seal (if the regulations in this chapter require it to be sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this chapter, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 433.12 of this chapter.

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch so included is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded.

(5) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this chapter; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a practitioner licensed by law to administer such drug; or

(ii) On his prescription issued in his professional practice.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

§ 514.155 Suspension of certification service for sponsors of animal drugs.

When the Commissioner finds that a person has:

(a) Obtained or attempted to obtain a certificate through fraud or through misrepresentation or concealment of a material fact; or

(b) Falsified the records required to be kept by § 510.350 of this chapter; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to take an inventory of stocks on hand, or otherwise to check the correctness of such records as required by § 510.350 of this chapter; or

(d) Failed to establish a system for maintaining the records required by § 510.300 of this chapter or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of that section, or has refused to permit access to, or copying, or verification of such records or reports; or

(e) Failed to conform to the requirements of good manufacturing practice prescribed by Subchapter C of this chapter; the Commissioner will immediately suspend service to such person under the regulations in this chapter. Upon request a hearing will be granted to such person to show cause why such service should be resumed.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

§ 514.160 Disposition of outdated animal drugs subject to section 512(n) of the act.

When certification becomes invalid because the expiration date is passed, such articles should not be disposed of for drug use either through commercial or charitable channels unless the articles have been assayed to establish potency and recertified.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

Subpart C—Hearing Procedures

§ 514.200 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner to refuse to approve an application or to withdraw the approval of an application will specify the grounds upon which he proposes to issue his order. On request of the applicant, the Commissioner will explain the reasons for his action. The notice of opportunity for a hearing will be published in the FEDERAL REGISTER and will specify that the applicant has 30 days after issuance of the notice within which he is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant elects to avail himself of the opportunity for a hearing, he is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the data in the application and from the reasons and a factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the withdrawal of approval of the application (for example, no adequate and well-controlled clinical investigations to support the claims of effectiveness have been identified), the Commissioner will enter an order on this data, stating his findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for

a hearing, the issues will be defined, an Administrative Law Judge will be named, and he shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(c) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in his appearance.

§ 514.201 Failure to file an appearance.

If the applicant fails to file a written appearance in answer to the notice of opportunity for a hearing, his failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

§ 514.202 Appearance of applicant.

If the applicant elects to avail himself of the opportunity for the hearing, he may appear in person or by counsel. If the applicant desires to be heard through counsel, the counsel will file with the Administrative Law Judge a written appearance.

§ 514.203 Administrative Law Judge.

The hearing will be conducted by an Administrative Law Judge appointed as provided in 5 U.S.C., section 3105, and designated for conducting the hearing. Any such designation may be made or revoked by the Commissioner at any time. Hearings will be conducted in an informal but orderly manner in accordance with these regulations and the requirements of the administrative procedure provisions of 5 U.S.C. The Administrative Law Judge will have the power to administer oaths and affirmations, to rule upon offers of proof and the admissibility of evidence, to receive relevant evidence, to examine witnesses, to regulate the course of the hearing, to hold conferences for the simplification of the issues, and to dispose of procedural requests, but will not have the power to decide any motion that involves final determination of the merits of the proceeding.

§ 514.204 Prehearing and other conferences.

The Administrative Law Judge, on his own motion or on the motion of the applicant or the Food and Drug Administration, may direct all parties or their representatives to appear at a specified time and place for a conference to consider:

(a) The simplification of the issues.

(b) The possibility of obtaining stipulations, admissions of facts, and documents.

(c) The limitation of the number of expert witnesses.

(d) The scheduling of witnesses to be called.

(e) The advance submission of all documentary evidence.

(f) Such other matters as may aid in the disposition of the proceeding.

The Administrative Law Judge shall make an order: Reciting the action taken at the conference, the agreements made by the parties or their representatives, and the schedule of witnesses for the hearing; and limiting the issues for the hearing to those not disposed of by admissions or agreements. Such order will control the subsequent course of the proceeding unless modified for good cause by subsequent order. The Administrative Law Judge may also direct all parties and their representatives to appear at conferences at any time during the hearing with a view to simplifying, clarifying, or shortening the hearing.

§ 514.205 Transcript of testimony.

Testimony given at a hearing shall be reported verbatim. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the Administrative Law Judge of their authenticity, relevancy, and materiality, shall be received in evidence subject to the provisions of 5 U.S.C. 556(d). Exhibits shall, if practicable, be submitted in quintuplicate. In case the required number of copies are not made available, the Administrative Law Judge shall exercise his discretion as to whether said exhibit shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the Administrative Law Judge. Where the testimony of a witness refers to a statute, report, or document, the Administrative Law Judge shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence or shall be incorporated in the record by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the Administrative Law Judge.

§ 514.206 Oral and written arguments.

(a) Unless the Administrative Law Judge shall issue an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The Administrative Law Judge shall announce at the hearing a reasonable period within which the parties or their representatives may file written arguments based solely upon the evidence received at the hearing, citing the pages of the transcript of the testimony or of properly identified exhibits where such evidence occurs.

§ 514.210 Hearing procedure, animal drugs.

Hearings held pursuant to § 514.155 will be conducted in accordance with the rules provided in this Part.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

Subpart D—Evidence

§ 514.220 Submission of documentary evidence in advance.

(a) All documentary evidence to be offered at the hearing shall be submitted to the Administrative Law Judge and to the parties sufficiently in advance of the offer of such documentary evidence for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The Administrative Law Judge after consultation with the parties at a conference called in accordance with § 514.204 shall make an order specifying the time at which documentary evidence shall be submitted. He shall also specify in his order the time within which objections to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documentary evidence not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the hearing examiner upon notice to the other parties within the time specified by the Administrative Law Judge in accordance with paragraph (b) of this section, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 514.221 Excerpts from documentary evidence.

When only portions of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the Administrative Law Judge and to the other parties. Only the excerpts so prepared and submitted shall be received in the record; however, the whole of the original document shall be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 514.222 Submission and receipt of evidence.

(a) Each witness, before proceeding to testify, shall be sworn or make affirmation.

(b) When necessary in order to prevent undue prolongation of the hearing, the Administrative Law Judge may limit the number of times any witness may

testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The Administrative Law Judge shall admit only evidence that is relevant, material, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the Administrative Law Judge is satisfied that the witness is properly qualified.

(e) If any person objects to the admission or rejection of any evidence, or other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the Administrative Law Judge. A ruling on any such objection, together with such offer of proof as has been made, shall be a part of the transcript.

Subpart E—Findings of Facts and Order

§ 514.230 Tentative order.

The Administrative Law Judge within a reasonable time shall prepare tentative findings of fact and a tentative order, which shall be served upon the applicant and the Food and Drug Administration or sent to them by certified mail. If no exceptions are taken to the tentative order within 20 days or such other time specified in such order, that order shall become final in accordance with § 514.232.

§ 514.231 Exceptions to the tentative order.

Within 20 days or such other time specified in the tentative order, the applicant or the Food and Drug Administration may transmit exceptions to the Administrative Law Judge, together with any briefs or argument in support thereof. If exception is taken to any tentative findings of fact, reference must be made to the pages or parts of the record relied upon, and a corrected finding of fact must be submitted. The applicant, if he files exceptions, shall state in writing whether he desires to make an oral argument.

§ 514.232 Issuance of final order.

Within a reasonable time after the filing of exceptions (if any), or after oral argument (if such argument is requested), the Commissioner shall issue the final order in the proceeding. The order will include the findings of fact upon which it is based.

Subpart F—Judicial Review

§ 514.235 Judicial review.

The General Counsel of the Department of Health, Education, and Welfare is hereby designated as the officer upon whom copies of petitions for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the final orders were based. The transcript and record shall be certified by the Commissioner.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Sec.

520.23 Acepromazine maleate tablets.
520.44 Acetazolamide sodium soluble powder.
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520.182 Bicyclohexylammonium fumagillin.
520.222 Bunamidine hydrochloride.
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520.680 Dimetridazole oral dosage forms.
520.680a Dimetridazole drinking water.
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520.704 Diphenylhydantoin sodium capsules.
520.763 Dithiazanine iodide oral dosage forms.
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520.784 Doxylamine succinate tablets.
520.823 Erythromcyin phosphate.
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520.1100 Griseofulvin.
520.1120 Haloxon oral dosage forms.
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520.1162 Ipronidazole hydrochloride soluble powder.
520.1204 Kanamycin sulfate, amino-pentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite oral.
520.1242 Levamisole hydrochloride oral dosage forms.
520.1242a Levamisole hydrochloride drench and drinking water.
520.1242b Levamisole hydrochloride tablet or oblet (bolus).
520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.
520.1263a Lincomycin hydrochloride monohydrate tablets.
520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.
520.1284 Sodium liothyronine tablets.
520.1320 Mebendazole oral.
520.1341 Megestrol acetate tablets.
520.1362 Meglumine diatrizoate and sodium diatrizoate oral solution.
520.1380 Methocarbamol tablets.
520.1422 Metoserpate hydrochloride.
520.1520 Niclosamide tablets.
520.1540 Nitrodan.
520.1660 Oxytetracycline.
520.1660a Oxytetracycline and carbomycin in combination.
520.1660b Oxytetracycline hydrochloride capsules.
520.1720 Phenylbutazone oral dosage forms.
520.1720a Phenylbutazone tablets and boluses.
520.1720b Phenylbutazone granules.
520.1760 Phthalofyne tablets.
520.1780 Piperacetazine tablets.
520.1801 Piperazine adipate.
520.1802 Piperazine-carbon disulfide complex with phenothiazine.
520.1803 Piperazine citrate capsules.
520.1840 Poloxalene.
520.1900 Primidone tablets.
520.1920 Prochlorperazine, isopropamide sustained release capsules.
520.1962 Promazine hydrochloride.
520.2002 Propiopromazine hydrochloride.
520.2022 Protokylol hydrochloride tablets.
520.2043 Pyrantel pamoate suspension.
520.2045 Pyrantel tartrate powder; pyran'el tartrate pellets.
520.2080 Ronnel.
520.2100 Selenium, vitamin E capsules.
520.2122 Spectinomycin dihydrochloride oral solution.
520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.
520.2123a Spectinomycin dihydrochloride pentahydrate tablets.
520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.
520.2160 Styrylpyridinium, diethylcarbamazine tablets.
520.2162 Styrlpyridinium chloride, diethylcarbamazine (as base).
520.2184 Sodium sulfachloropyrazine monohydrate.
520.2200 Sulfachlorpyridazine oral dosage forms.
520.2200a Sulfachlorpyridazine, bolus.
520.2200b Sulfachlorpyridazine medicated milk and drinking water.
520.2220 Sulfadimethoxine oral dosage forms.
520.2220a Sulfadimethoxine drinking water and drench.
520.2220b Sulfadimethoxine tablets and boluses.
520.2220c Sulfadimethoxine oral suspension.
520.2240 Sulfaethoxypyridazine.
520.2240a Sulfaethoxypyridazine drinking water.
520.2240b Sulfaethoxypyridazine tablets.
520.2260 Sulfamethazine tablets and bolus.
520.2280 Sulfamethizole and methenamine mandelate tablets.
520.2300 Sulfamethoxypyridazine tablets.
520.2301 Acetyl sulfamethoxypridazine oral suspension.
520.2320 Sulfamitran and aklomide in combination.
520.2362 Thenium closylate tablets.
520.2380 Thiabendazole oral dosage forms.
520.2380a Thiabendazole top dressing and mineral protein feed block.
520.2380b Thiabendazole drench or oral paste.
520.2380c Thiabendazole bolus.
520.2380d Thiabendazole, piperazine citrate suspension.
520.2460 Ticarbodine oral dosage forms.
520.2460a Ticarbodine tablets.
520.2460b Ticarbodine capsules.
520.2480 Triamcinolone tablets.
520.2481 Triamcinolone acetonide tablets.
520.2520 Trichlorfon oral dosage forms.
520.2520a Trichlorfon oral.
520.2520b Trichlorfon and atropine.
520.2560 Trifluomeprazine tablets.
520.2582 Triflupromazine hydrochloride tablets.
520.2604 Trimeprazine tartrate and prednisolone tablets.
520.2640 Tylosin.

AUTHORITY: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).

§ 520.23 Acepromazine maleate tablets.

(a) *Chemical name.* [10-[3-(Dimethylamino) propyl] phenothiazin-2-ylmethyl ketone] maleate.

(b) *Specifications.* Each tablet contains either 10 or 25 milligrams of acepromazine maleate.

(c) *Sponsor.* See No. 000046 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used as a tranquilizer in dogs and cats.

(2) The drug is administered orally to dogs at a dosage level of 0.25 to 1.0 milligram of acepromazine maleate per pound of body weight and to cats at a dosage level of 0.5 to 1.0 milligram of acepromazine maleate per pound of body weight. Dosage may be repeated as required.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.44 Acetazolamide sodium soluble powder.

(a) *Specifications.* The drug is in a powder form containing acetazolamide sodium, USP equivalent to 25 percent acetazolamide activity.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an aid in the treatment of mild congestive heart failure and for rapid reduction of intraocular pressure.

(2) It is administered orally at a dosage level of 5 to 15 milligrams per pound of body weight daily.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.62 Aminopentamide hydrogen sulphate tablets.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* Each tablet contains 0.2 milligram of the drug.

(c) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by oral tablet every 8 to 12 hours, as follows:

Weight of animal in pounds:	*Dosage in milligrams*
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.82 Aminopropazine fumarate oral dosage forms.

§ 520.82a Aminopropazine fumarate tablets.

(a) *Specifications.* The drug is in tablet form. Each tablet contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.

(2) It is administered at a dosage level of 1 to 2 milligrams per pound of body weight. The dosage can be repeated every 12 hours, as indicated.

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

§ 520.82b Aminopropazine fumarate, neomycin sulfate tablets.

(a) *Specifications.* The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base and neomycin sulfate equivalent to 50 milligrams of neomycin base.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.

(2) It is administered at a dosage level of one to two tablets per 10 pounds of body weight twice daily for 3 days.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.100 Amprolium oral dosage forms.

§ 520.100a Amprolium drinking water.

(a) *Chemical name.* 1-(4-Amino-2-*n*-propyl -5- pyrimidinylmethyl) -2- picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 000006 in § 510.600 (c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens and turkeys*—(i) *Amount.* 20 percent soluble powder.

(ii) *Indications for use.* Treatment of coccidiosis.

(iii) *Limitations.* Administer at the 0.012 percent level in drinking water as soon as coccidiosis is diagnosed and continue for from 3 to 5 days (in severe outbreaks, give amprolium at the 0.024 percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) *Calves*—(i) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(b) *Limitations.* Add 16 fluid ounces of the 9.6 percent solution to each 100 gallons of drinking water; or 4 ounces of the soluble powder to each 50 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(b) *Limitations.* Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each 100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

§ 520.100b Amprolium drench.

(a) *Chemical name.* 1-(4-Amino-2-*n*-propyl -5- pyrimidinylmethyl) -2- picolinium chloride hydrochloride.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is used for calves as follows:

(1) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) *Amount.* 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Add 1½ fluid ounces of the 9.6 percent solution to 1 pint of water or 1½ ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1

fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

§ 520.120 Anthelin tablets.

(a) *Specifications.* Anthelin tablets contain anthelin as the active ingredient.

(b) *Sponsor.* See No. 017220 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the removal of tapeworms (*Taenia* and *Dipylidium spp.*) from dogs.

(2) The tablets are administered orally to dogs at a dosage level of 4.7 milligrams of anthelin per pound of body weight up to a maximum dosage of 211.5 milligrams of anthelin for dogs 45 pounds or over. Only milk is fed 24 hours prior to treatment. The dosage is repeated in one week if indicated.

(3) Do not administer to sick, feverish, weak or undernourished dogs. Depression, nausea, vomiting and colic are signs of overdosage. If vomiting is a problem, a light feeding within 1 hour after administering the drug is recommended. If no catharsis occurs within 3 hours an enema will facilitate passage of large masses of tapeworms. Dogs may be fed their normal ration 4 to 8 hours after medication.

§ 520.182 Bicyclohexylammonium fumagillin.

(a) *Specifications.* The drug is a soluble powder containing bicyclohexylammonium fumagillin and appropriate phosphate buffers.

(b) *Sponsor.* See No. 043731 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the prevention of nosema in honey bees.

(2) It is administered usually in a 2:1 sugar sirup containing a concentration of from 75 to 100 milligrams of fumagillin activity per gallon of sugar sirup.

(3) Colonies used for package production should be fed medicated sirup as a principal food supply for a month prior to stocking nuclei or shaking packages for market.

(4) The medicated sirup should not be fed immediately before or during the honey flow.

§ 520.222 Bunamidine hydrochloride.

(a) *Chemical name.* *N,N*-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) *Specifications.* The drug is an oral tablet containing bunamidine hydrochloride.

(c) *Sponsor.* See No. 011492 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms *Dipylidium caninum* and *Taenia pisiformis* and to cats for the treatment of the tapeworms *Dipylidium caninum* and *Taenia taeniaeformis.*

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

(4) For use only by or on the order of a licensed veterinarian.

§ 520.240 Butonate liquid.

(a) *Chemical name.* O,O-Dimethyl (2,2,2-trichloro-1-*n*-butyryl oxyethyl) phosphonate.

(b) *Specifications.* Butonate liquid veterinary contains 13 percent butonate by weight in a suitable base.

(c) *Sponsor.* See No. 011536 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) It is used in horses other than foals (sucklings and young weanlings) for the removal and control of bots (*Gastrophilus intestinalis, G. nasalis*) and ascarids (*Parascaris equorum*).

(2) It is administered by a stomach tube at a dosage level of 1 fluid ounce per 200 pounds of body weight. The dose is emulsified in a convenient amount of water (½ to 2 pints) at the time of treatment before administration.

(3) The drug should not be given to horses which are severely debilitated, suffering from diarrhea or severe constipation, infectious disease, toxemia or colic until such conditions are corrected with proper therapy.

(4) This drug is a cholinesterase inhibitor. Do not use this drug in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides or chemicals.

(5) Not for use in horses intended for food.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.260 n-Butyl chloride caspules.

(a) (1) *Specifications.* *n*-Butyl chloride capsules, veterinary contain 272 milligrams or 816 milligrams of *n*-butyl chloride in each capsule.

(2) *Sponsor.* See No. 000031 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*) from dogs and of the ascarid (*Toxocara cati*) and hookworm (*Ancylostoma tubaeforme*) from cats.

(ii) (*a*) Animals should not be fed for 18 to 24 hours before being given the drug. Puppies and kittens should be wormed at 6 weeks of age. However, if heavily infested, they may be wormed at 4 or 5 weeks of age. Administration of the drug should be followed in ½ to 1 hour with a teaspoonful to a tablespoonful of milk of magnesia or 1 or 2 milk of magnesia tablets. Normal rations may be resumed 4 to 8 hours after treatment. Puppies and kittens should be given a repeat treatment in a week or 10 days. After that they should be treated every 2 months (or as symptoms reappear) until a year old. When the puppy or kitten is a year old, one treatment every 3 to 6 months is sufficient.

(*b*) For dogs or cats that have been wormed regularly, treatment every 3 to 6 months will be sufficient. If a dog or cat has not been wormed previously and has the symptoms of large roundworms a dose should be given and repeated in 10 days. Removal of hookworms may require 3 or 4 doses at 10-day intervals.

(c) Puppies, dogs, cats, or kittens weighing 1 to 3 pounds should be given 2 capsules per dose which contain 272 milligrams of *n*-butyl chloride each. Such animals weighing 4 to 5 pounds should be given 3 such capsules. Animals weighing 6 to 7 pounds should be given 4 such capsules and animals weighing 8 to 9 pounds should be given 5 such capsules. Animals weighing 10 to 20 pounds should be given 3 capsules which contain 816 milligrams of *n*-butyl chloride each, animals weighing 20 to 40 pounds should be given 4 such capsules and animals weighing over 40 pounds should be given 5 such capsules with the maximum dosage being 5 capsules, each of which contains 816 milligrams of *n*-butyl chloride.

(iii) A veterinarian should be consulted before using in severely debilitated dogs or cats and also prior to repeated use in cases which present signs of persistent parasitism.

(b) (1) *Specifications.* *n*-Butyl chloride capsules, veterinary contain 221, 442, 884, or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.

(2) *Sponsor.* See No. 015563 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*) from dogs.

(ii) (*a*) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal rations may be resumed 4 to 8 hours after treament.

(*b*) The drug is administered orally to dogs. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 1¼ pound of body weight. Capsules containing 442 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride

are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over.

(iii) A veterinarian should be consulted before using in severly debilitated dogs.

(c) (1) *Specifications.* *n*-Butyl chloride capsules, veterinary contain 884 or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.

(2) *Sponsor.* See No. 000115 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancyclostoma caninum, Ancyclostoma braziliense, and Uncinaria stenocephala*) from dogs.

(ii) (*a*) Dogs should not be fed for 18 to 24 hours before being given he drug. Administration of the drug should be followed in ½ ot 1 hour with a mild cathartic. Normal rations may be resumed 4 to 8 hours after treatment.

(*b*) The drug is administered orally to dogs. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: weighing under 5 pounds, 1 capsule; weighing 5–10 pounds, 2 capsules; weighing 10–20 pounds, 3 capsules; weighing 20–40 pounds, 4 capsules; over 40 pounds, 5 eapsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dogs to dogs weighing 5–10 pounds and 2 capsules per dog to dogs weighing 20–40 pounds. Capsules containing 4.42 grams of -butyl chloride are administsered at dosage level of 1 capsule per dog to dogs weighing 40 pounds or over.

(iii) A veterinarian should be consulted before using in severely debilitated dogs.

§ 520.300 Cambendazole suspension.

(a) *Specifications.* Each fluid ounce contains 0.9 gram of cambendazole.

(b) *Sponsor.* No. 000006 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses for the control of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles (*Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(2) It is administered by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares or to stallions at stud.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.420 Chlorothiazide tablets.

(a) *Specifications.* Each tablet contains 0.25 gram of chlorothiazide.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use in dogs for the treatment of congestive heart failure and renal edema.

(2) The usual dosage range is 5 to 10 milligrams of chlorothiazide per pound of body weight; a dose is administered two or three times each day. The dosage must be adjusted to meet the changing needs of the individual animal. In mild and responsive cases, it is suggested that a dose of 5 milligrams per pound of body weight be administered two or three times daily. In moderately edematous and moderately responsive animals, a dose of 7.5 to 10 milligrams per pound of body weight may be administered three times each day. Severe conditions may require higher doses. Certain animals may respond adequately to intermittent therapy; in these cases, the drug may be administered either every other day or for 3 to 5 days each week.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.443 Chloropromazine hydrochloride.

(a) *Specifications.* The drug is in tablet form with the tablets containing chlorpromazine hydrochloride as the active drug ingredient.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered orally to dogs and cats as a tranquilizer, potentiator, and antiemetic with a sedating effect.

(2) It is administered orally to dogs and cats at a dosage level of one tablet containing 10 milligrams of chlorpromazine hydrochloride per 7 pounds body weight or at a dosage level of one tablet containing 25 milligrams of chlorpromazine hydrochloride per 17 pounds body weight. It is administered one to four times daily depending upon the size of the dose and the needs of the patient.

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.500 Coumaphos crumbles.

(a) *Chemical name.* *O,O*-Diethyl *O*-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl-phosphorothioate.

(b) *Specifications.* Coumaphos Crumbles contain 0.32 percent coumaphos.

(c) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(d) *Special considerations.* Adequate directions and warnings for use must be given and shall include a statement that coumaphos is a cholinesterase inhibitor and that animals being treated with coumaphos should not be exposed during or within a few days before or after treatment with any other cholinesterase inhibiting drugs, insecticides, pesticides, or chemicals.

(e) *Related tolerances.* See 40 CFR 180.189.

(f) *Conditions of use.* It is used as a top dressing on the daily feed ration of cattle for the control of gastrointestinal roundworms (*Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., and *Trichostrongylus* spp.). It is administered at the rate of 1 ounce of coumaphos crumbles per 100 pounds of body weight per day for six consecutive days. Should conditions warrant, treatment should be repeated at 30 day intervals. Not to be fed to cattle less than 3 months old. Not to be fed to sick animals or animals under stress such as those just shipped, dehorned, castrated, or weaned within the previous 3 weeks. Not to be used in conjunction with oral drenches or with feeds containing phenothiazine.

§ 520.540 Dexamethasone oral dosage forms.

§ 540.540a Dexamethasone powder.

(a) *Specifications.* Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

(b) *Sponsor.* See No. 000085 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.540b Dexamethasone bolus.

(a) *Specifications.* Dexamethasone bolus contains 10 milligrams of dexamethasone in each bolus which is half-scored.

(b) *Sponsor.* See No. 000085 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Dexamethasone bolus, is indicated in cases where cattle and horses require additional steroid therapy following its

parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered orally at a dosage level of 5 to 10 milligrams per animal the first day, then 5 milligrams per day as required.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.580 Dichlorophene and toluene capsules.

(a) *Chemical name.* 2,2'-Methylenebis (4-chlorophenol) and toluene.

(b) *Specifications.* (1) Dichlorophene has a melting point range of 169° C. to 178° C. It has a minimum assay of 94 percent as determined by titration with a standard solution of 0.1*N* sodium methoxide using thymol blue to determine the visual end point.

(2) The toluene meets the U.S.P. requirements for toluene reagent and passes the thiophene test for benzene, which is found in the seventeenth revision of the U.S.P.

(c) *Sponsor.* See Nos. 011519, 000010, and 011536 in § 510.600(c) of this chapter.

(d) *Conditions of use.* It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) and as an aid in the removal of tapeworms (*Taenia pisiformis, Dipylidium caninum* and *Echinococcus granulosus*) from dogs and cats in suitable capsules which provide a dosage level of 100 milligrams of dichlorophene per pound of body weight and 120 milligrams of toluene per pound of body weight. Solid foods and milk should be withheld for at least 12 hours prior to administration of the drug and for 4 hours afterwards.

§ 520.600 Dichlorvos.

(a) *Chemical name.* 2,2-Dichlorvinyl dimethyl phosphate.

(b) [Reserved]

(c) *Sponsor.* See No. 011461 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.180 of this chapter.

(e) *Conditions of use in swine.* (1) It is recommended for the removal and control of sexually mature (adult), sexually immature and/or 4th stage larvae of the whipworm (*Trichuris suis*), nodular worms (*Oesophagostomum* sp.), large round-worm (*Ascaris suum*), and the mature thick stomach worm (*Ascarops strongylina*) occurring in the lumen of the gastrointestinal tract of pigs, boars, and open or bred gilts and sows.

(2) The preparation should be added to the indicated amount of feed as set forth in paragraph (e) (2) of this section and administered shortly after mixing, as follows:

Weight of animal in pounds	Pounds of feed to be mixed with each 0.03 ounce of dichlorvos	Pounds of mixed feed to be administered to each pig as a single treatment	Number of pigs to be treated per 0.03 ounce of dichlorvos
20-30	4	0.33	12
31-40	5	0.56	9
41-60	6	1.00	6
61-80	5	1.00	5
81-100	4	1.00	4
Adult Gilts, Sows, and Boars	16	4.00	4

(3) Do not use this product on animals either simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. The preparation should be mixed thoroughly with the feed on a clean, impervious surface. Do not allow swine access to feed other than that containing the preparation until treatment is complete. Do not treat pigs with signs of scours until these signs subside or are alleviated by proper medication. Resume normal feeding schedule afterwards. Swine may be retreated in 4 to 5 weeks.

(f) *Conditions of use in dogs.* (1) For removal of *Toxocara canis* and *Toxascaris leonina* (roundworms), *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms), and *Trichuris vulpis* (whipworm) residing in the lumen of the gastrointestinal tract.

(2) The drug is in capsule form for direct administration and in pellet form for administration in about one-third of the regular canned dog food ration or in ground meat. Dogs may be treated with any combination of capsules and/or pellets so that the animal receives a single dose equaling 12 to 15 milligrams of the active ingredient per pound of body weight. One-half of the single recommended dosage may be given, and the other half may be administered 8 to 24 hours later. This split dosage schedule should be used in animals which are very old, heavily parasitized, anemic, or otherwise debilitated. The drug should not be used in dogs weighing less than 2 pounds.

(3) In some dogs, efficacy against *Trichurias vulpis* (whipworm) may be erratic. Dogs that do not develop a negative stool for *Trichuris vulpis* ova 10 to 14 days following; initial treatment should be re-treated. If a negative stool is not obtained in 10 to 14 days following re-treatment, alternate means of therapy should be considered.

(4) Do not use in dogs infected with *Dirofilaria immitis.*

(5) Do not use with other anthelmintics, taeniacides, antifilarial agents, muscle relaxants, or tranquilizers.

(6) The drug is a cholinesterase inhibitor. Not for use simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(7) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(g) *Conditions of use in horses when administered in grain.* (1) It is recommended for the removal and control of bots (*Gastrophilus intestinalis, G. nasalis*), large strongyles (*Strongylus vulgaris, S. equinus, S. edentatus*), small strongyles (of the genera *Cyathostomum, Cylicocercus, Cylicocyclus, Cylicodontophorus, Triodontophorus, Poteriostomum, Gyalocephalus*), pinworms (*Oxyuris equi*), and large roundworm (*Parascaris equorum*) in horses including ponies and mules. Not for use in foals (sucklings and young weanlings).

(2) For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or a diagnostic laboratory prior to worming.

(3) It is administered in the grain portion of the ration at a dosage of 14.2 milligrams to 18.5 milligrams per pound of body weight as a single dose. It may be administered at one-half of the single recommended dosage and repeated 8 to 12 hours later in the treatment of very aged, emaciated or debilitated subjects or those reluctant to consume medicated feed. In suspected cases of severe ascarid infection sufficient to cause concern over mechanical blockage of the intestinal tract, the split dosage should be utilized.

(4) Do not use in horses which are severely debilitated, suffering from diarrhea or severe constipation, infectious disease, toxemia or colic. Do not administer in conjunction with or within 1 week of administration of muscle relaxant drugs, phenothiazine derived transquilizers or central nervous system depressant drugs. Horses should not be subjected to insecticide treatment for 5 days prior to or after treating with the drug. Do not administer to horses afflicted with chronic alveolar emphysema (heaves) or related respiratory conditions. The product is a cholinesterase inhibitor and should not be used simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals.

(5) Do not use in animals other than horses, ponies, and mules. Do not use in horses, ponies, and mules intended for food purposes. Do not allow fowl access to feed containing this preparation or to fecal excrement from treated animals.

(h) *Conditions of use in horses when administered orally by syringe.* (1) It is recommended for the removal and control of first, second, and third instar bots (*Gastrophilus intestinalis* and *G. nasalis*), sexually mature and sexually immature (4th stage) ascarids (*Parascaris equorum*) in horses and foals.

(2) The product is in the form of a gel which is administered directly from a syringe onto the horse's tongue. The product is administered at a dosage level of 20 milligrams of dichlorvos per kilogram of body weight for the removal of bots and ascarids. The same dosage level is repeated every 21 to 28 days for the control of bots and ascarids. For the control of bots only, the repeat dosage is 10 milligrams per kilogram of body weight every 21 to 28 days during bot fly season.

(3) Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides or chemicals. Do not administer in conjunction with or within 1 week of administration of muscle-relaxant drugs, phenothiazine derived tranquilizers, or central nervous system depressants.

(4) Do not use in horses which are severely debilitated or suffering from diarrhea or severe constipation, infectious disease, toxemia, or colic. Do not administer to horses affected with chronic alveolar emphysema (heaves) or other respiratory conditions.

(5) Do not use in horses intended for food purposes.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(i) *Conditions of use; in cats and puppies.* (1) It is indicated for the removal and control of roundworms (*Toxocara canis, Toxocara cati, Toxascaris leonina*) and hookworms (*Ancylostoma caninum, Ancylostoma tubaeforme, Uncinaria stenocephala*) occurring in the intestinal tracts of cats and puppies.

(2) The drug is in tablet form and is administered orally at a dosage level of 5 mg of the active ingredient per pound of body weight.

(3) Do not administer to puppies or cats showing signs of constipation, mechanical blockage of the intestinal tract, impaired liver function, or to animals recently exposed to or showing signs of infectious disease. The drug is a cholinesterase inhibitor and should not be used simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(4) Do not use in animals under 10 days of age or under 1 pound of body weight.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.620 Diethylcarbamazine.

(a) *Chemical name.* N,N-Diethyl-4-methyl-1-piperazine-carboxamide.

(b) *Specifications.* Each pound of the drug contains 30 grams of diethylcarbamazine (as base).

(c) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is administered to dogs to aid in the continual control of large roundworms (*Toxocara canis*) and to aid in the prevention of heartworm disease (*Dirofilaria immitis*). In those areas where roundworms are suspected or known to be a problem, it is added to the daily diet. In those areas where heartworms are endemic, it is added to the daily diet at the beginning of the mosquito activity and treatment is continued throughout the mosquito season and for approximately 1 month thereafter.

(2) It is administered daily in meal or moist feeds as follows:

Weight of animal in pounds	Recommended amount per day	Dosage in milligrams
20	¼ level teaspoonful	32
50	⅝ level teaspoonful	70
100	1 level teaspoonful	140

(3) Dogs with established heartworm infections should not receive diethylcarbamazine until they have been converted to a negative status.

(4) For use only by or on the order of a licensed veterinarian.

§ 520.622 Diethylcarbamazine citrate oral dosage forms.

§ 520.622a Diethylcarbamazine citrate tablets.

(a) (1) *Specifications.* Diethylcarbamazine citrate tablets contain 50, 200, or 400 milligrams of diethylcarbamazine citrate per tablet.

(2) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used as an aid in the treatment of ascarids in dogs and cats and for the prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) For the treatment of ascarids in dogs and cats, the tablets are administered orally or pulverized and given in the feed or water at a dosage level of 25 to 50 milligrams of diethylcarbamazine citrate per pound of body weight. A repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose.

(iii) For the prevention of heartworm disease in heartworm endemic areas dogs should be given a daily dose of 3 milligrams of diethylcarbamazine citrate per pound of body weight.

(iv) Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Diethylcarbamazine citrate tablets contain 100, 200 or 300 milligrams of diethylcarbamazine citrate per tablet.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs for the prevention of infection with *Dirofilaria immitis* (heartworm disease) and as an aid in the treatment of ascarid infections (*Toxocara canis* and *Toxascaris leonina*) in dogs.

(ii) For the prevention of heartworm disease in dogs the drug is given orally once a day at a dosage rate of 3 milligrams of diethylcarbamazine citrate per pound of body weight. Young dogs may be started on the prevention program at 2 months of age. For treatment of ascarid infection in dogs, the drug is given orally at a dosage rate of 25 to 50 milligrams of diethylcarbamazine citrate per pound of body weight. A repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestines from the lungs after the initial treatment.

(iii) Use of the drug is not recommended in dogs with active *D. immitis* infections.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.622b Diethylcarbamazine citrate syrup.

(a) (1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See No. 021188 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina*. It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dosage rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the prevention of infection with *Dirofilaria immitis* in dogs.

(ii) The drug may be added to the daily ration at a dosage rate of 3.0 milligrams per pound of body weight or given directly by mouth at the same dosage rate.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administering this drug.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) (1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See No. 015563 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for use in dogs between the

ages of 4 weeks and 8 months of age, for the removal of *Toxocara canis*.

(ii) The drug is administered at a dosage level of 50 milligrams per pound of body weight divided into two equal doses and administered 8–12 hours apart (morning and night) mixed with either dry or wet food.

(iii) Dogs older than 8 months of age may be infected with *Dirofilaria immitis*. Use of the drug is contraindicated in dogs with active *D. immitis* infections.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.680 Dimetridazole oral dosage forms.

§ 520.680a Dimetridazole drinking water.

(a) *Chemical name.* 1,2-Dimethyl-5-nitroimidazole.

(b) *Specifications.* (1) Melting point range: 137° C. to 141° C.

(2) Assay (dry basis): 98 to 101 percent (by titration with perchloric acid in acetic acid).

(c) *Sponsor.* See No. 017210 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.210 of this chapter.

(e) *Conditions of use.* It is used in the drinking water for turkeys as follows:

(1) *Amount.* 0.01 percent.

(i) *Indications for use.* Prevention of blackhead (histomoniasis, infectious enterohepatitis).

(ii) *Limitations.* As sole source of drinking water; do not give to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

(2) *Amount.* 0.02 percent.

(i) *Indications for use.* Treatment of blackhead (histomoniasis, infectious enterohepatitis).

(ii) *Limitations.* As sole source of drinking water; do not give to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

(3) *Amount.* 0.04 percent.

(i) *Indications for use.* Treatment of severe outbreaks of blackhead (histomoniasis, infectious enterohepatitis).

(ii) *Limitations.* As sole source of drinking water; treat for 5 days only; do not give to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

§ 520.680b Dimetridazole tablets.

(a) *Chemical name.* 1,2-Dimethyl-5-nitroimidazole.

(b) *Specifications.* (1) Melting point range: 137° C to 141° C.

(2) Assay (dry basis): 98 to 101 percent (by titration with perchloric acid in acetic acid).

(c) *Sponsor.* See No. 017210 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.210 of this chapter.

(e) *Conditions of use.* It is used in tablets for turkeys as follows:

(1) *Amount.* 125 milligrams per tablet.

(2) *Indications for use.* Treatment of blackhead (histomoniasis, infectious enterohepatitis).

(3) *Limitations.* Administer 1 tablet per bird weighing not less than 1 pound nor more than 10 pounds, 2 tablets per bird over 10 pounds; do not give to birds producing eggs for human consumption; do not administer within 5 days of slaughter; as sole source of dimetridazole.

§ 520.704 Diphenylhydantoin sodium capsules.

(a) *Specifications.* Diphenylhydantoin sodium capsules conform to U.S.P. XVIII requirements.

(b) *Sponsor.* See No. 000071 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for use in the control of epileptiform convulsions in dogs.

(2) An initial dose of from 4 to 8 milligrams per pound of body weight in divided doses is suggested with the dose then gradually increased or decreased to the daily minimum amount necessary to maintain control.

(3) Since control with the drug requires several days, the transition from other anticonvulsants to this drug should be gradual. Sudden withdrawal of other anticonvulsants, including phenobarbital, should be avoided in order to exercise proper control of the convulsions.

(4) For use only by or on the order of a licensed veterinarian.

§ 520.763 Dithiazanine iodide oral dosage forms.

§ 520.763a Dithiazanine iodide tablets.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl - 2 - benzothiazolinylidene) - 1,3-pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

(c) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (*Toxocara canis, Toxascaris leonina*)	10	3-5
Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*)	10	7
Whipworms (*Trichuris vulpis*)	10	7
Strongyloides (*Strongyloides canis, Strongyloides stercoralis*)	10	10-12
Heartworm microfilariae (*Dirofilaria immitus*)	3-5	7-10
Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.		

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.763b Dithiazanine iodide powder.

(a) *Chemical name.* 3-ethyl-2-[5-(3-ethyl - 2 - benzothiazolinylidene) - 1,3-pentadienyl]-benzothiazoliumiodide.

(b) *Specifications.* Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

(c) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (*Toxocara canis, Toxascaris leonina*)	10	3-5
Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*)	10	7
Whipworms (*Trichuris vulpis*)	10	7
Strongyloides (*Strongyloides canis, Strongyloides stercoralis*)	10	10-12
Heartworm microfilariae (*Dirofilaria immitus*)	3-5	7-10
Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy or adult worms.		

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.784 Doxylamine succinate tablets.

(a) *Specifications.* The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams per pound of body weight per day divided into 3 or 4 equal doses. It is administered orally to dogs and cats at a dosage level of 2 to 3 milligrams per pound of body weight per day divided into 3 or 4 equal doses.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.823 Erythromycin phosphate.

(a) *Specifications.* Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the

same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor.* See No. 043731 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Broiler and replacement chickens*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of chronic respiratory disease due to *Mycoplasma gallisepticum* susceptible to erythromycin.

(iii) *Limitations.* Administer for 5 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(2) *Replacement chickens and chicken breeders*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of infectious coryza due to *Hemophilus gallinarum* susceptible to erythromycin.

(iii) *Limitations.* Administer for 7 days; do not use in replacement pullets over 16 weeks of age; do not use in chickens producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

(3) *Growing turkeys*—(i) *Amount.* 0.500 gram per gallon.

(ii) *Indications for use.* As an aid in the control of blue comb (nonspecific infectious enteritis) caused by organisms susceptible to erythromycin.

(iii) *Limitations.* Administer for 7 days; do not use in turkeys producing eggs for human consumption; to assure effectiveness, treated birds must consume enough medicated water to provide a therapeutic dosage; solutions older than 3 days should not be used; withdraw 1 day before slaughter.

§ 520.863 Ethylisobutrazine hydrochloride tablets.

(a) *Specifications.* Each tablet contains either 10 milligrams or 50 milligrams of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is administered orally to dogs as a tranquilizer.

(2) It is administered once daily at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight.

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1100 Griseofulvin.

(a) *Chemical name.* 7-Chloro-2',4,6-trimethoxy-6'-methylspiro [benzofuran-2(3H),1'-[2]-cyclohexene]-3,4'-dione.

(b) Specifications. Complies with U.S.P. for griseofulvin microsize.

(c) *Sponsor.* (1) See No. 000085 in § 510.600(c) of this chapter for the sponsor of the usages provided by paragraph (d) (1) and (3) of this section.

(2) See No. 000029 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d)(2) of this section.

(d) *Conditions of use.* (1) As a soluble powder for horses, it is administered as a drench or as a top dressing on feed. It is used for equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum.* Administer for not less than 10 days a daily dose as follows: Adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

(2) In capsules containing 125 milligrams of griseofulvin for use in dogs and cats by oral administration at a dosage level of 10 milligrams per pound of body weight daily in a single or divided dose. It is used for the treatment of infections caused by dermatophytic fungi of the skin, hair, and nails caused by *Trichophyton mentagrophytes, T. schoenleini, T. verrucosum, Epidermophyton floccosum, Microsporum gypseum,* and *M. canis.* Treatment should be continued for 3 to 4 weeks in skin and hair infections and up to 4 months treatment is required in nail infections. The capsules may be taken apart and the contents put on food to facilitate administration. For use only by or on the order of a licensed veterinarian.

(3)(i) Boluses containing 2.5 grams of griseofulvin are used in horses for treating ringworm infection caused by *Trichophyton equinum.* It is administered to adult horses at a level of one bolus per day, to yearlings at one-half to one bolus per day, and to foals at one-half bolus per day. All three dosage levels should be administered for a period of not less than 10 days. In responsive cases, treatment should be continued until all infected areas are proven negative by appropriate culture. Not for use in horses intended for food.

(ii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Chemical name.* 3-Choloro-7-hydoxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications.* Haloxon assay of not less than 96 percent by infrared spectrum at 8.62 microns.

(c) *Sponsor.* See No. 011492 in § 510.600(c) of this chapter.

(d) *Special considerations.* Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(e) *Related tolerances.* See § 556.310 of this chapter.

(f) *Conditions of use.* It is used as a drench as follows:

(1) *Cattle*—(i) *Amount.* 141.5 grams per packet.

(ii) *Indications for use.* Control of gastrointestinal roundworms of the genera *Haemonchus, Ostertagia, Trichostrongylus,* and *Cooperia.*

(iii) *Limitations.* (a) Dissolve each packet in 32 fluid ounces of water and administer as follows:

Weight of animal (pounds):	Dose (fluid ounces)
Up to 100	½
100 to 150	¾
150 to 200	1
200 to 300	1½
300 to 450	2
450 to 700	3
700 to 1,000	4
1,000 to 1,200	5
Over 1,200	6

(b) Do not treat within 1 week of slaughter; do not treat dairy animals of breeding age; animals should be retreated in 3 to 4 weeks.

(2) *Sheep and goats*—(i) *Amount.* 44.9 grams per packet.

(a) *Indications for use.* Control of gastrointestinal roundworms of the genera *Haemonchus, Ostertagia,* and *Cooperia* in sheep and *Haemonchus* in goats.

(b) *Limitations.* (1) Dissolve each packet in 32 ounces of water and administer as follows:

Weight of animal (pounds):	Dose (fluid ounces)
Up to 50	½
50 to 90	1
90 to 150	1½
Over 150	1

(2) Do not treat within 1 week of slaughter; do not treat dairy goats of breeding age; heavily parasitized animals should be retreated in 3 weeks.

(ii) *Amount.* 141.5 grams per packet.

(a) *Indications for use.* Control of gastrointestinal roundworms of the genera *Haemonchus, Ostertagia,* and *Cooperia* in sheep and *Haemonchus* in goats.

(b) *Limitations.* (1) Dissolve each packet in 32 fluid ounces of water and administer as a drench as follows:

Weight of animal (pounds):	Dose (milliliter)
Up to 21	2.5
22 to 30	4
30 to 50	6
50 to 80	10
80 to 120	15
Over 120	20

(2) Do not treat within 1 week of slaughter; do not treat dairy goats of breeding age; animals should be retreated in 3 to 4 weeks.

§ 520.1120b Haloxon boluses.

(a) *Chemical name.* 3-Chloro-7-hydroxy - 4-methylcoumarin bis(2-chloroethyl) phosphate.

(b) *Specifications.* Each bolus contains 10.1 grams of haloxon.

(c) *Sponsor.* See No. 011492 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.310 of this chapter.

(e) *Conditions of use.* (1) Haloxon bolus is an anthelmintic used in cattle for the control of gastrointestinal round worms of the genera *Haemonchus, Ostertagia, Trichostrongylus* and *Cooperia.*

(2) It is administered as follows:

Weight of animal (pounds):	Dose (*bolus(s)*)
200 to 300	½
350 to 600	1
650 to 800	1½
850 to 1,200	2
Over 1,200	3

(3) For most effective results, re-treat animals in 3 to 4 weeks. If reinfection is likely to occur, additional re-treatments may be necessary.

(4) Do not use any drug, pesticide or other chemical having cholinesterase inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(5) Do not treat animals within one week of slaughter.

(6) Do not treat dairy animals of breeding age or older.

§ 520.1162 Ipronidazole hydrochloride soluble powder.

(a) *Chemical name.* 2-isopropyl-1-methyl-5-nitroimadazole hydrochloride.

(b) *Specifications.* Each gram of ipronidazole hydrochloride soluble powder contains the equivalent of 823 milligrams of ipronidazole.

(c) *Sponsor.* See No. 000004 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.340 of this chapter.

(e) *Special considerations.* Ipronidazole hydrochloride soluble powder may be used as provided for in this section in conjunction with 0.00625 percent ipronidazole in turkey feed as provided for in § 558.305 of this chapter.

(f) *Conditions of use.* (1) The drug is used for the treatment of blackhead (histomoniasis) in turkeys.

(2) The drug is added to drinking water in an amount to provide a concentration of 0.0125 percent ipronidazole.

(3) The drug is administered for a treatment period of 7 consecutive days.

(4) Withdraw 5 days before slaughter. Do not administer to turkeys producing eggs for food.

§ 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite oral.

(a) *Specifications.* Each tablet or each five milliliters of suspension of the drug contains: 100 milligrams of kanamycin as the sulfate (the kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by § 444.30 of this chapter), 0.033 milligram of aminopentamide hydrogen sulfate, 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgite.

(b) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is administered orally to dogs for the symptomatic relief of acute bacterial diarrhea caused by kanamycin-susceptible organisms.

(2) The drug is recommended for use at the rate of one tablet or one teaspoonful (5 milliliters) of suspension per 20 pounds of body weight every 8 hours. Animals weighing under 10 pounds should be given one-half the above amount every 8 hours. The initial dose should be twice the amount of a single dose. Maximum dosage should not exceed three times the recommended dose.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.1242 Levamisole hydrochloride oral dosage forms.

§ 520.1242a Levamisole hydrochloride drench and drinking water.

(a) *Chemical name.* (-)-2,3,5,6-Tetrahydro-6-phenylimidazo[2,1-*b*] thiazole monohydrochloride.

(b) *Specifications:* Assay of not less than 98 percent by nonaqueous titration with *0.1N* potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Sponsor.* (1) See No. 010042 in § 510.600(c) of this chapter for conditions of use provided for in paragraph (f) of this section.

(2) See No. 011716 in § 510.600(c) of this chapter for conditions of use provided for in paragraph (f)(2) of this section.

(d) [Reserved]

(e) *Related tolerances:* Section 556.350 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Cattle*—(i) *Amount.* 46.8 grams per packet.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagotomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Dissolve in water to provide 32 fluid ounces of drench solution and administer as a drench at ¼ ounce 0.365 gram) per 100 pounds of body weight as a single dose; or dissolve in water to provide 8.75 fluid ounces of concentrate solution and administer as a drench at 2 cubic centimeters (0.365 gram) per 100 pounds of body weight as a single oral dose by syringe; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; not for use in dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* 4.68 grams per packet.

(a) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia*), and lungworms (*Dictyocaulus*).

(b) *Limitations.* Dissolve in 1 gallon (128 fluid ounces) of water and administer as a single drench at 1 ounce (0.365 gram) per 100 pounds of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 72 hours of treatment; consult veterinarian before using in severely debilitated animals.

(ii) *Amount.* 11.7 grams per packet.

(a) *Indications for use.* Anthelmintic effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).

(b) *Limitations.* Dissolve in 1 quart (32 fluid ounces) of water and administer as a single drench at 1 ounce (0.365 gram) per 100 pounds of body weight or dissolve 1 packet in 10.9 fluid ounces of water and administer as a single drench at 1 cubic centimeter (0.036 gram) per 10 pounds of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 72 hours of treatment; consult veterinarian before using in severely debilitated animals.

(3) *Swine*—(i) *Amount.* 18.15 grams per bottle.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*).

(iii) *Limitations.* Dissolve in water to provide 500 cubic centimeters of concentrate solution, add 10 cubic centimeters (2 teaspoons) of this concentrate solution to each gallon of drinking water; allow one gallon of medicated water for each 100 pounds of body weight of pigs to be treated; no other source of water should be offered; pigs maintained under conditions of constant exposure to worms may require re-treatment within 4 to 5 weeks after the first treatment; do not administer within 72 hours of slaughter for food.

§ 520.1242b Levamisole hydrochloride tablet or oblet (bolus).

(a) *Chemical name.* (-)-2,3,5,6-Tetrahydro-6-phenylimidazo[2,1-*b*] thiazole monohydrochloride.

(b) *Specifications.* Assay of not less than 98 percent by nonaqueous titration with 0.1 *N* potassium isopropoxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Sponsor.* (1) See No. 010042 in § 510.600(c) of this chapter for conditions of use provided for in paragraph (f) of this section and § 520.1242a(f).

(2) See No. 011716 in § 510.600(c) of this chapter for conditions of use provided for in paragraph (f) of this section and § 520.1242a(f).

(d) [*Reserved*]

(e) *Related tolerances.* See § 556.350 of this chapter.

(f) *Conditions of use.* (1) It is used in an oblet for cattle as follows:

(i) *Amount.* 2.19 grams per oblet.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagotomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Administer as a single dose as follows: 250 to 450 pounds, ½ oblet; 450 to 750 pounds, 1 oblet; and 750 to 1,050 pounds, 1½ oblets; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; not for use in dairy animals of breeding age; consult veterinarian before using in severely debilitated animals.

(2) It is used in a tablet for sheep as follows:

(i) *Amount.* 0.184 gram per tablet.

(ii) *Indications for use.* Anthelmintic effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Administer one tablet for each 50 pounds of body weight; conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 72 hours of treatment; consult a veterinarian before using in severely debilitated animals.

§ 520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.

§ 520.1263a Lincomycin hydrochloride monohydrate tablets.

(a) *Specifications.* The lincomycin hydrochloride monohydrate meets the specifications prescribed by § 453.30(a)(1) of this chapter. The quantity of antibiotic activity cited in this section refers to the equivalent weight of the base activity of the drug.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated in infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci.

(2) It is administered orally to dogs and cats at a dosage level of 10 mgs per pound of body weight every 12 hours, or 7 mgs per pound of body weight every 8 hours. Treatment may be continued for periods as long as 12 days if clinical judgment indicates.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1263b Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder.

(a) *Specifications.* The lincomycin hydrochloride monohydrate meets the specifications prescribed by § 453.30(a)(1) of this chapter. The spectinomycin sulfate tetrahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces spectabilis* or the same antibiotic substance produced by any other means. The quantity of total antibiotic activity cited in this section refers to the equivalent weight of the base activity of the drugs. Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate are present in the drug in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.600 and 556.360 of this chapter.

(d) *Conditions of use.* (1) It is administered, in the drinking water of chickens up to 7 days of age as an aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection), caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

(2) For aid in the control of these conditions it is administered in the drinking water at a level of 2 grams of antibiotic activity per gallon of water as the sole source of water for the first 5 to 7 days of life.

§ 520.1284 Sodium liothyronine tablets.

(a) *Specifications.* Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.

(b) *Sponsor.* See No. 011519 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated in cases of hypothyroidism in dogs.

(2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8 μg per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1320 Mebendazole oral.

(a) *Chemical name of mebendazole.* Methyl 5-benzoylbenzimindazole-2-carbamate.

(b) *Specifications.* The drug is an oral powder in which each gram contains 166.7 milligrams of mebendazole.

(c) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used in horses in the treatment of infections caused by large roundworms (*Parascaris equorum*), large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles (*Cyclicocyclus spp., Gyalocephalus spp., Poteriostumum spp., Trichonema spp., Triodontophorus spp.*), and pinworms (*oxyuris equi*), including many larval stages.

(2) The drug is administered at 1 gram of mebendazole per 250 pounds of body weight per dose.

(3) The drug is administered in either of the following ways:

(i) Sprinkling directly on the grain portion of the ration; or

(ii) By dissolving in 2–4 pints of water and administering by stomach tube.

(4) The drug is compatible with carbon disulfide, which can be used concurrently for bot control (*Gastrophilus spp.*). Routine cautions regarding the use of carbon disulfide must be observed.

(5) Do not administer to horses intended for use as food.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1341 Megestrol acetate tablets.

(a) *Specifications.* Each tablet contains 5 or 20 milligrams of megestrol acetate.

(b) *Sponsor.* No. 000085 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in female dogs for the postponement of estrus and the alleviation of false pregnancy.

(2) It is administered orally, intact, or crushed and mixed with food as follows:

(i) For the postponement of estrus by proestrus treatment, 1 milligram per pound of body weight per day for 8 days.

(ii) For the postponement of estrus by anestrus treatment, 0.25 milligram per pound of body weight per day for 32 days.

(iii) For alleviation of false pregnancy, 1 milligram per pound of body weight per day for 8 days.

(3) Full dosage regimen must be completed to produce the desired effect.

(4) Examination of vaginal smears is recommended to confirm detection of proestrus.

(5) Do not administer for more than two consecutive treatments.

(6) Once therapy is started, the animal should be confined for 3 to 8 days or until cessation of bleeding, since dogs in proestrus accept a male.

(7) Do not use prior to or during first estrus cycle.

(8) Do not use in pregnant animals.

(9) Do not use in the presence of a disease of the reproductive system or with mammary tumors.

(10) Should estrus occur within 30 days after cessation of treatment, mating should be prevented.

(11) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1362 Meglumine diatrizoate and sodium diatrizoate oral solution.

(a) *Specifications.* Meglumine diatrizoate oral solution is a water soluble radiopaque medium containing 66 percent meglumine diatrizoate and 10 percent sodium diatrizoate.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for radiography of the gastrointestinal tract in dogs and cats.

(2) It is administered orally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. It is administered rectally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1380 Methocarbamol tablets.

(a) *Chemical name.* 3-(O-Methoxyphenoxy)-1,2-propanediol 1-carbamate.

(b) *Specifications.* Each tablet contains 500 milligrams of methocarbamol.

(c) *Sponsor.* See No. 000031 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is administered to dogs and cats as an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

(2) Dosage is based upon severity of symptoms and response noted. The usual initial dose is 60 milligrams per pound of body weight in two or three equally divided doses followed by 30 to 60 milligrams per pound of body weight each following day, usually not to exceed 14 to 21 days.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.1422 Metoserpate hydrochloride.

(a) *Chemical name.* Methyl-o-methyl-18-epireserpate hydrochloride.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Related tolerances.* See § 556.410 of this chapter.

(d) *Conditions of use.* It is used in drinking water for replacement chickens as follows:

(1) *Amount.* 568.5 milligrams per gallon (0.015 percent).

(i) *Indications for use.* As a tranquilizer for flock treatment of chickens prior to handling.

(ii) *Limitations.* To be used one time as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

(2) *Amount.* 2 to 4 milligrams per 2.2 pounds of body weight.

(i) *Indications for use.* As an aid in control of hysteria.

(ii) *Limitations.* To be used as a treatment for replacement chickens up to 16 weeks of age; usual drinking water should be withheld prior to treatment to provide adequate consumption of medicated drinking water; the drug should be administered at a dosage level of 4 milligrams per 2.2 pounds of body weight followed by 2 treatments at 4-day intervals of 2 milligrams per 2.2 pounds of body weight; not for use in laying chickens; chickens slaughtered within 72 hours following treatment must not be used for food.

§ 520.1520 Niclosamide tablets.

(a) *Chemical name.* 2',5-Dichloro-4'-nitrosalicylanilide.

(b) *Specifications.* Niclosamide tablets contain niclosamide in a tablet intended for oral administration.

(c) *Sponsor.* See No. 000859 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for removal of tapeworms from dogs (*Dipylidium caninum, Taenia pisiformis, Taenia hydatigena*) and cats (*Taenia taeniaeformis*).

(2) The drug is administered orally at the rate of 500 milligrams of niclosamide per 7 pounds of body weight. An overnight fast is recommended. Treatment may be repeated should tapeworm proglottids reappear due to reinfection or underdosing.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1540 Nitrodan.

(a) *Chemical name.* 3-Methyl-5-[(p-nitrophenyl)azo]rhodanine.

(b) *Specifications.* The drug consists of a suitable and harmless food supplement containing 3 percent of nitrodan.

(c) *Sponsor.* See No. 011492 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) It is indicated for use in dogs as an aid in the continuous control of intestinal worm infections caused by the hookworms *Ancylostoma caninum* and *Uncinaria stenocephala* and by the common dog ascarid *Toxocara canis.*

(2) Administer, on a continuous basis, 1 level teaspoonful (approximately 2 grams) of food supplement (60 milligrams of nitrodan) daily for each 10 pounds of body weight.

§ 520.1660 Oxytetracycline.

§ 520.1660a Oxytetracycline and carbomycin in combination.

(a) *Specifications.* (1) Oxytetracycline: The antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(2) Carbomycin: The antibiotic substance produced by growth of *Streptomyces halstedii* or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 000069 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The quantities of oxytetracycline in paragraph (e) of this section refer to the activity of oxytetracycline hydrochloride and the quantities of carbomycin listed refer to the activitiy of an appropriate standard.

(d) *Related tolerances.* See §§ 556.110 and 556.500 of this chapter.

(e) *Conditions of use.* It is used as oxytetracycline hydrochloride plus carbomycin base in drinking water of chickens as follows:

(1) *Amount.* 1.0 gram of oxytetracycline and 1.0 gram carbomycin per gallon.

(2) *Indications for use.* As an aid in the prevention and treatment of complicated chronic respiratory disease (air-sac infection) caused by *Mycoplasma gallisepticum* and secondary bacterial organisms associated with chronic respiratory disease such as *E. coli.*

(3) *Limitations.* Administer for not more than 5 days; not for use in chickens producing eggs for human consumption; withdraw 24 hours before slaughter.

§ 520.1660b Oxytetracycline hydrochloride capsules.

(a) *Specifications.* The drug is in capsule form with each capsule containing 125 or 250 milligrams of oxytetracycline hydrochloride. Oxytetracycline is the antibiotic substance produced by growth of *Streptomyces rimosus* or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 000069 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats for the treatment of bacterial pneumonia caused by *Brucella bronchiseptica,* tonsilitis caused by *Streptococcus hemolyticus,* bacterial enteritis caused by *Escherichia coli,* urinary tract infections caused by *Escherichia coli,* and wound infections caused by *Staphylococcus aureus.*

(2) The drug is administered orally to dogs and cats at a dosage level of 25–50 milligrams per pound of body weight per day in divided doses at 12-hour intervals. The drug can be used for continuation of compatible antibiotic therapy following parenteral oxytetracycline administration where rapidly attained, sustained antibiotic blood levels are required. The duration of treatment required to obtain favorable response will depend to some extent on the severity and degree of involvement and the susceptibility of the infectious agent. Clinical response to antibiotic therapy usually occurs within 48 to 72 hours. If improvement is not observed within that period, the diagnosis and course of treatment should be reconsidered. To assure adequate treatment, administration of the drug should continue for at least 48 hours following favorable clinical response.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1720 Phenylbutazone oral dosage forms.

§ 520.1720a Phenylbutazone tablets and boluses.

(a)(1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams or 1 gram of phenylbutazone per tablet and/or the drug is in a bolus containing 4 grams of phenylbutazone per bolus.

(2) *Sponsor.* See No. 017220 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the relief of inflammatory conditions associated with the musculoskeletal systems in dogs and horses.

(ii) It is administered to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily with a maximum dosage level of 800 milligrams per day regardless of body weight. It is used at a relatively high-dosage level for the first 48 hours and then reduced gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing desired clinical response. It is used in horses at a dosage level of 1 to 2 grams per 500 pounds of body weight but not to exceed 4 grams per animal daily with a relatively high dosage level given for the first 48 hours which is reduced gradually to a maintenance dosage level which is maintained at the lowest dosage level capable of producing the desired clinical response.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) Not for use in animals intended for food purposes.

(b) (1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams or 1 gram of phenylbutazone per tablet.

(2) *Sponsor.* See No. 011757 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the relief of inflammatory conditions associated with the musculoskeletal system in dogs and horses.

(ii) It is administered to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily with a maximum dosage level of 800 milligrams per day regardless of body weight. It is used at a relatively high dosage level for the first 48 hours and then reduced gradually to a maintenance dosage level with the lowest dosage maintained at a level capable of producing desired clinical response. It is used in horses at a dosage level of 1 to 2 grams per 500 pounds of body weight but not to exceed 4 grams per animal daily with a relatively high dosage level given for the first 48 hours which is reduced gradually to a maintenance dosage level which is maintained at the lowest dosage level capable of producing the desired clinical response.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) Not for use in animals intended for food purposes.

(c) (1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams or 200 milligrams of phenylbutazone.

(2) *Sponsor.* See No. 000010 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the relief of inflammatory conditions associated with the musculoskeletal system in dogs.

(ii) It is administered to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily with the maximum dosage level of 800 milligrams per day regardless of body weight. It is used at a relatively high dosage level for the first 48 hours and then reduced gradually to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) (1) *Specifications.* The drug is in tablet form with each tablet containing 1 gram of phenylbutazone.

(2) *Sponsor.* See No. 011398 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

(ii) It is administered orally to horses as a non-hormonal, antiinflammatory agent at a dosage level of 1 to 2 grams per 500 pounds of body weight daily but not to exceed 4 grams per animal daily.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) Not for use in horses intended for food.

(e) (1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams or 1 gram of phenylbutazone per tablet.

(2) *Sponsor.* See No. 000856 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used as an aid in relieving inflammation associated with musculoskeletal conditions such as arthritides (osteoarthritis) in the horse and dogs and intervertebral disc syndrome in dogs.

(ii) It is administered to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily with a maximum dosage level of 800 milligrams per day regardless of body weight. Dosage should be reduced as symptoms regress. It is used in horses at a dosage level of 2 to 4 grams per 1,000 pounds of body weight but not to exceed 4 grams per animal daily. The dosage should be gradually reduced to a maintenance dosage, the lowest dosage required to produce clinical response.

(iii) Not for use in horses intended for food.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(f) (1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams or 1 gram of phenylbutazone.

(2) *Sponsor.* See No. 000031 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used as an aid in the management of musculoskeletal conditions in dogs such as arthritides, osteoarthritis, and inflammation associated with intervertebral disc syndrome.

(ii) It is administered orally to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily with a maximum dosage level of 800 milligrams per day regardless of body weight. Dosage should be reduced as symptoms regress.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(g) (1) *Specifications.* The drug is in tablet form with each tablet containing 1 gram of phenylbutazone.

(2) *Sponsor.* See No. 000864 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the relief of inflammatory conditions associated with the musculoskeletal system in dogs and horses.

(ii) It is administered orally at the following dosage levels:

(*a*) To dogs at 20 milligrams per pound of body weight in three divided doses daily, not to exceed dosage level of 800 milligrams per day regardless of body weight.

(*b*) To horses at 1 to 2 grams per 500 pounds of body weight, not to exceed dosage level of 4 grams per day.

(c) Dosage should be reduced as symptoms regress.

(iii) Not to be used in horses intended for food.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(h) (1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams of phenylbutazone.

(2) *Sponsor.* See No. 011519 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the relief of inflammatory conditions associated with the musculoskeletal system in dogs.

(ii) It is administered orally to dogs at a dosage level of 20 milligrams per pound of body weight in three divided doses daily given at 8 hour intervals with a maximum dosage level of 800 milligrams per day regardless of body weight.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(i) (1) *Specifications.* The drug is in tablet form with each tablet containing 1 gram of phenylbutazone.

(2) *Sponsor.* See No. 000591 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

(ii) It is administered orally to horses at a dosage level of 1 to 2 grams per 500 pounds of body weight per day. The total daily dose should not exceed 4 grams per animal daily.

(iii) Not for use in horses intended for food.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(j) (1) *Specifications.* The drug is in tablet form with each tablet containing 100 milligrams of phenylbutazone.

(2) *Sponsor.* See No. 000591 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for the relief of inflammatory conditions associated with the musculoskeletal system in dogs.

(ii) It is administered orally to dogs at a dosage level of 20 milligrams per lb. of body weight in 3 divided doses daily. The total daily dose should not exceed

800 milligrams per animal. The drug is used at a relatively high dosage level for the first 48 hours and then gradually reduced to a maintenance dosage level capable of producing the desired clinical response.

(iii) Federal law restrict the drug to use by or on the order of a licensed veterinarian.

§ 520.1720b Phenylbutazone granules.

(a) *Specifications.* The drug is in granular form with each 27-gram package containing 8 grams of phenylbutazone.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered orally to horses at a rate of 1 to 2 grams per 500 pounds of body weight; dose is not to exceed 4 grams daily. A relatively high dose is used for the first 48 hours. The dose is then reduced gradually to a maintenance level and is maintained at the lowest level capable of producing the desired clinical response.

(3) Treated animals should not be slaughtered for food purposes.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1760 Phthalofyne tablets.

(a) *Specifications.* Phthalofyne tablets contain 456 milligrams, 912 milligrams, and 2.28 grams of phthalofyne.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the treatment of whipworm (*Trichuris vulpis*) infection in dogs.

(2) It is recommended that dogs be fasted 24 hours prior to a single dose. The drug is administered at a level of one tablet of 456 milligrams per 5 pounds of body weight, one tablet of 912 milligrams per 10 pounds of body weight or one tablet of 2.28 grams per 25 pounds of body weight. An alternative procedure of two doses each administered following light meals in morning and evening is recommended in obstinate cases. The same schedule, noted above, is used for each dose.

§ 520.1780 Piperacetazine tablets.

(a) *Specifications.* Each tablet contains 1 milligram of piperacetazine.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats as a tranquilizer, sedative, and antiemetic agent and for the symptomatic relief of pruritis.

(2) Method of administration:

(i) *Tranquilization.* It is administered initially at the recommended average dosage level of 0.5 milligram per 10 pounds of body weight (1 tablet for every 20 pounds) repeated at 6- to 12-hour intervals for tranquilizing effect. Subsequent doses and the intervals between them may be adjusted as indicated.

(ii) *Sedation.* When sedation is desired, the drug is administered at a dosage level of 1 milligram (1 tablet) per 5 to 10 pounds of body weight. The tablets may be used as supportive therapy following use of the drug in injectable form.

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) For use only by or on the order of a licensed veterinarian.

§ 520.1801 Piperazine adipate.

(a) *Specifications.* The drug contains 98.5 percent minimum piperazine adipate.

(b) *Sponsor.* See No. 011769 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered to dogs and cats for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and in horses for the removal of ascarids (*Parascaris equorum*), strongyles (*Strongylus vulgaris*), small strongyles, and pinworms (*Oxyuris equi*).

(2) Administer orally as a drench or in as much drinking water or feed as the animals will consume in one day at a dosage level of ½ oz. per 100 pounds of body weight to horses and at a dosage level of 1 gram per 18 pounds of body weight to dogs and cats.

(3) May be repeated at intervals of 3 weeks should reinfection occur.

(4) Do not use in horses intended for food.

§ 520.1802 Piperazine-carbon disulfide complex with phenothiazine.

(a) *Specifications.* Each fluid ounce of piperazine-carbon disulfide complex with phenothiazine contains 5 grams of piperazine-carbon disulfide complex and 0.83 gram of phenothiazine. The piperazine-carbon disulfide complex is composed of equimolar parts of piperazine and carbon disulfide so that 1 gram of piperazine-carbon disulfide complex contains 530 milligrams of piperazine and 470 milligrams of carbon disulfide.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus spp.*), small strongyles (*Cylicostome spp.*), large strongyles (*Strongylus spp.*), and pinworms (*Oxyuris equi*) from horses and ponies.

(2) It is administered by stomach tube or dose syringe at the rate of 1 fluid ounce per 100 pounds of body weight.

(3) Treatment of debilitated and anemic animals is contraindicated and animals obviously sick with infectious diseases or currently or recently affected with gastrointestinal disorders such as colic, enteritis, and diarrhea should not be treated.

(4) For use only by or on the order of licensed veterinarian.

§ 520.1803 Piperazine citrate capsules.

(a) *Specifications.* Piperazine citrate capsules contain piperazine citrate equivalent to 140 milligrams of piperazine base in each capsule.

(b) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*).

(2) The contents of 1 capsule should be mixed with the food of the animal for each 5 pounds, or fraction thereof of body weight, except dogs weighing over 25 pounds should be given the contents of 6 capsules. The drug should be mixed in ½ of the regular feeding and when the animal has finished eating the dosed food, the remainder of the food may be given. Dogs and cats may be wormed at 6 to 8 weeks of age. The first treatment should be repeated 10 days later. Reinfection may occur. Repeat treatment if indicated.

(3) Severely debilitated animals should not be wormed except on the advice of a veterinarian.

§ 520.1840 Poloxalene.

(a) *Chemical name.* Polyoxypropylene-polyoxyethylene glycol nonionic block polymer.

(b) *Specifications.* (1) Molecular weight range: 2,850 to 3,150.

(2) Hydroxyl number: 35.7 to 39.4.

(3) Cloud point (10 percent solution): 42° C.–46° C.

(4) Structural formula:

$$HO(CH_2\text{-}CH_2\text{-}O)_{(11-13)}(\underset{CH_3}{\underset{|}{CH}}\text{-}CH_2\text{-}O)_{(33-36)}(CH_2\text{-}CH_2\text{-}O)_{(11-13)}H$$

(c) *Sponsor.* (1) See No. 011519 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d)(1) of this section.

(2) See No. 000007 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d)(2) of this section.

(d) *Conditions of use.* (1) For treatment of legume (alfalfa, clover) bloat in cattle. Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

(2) For control of legume (alfalfa, clover) bloat in cattle. Administer, in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 oz. of block (1.5 grams poloxalene) per 100 lbs. of body weight per day.

§ 520.1900 Primidone tablets.

(a) *Specifications.* Primidone tablets contain primidone as the active ingredient.

(b) *Sponsor.* See No. 000046 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use in dogs for control of convulsions associated with true epilepsy, epileptiform seizures, virus encephalitis, distemper, and hardpad disease.

(2) The drug is administered at a dosage level of 250 milligrams of primidone for each 10 pounds of body weight per day. When convulsions are frequent, the daily dosage should be divided and given at intervals. The tablets may be administered directly to the dog or crumbled and sprinkled on food.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1920 Prochlorperazine, isopropamide sustained release capsules.

(a) *Specifications.* Prochlorperazine, isopropamide sustained release capsules contain either:

(1) 3.33 milligrams of prochlorperazine (as the dimaleate) and 1.67 milligrams of isopropamide (as the iodide), or

(2) 10 milligrams of prochlorperazine (as the dimaleate) and 5 milligrams of isopropamide (as the iodide).

(b) *Sponsor.* See No. 011519 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the treatment of dogs in which gastrointestinal disturbances are associated with emotional stress.

(2) (i) Capsules described in paragraph (a) (1) of this section are administered orally to dogs weighing from 4 to 15 pounds at the rate of 1 capsule twice daily. These capsules are administered orally to dogs weighing from 16 to 30 pounds at the rate of 1 or 2 capsules twice daily. For dogs weighing less than 4 pounds, administer orally an appropriate fraction of the contents of one of these capsules.

(ii) Capsules described in paragraph (a) (2) of this section are given to dogs weighing 30 pounds and over at the rate of 1 capsule twice daily.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.1962 Promazine hydrochloride.

(a) *Chemical name.* 10-[3-(Dimethylamino) propyl]phenothiazine monohydrochloride.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) [Reserved]

(e) *Conditions of use.* (1) The drug is used for quieting excitable, unruly, or intractable horses. It is administered at a dosage level of 0.45 to 0.9 milligrams of promazine hydrochloride per pound of body weight mixed with an amount of feed that will be readily consumed.

(2) Do not use in horses intended for food.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2002 Propiopromazine hydrochloride.

(a) *Chemical name.* 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazin-2-yl]-, monohydrochloride.

(b) *Specifications.* The drug is administered in a chewable tablet containing 10 or 20 milligrams of propiopromazine hydrochloride.

(c) *Sponsor.* See No. 013947 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs as a tranquilizer. It is used as an aid in handling difficult, excited, and unruly dogs, and in controlling excessive kennel barking car sickness, and severe dermatitis. It is also indicated for use in minor surgery and prior to routine examinations, laboratory procedures, and diagnostic procedures.

(2) It is administered at the rate of 0.5 to 2 milligrams of propiopromazine hydrochloride per pound of body weight once or twice daily depending upon the degree of tranquilization desired.

NOTE: Not for use with organophosphates and/or procaine hydrochloride, as phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Overdosage may produce significant depression.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.2022 Protokylol hydrochloride tablets.

(a) *Specifications.* The drug is in tablet form with each tablet containing 0.5 or 2 milligrams of protokylol hydrochloride.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats for the relief of bronchial spasm.

(2) It is administered three times a day (after feeding) at a level of 2 to 4 milligrams to dogs, 1 to 2 milligrams to cats, 0.5 to 1 milligram to puppies, and and 0.25 to 0.5 milligram to kittens.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2043 Pyrantel pamoate suspension.

(a) *Specifications.* Pyrantel pamoate suspension contains 50 milligrams of pyrantel base as pyrantel pamoate per milliliter.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses and ponies for the removal and control of infections from the following mature parasites:

(i) Large strongyles (*Strongylus vulgaris, Strongylus edentatus, Strongylus equinus*),

(ii) Small strongyles (*Trichonema sp., Triodontophorus*),

(iii) Pinworms (*Oxyuris*), and

(iv) Large roundworms (*Parascaris*).

(2) It is administered as a single dose at 3 milligrams of pyrantel base per pound of body weight mixed with the usual grain ration, or by stomach tube or dose syringe.

(3) It is recommended that severely debilitated animals not be treated with this drug.

(4) Not for use in horses and ponies to be slaughtered for food purposes.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.

(a) *Specifications.* (1) Pyrantel tartrate powder horse wormer contains 11.3 percent and swine wormer 10.6 percent pyrantel tartrate.

(2) Pyrantel tartrate pellets colt and horse wormer contains 1.25 percent pyrantel tartrate.

(b) *Sponsor.* (1) See No. 000069 in § 510.600(c) of this chapter for conditions of use provided for in paragraph (d) (1) and (2) of this section.

(2) See No. 017800 in § 510.600(c) of this chapter, for conditions of use provided for in paragraph (d) (3) of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Conditions of use.* It is used in: (1) Horses and ponies:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris, Strongylus edentatus, Strongylus equinus*), small strongyles (*Trichonema spp., Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted ration. The ration is administered as a single treatment as the sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

(iii) Fast pigs over night for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris, Strongylus edentatus, Strongylus equinus*), small strongyles (*Trichonema spp., Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(ii) It is administered as a single dose at 12.5 milligrams of pyrantel tartrate per 2.2 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug.

(iv) Warning: Do not use in horses or colts intended for food.

§ 520.2080 Ronnel.

(a) *Chemical name.* *O,O*-Dimethyl *O*-(2,4,5-trichlorophenyl) phosphorothioate.

(b) *Sponsor.* See No. 021930 in § 510.-600(c) of this chapter.

(c) *Related tolerances.* See 40 CFR 180.177.

(d) *Conditions of use.* Administer to beef cattle and nonlactating dairy animals as sole source of ronnel. Feed mineral block containing 5.5 percent of ronnel at the rate of 0.25 pound per 100 pounds of animal weight per month for not less than 75 days. Withdraw from dairy animals 10 days before calving. If dairy cows or heifers freshen during medication, or if medication has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment. Withdraw 10 days prior to slaughter. Labeling shall also include a warning that ronnel is a cholinesterase inhibitor. Do not use this product simultaneously or within a few days before or after exposure to cholinesterase inhibiting drugs, pesticides, or chemicals.

§ 520.2100 Selenium, vitamin E capsules.

(a) *Specifications.* The capsules contain 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium) and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to .25 milligram of selenium and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate.)

(b) *Sponsor.* See No. 000845 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

(2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2122 Spectinomycin dihydrochloride oral solution.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. The drug is packaged as an aqueous solution containing 50 milligrams of spectinomycin activity per milliliter.

(b) *Sponsors.* (1) See No. 043731 in § 510.600(c) of this chapter.

(2) See No. 013947 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.

(2) It is administered orally at the rate of 50 milligrams per 10 pounds body weight twice daily for 3 to 5 days.

(3) Do not administer to pigs over 15 pounds body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

§ 520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.

§ 520.2123a Spectinomycin dihydrochloride pentahydrate tablets.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 043731 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs in the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(2) The drug is administered orally to provide 10 milligrams per pound of body weight twice daily. The tablets may be placed in the animal's mouth or crushed and administered in milk or in the feed. Dosage may be continued for 4 consecutive days. Should no improvement be observed, discontinue drug and redetermine diagnosis.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 043731 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Related tolerances.* See § 556.600 of this chapter.

(e) *Conditions of use.* (1) It is administered in the drinking water of growing chickens at 2 grams of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination It is administered as an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO). Do not administer to laying chickens. Do not administer within 5 days of slaughter.

(2) It is administered in the drinking water of floor-raised broiler chickens at 0.5 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination. It is administered for increased rate of weight gain and improved feed efficiency. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

(3) It is administered in drinking water of broiler chickens at 1 gram of spectinomycin per gallon of water as the only source of drinking water for the first 3 to 5 days of life as an aid in controlling infectious synovitis due to *Mycoplasma synoviae*. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

§ 520.2160 Styrylpyridinium, diethylcarbamazine tablets.

(a) *Chemical names.* Styrylpyridinium: 2-(*p*-chlorostyryl)-1-methylpyridinium. Diethylcarbamazine: *N,N*-diethyl-4-methyl-1-piperazinecarboxamide.

(b) *Specifications.* Each tablet contains 50 milligrams of styrylpyridinium chloride and 60 milligrams of diethylcarbamazine citrate.

(c) *Sponsor.* See No. 010042 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) Use in dogs as an aid in the control of large roundworms (*Toxocara canis*) and hookworms (*Ancylostoma caninum*), and in the prevention of heartworm disease (*Dirofilaria immitis*).

(2) Administer orally at a rate of one tablet per 20 pounds of body weight per day.

(3) Do not use in dogs that may be infected with heartworms.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2162 Styrylpyridinium chloride, diethylcarbamazine (as base).

(a) *Chemical name.* (1) For styrylpyridinium chloride: 2-(*p*-Chlorostyryl-1-methylpyridinium chloride.

(2) For diethylcarbamazine: *N,N*-Diethyl-4-methyl-1-piperazinecarboxamide.

(b) *Specifications.* Each cubic centimeter of the drug contains 50 milligrams

of styrylpyridinium chloride and 30 milligrams of diethylcarbamazine (as base).

(c) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is used or intended for use by oral administration to dogs for the control of hookworms (*Ancylostoma caninum*) and roundworms (*Toxocara canis*) and as an aid in the prevention of heartworm disease (*Dirofilaria immitis*).

(2) During period of exposure to heartworm, hookworm, and/or roundworm infection, administer the drug in food daily at 1 cubic centimeter per 20 pounds of body weight. Periodic examinations for hookworms, large roundworms, and heartworms should be made to assure that medication is given properly. Dogs with established heartworm infections should not be treated with the drug until they have been converted to a negative status. Administration to heartworm infected dogs may cause adverse reactions due to pulmonary occlusion.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.2184 Sodium sulfachloropyrazine monohydrate.

(a) *Chemical name.* 2-Sulfamido-6-chloroxyrazine, sodium.

(b) *Sponsor.* See Nos. 010042 and 000003 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.625 of this chapter.

(d) *Conditions of use.* It is used in the drinking water of broilers, breeder flocks, and replacement chickens as follows:

(1) *Amount.* 0.03 percent.

(2) *Indications for use.* Treatment of coccidiosis.

(3) *Limitations.* Administer in drinking water for 3 days as sole source of drinking water and sulfonamide medication; withdraw 4 days prior to slaughter; not to be administered to chickens producing eggs for human consumption.

§ 520.2200 Sulfachlorpyridazine oral dosage forms.

§ 520.2200a Sulfachlorpyridazine, bolus.

(a) *Chemical name.* *N'*-6-Chloro-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range: 190° C. to 191° C.

(c) *Sponsor.* See No. 000003 in § 510.600 (c) of this chapter.

(d) *Related tolerances.* See § 556.630 of this chapter.

(e) *Conditions of use.* It is used in calves as follows:

(1) *Amount.* 30 to 45 milligrams per pound body weight per day.

(2) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(3) *Limitations.* Administer in a bolus containing 2 grams of sulfachlorpyridazine for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 7 days after the last treatment.

§ 520.2200b Sulfachlorpyridazine medicated milk and drinking water.

(a) *Chemical name.* N'-(6-Chloro-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range: 190° C. to 191°C.

(c) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.630 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Calves*—(i) *Amount.* 30 to 45 milligrams per pound body weight per day.

(ii) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Administer as the sodium salt of sulfachlorpyridazine in milk or milk-replacer formulations for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 7 days after the last treatment.

(2) *Swine*—(i) *Amount.* 20 to 35 milligrams per pound body weight per day.

(a) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(b) *Limitations.* Administer as the sodium salt of sulfachlorpyridazine in drinking water for 1 to 5 days; for individual treatment, administer orally in divided doses twice daily; treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

(ii) *Amount.* 20 to 35 milligrams per pound body weight per day.

(a) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(b) *Limitations.* Administer individually in an oral suspension containing 50 milligrams of sulfachlorpyridazine per milliliter in divided doses twice daily for 1 to 5 days; treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

§ 520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine drinking water and drench.

(a) *Chemical name.* N'-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Sponsors.* Firms identified by numbers in § 510.600(c) of this chapter have been granted approvals for specific conditions of use as indicated in paragraph (e) of this section as follows:

(1) To 000004: approval for use as in paragraph (e) (1), (2) and (3).

(2) [Reserved]

(3) [Reserved]

(4) [Reserved]

(c) *Special considerations.* Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders.

(d) *Related tolerances.* See § 556.640 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Broiler and replacement chickens only.* (i) *Amount.* 1.875 (0.05 percent) grams per gallon.

(ii) *Indications for use.* Treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) *Limitations.* Administer for 6 consecutive days; do not administer to chickens over 16 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(2) *Meat-producing turkeys only.* (i) *Amount.* 0.938 (0.025 percent) grams per gallon.

(ii) *Indications for use.* Treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) *Limitations.* Administer for 6 consecutive days; do not administer to turkeys over 24 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(3) *Dairy calves, dairy heifers, and beef cattle only.* (i) *Amount.* 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon.

(ii) *Indications for use.* Treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

(iii) Administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days; in drinking water or drench; available as a sulfadimethoxine soluble powder or a 12.5 percent sulfadimethoxine sodium solution (3.75 grams sulfadimethoxine per fluid ounce); if no improvement within 2 to 3 days, reevaluate diagnosis; do not treat beyond 5 days; withdraw 7 days before slaughter.

§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) *Chemical name.* N'-(2-6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Sponsors.* Firms identified by numbers in § 510.600(c) of this chapter have been granted approvals for specific conditions of use as indicated in paragraph (e) of this section as follows:

(1) To 000004: approval for use as in paragraph (e) (1) of this section.

(2) To 011825: approval for use as in paragraph (e) (2) (i) of this section.

(3) To 011716: approval for use as in paragraph (e) (2) (ii) of this section.

(4) To 000859: approval for use as in paragraph (e) (2) (i) of this section, for dogs only.

(c) [Reserved]

(d) *Related tolerances.* See § 556.640 of this chapter.

(e) It is used as follows:

(1) *Cattle*—(i) *Amount.* 1.25 to 2.5 grams per 100 pounds body weight.

(ii) *Indications for use.* Treatment of foot rot, bacterial pneumonia, shipping fever, and calf diphtheria.

(iii) *Limitations.* Administer 2.5 grams per 100 pounds body weight for

1 day followed by 1.25 grams per 100 pounds body weight per day; treat from 4 to 5 days; do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food.

(2) *Dogs and cats*—(i) *Amount.* 1.25 to 2.5 grams per 100 pounds of body weight.

(*a*) *Indications for use.* For treatment of respiratory infections, genitourinary tract infections, enteritis and soft tissue infections in dogs and cats when caused by streptococci, staphylococci, escherichia, salmonella or shigella organisms sensitive to sulfadimethoxine and for the treatment of canine bacterial enteritis associated with coccidiosis and canine salmonellosis.

(*b*) *Limitations.* Administer 2.5 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight daily thereafter for 3 to 5 days; in most cases 3 to 5 days of treatment is adequate; however, treatment should be continued until the animal is without clinical signs for 48 hours; animals must maintain adequate water intake during treatment; for use by or on the order of a licensed veterinarian.

(ii) *Amount.* 12.5 to 25 milligrams per pound body weight.

(*a*) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.

(*b*) *Limitations.* Administer 25 milligrams per pound body weight for first day followed by 12.5 milligrams per pound body weight per day until the animal is free of symptoms for 48 hours, for use only by or on the order of a licensed veterinarian.

§ 520.2220c Sulfadimethoxine oral suspension.

(a) *Chemical name.* *N'*-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Specifications.* Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.

(c) *Sponsor.* See Nos. 000004 and 011716 in § 510.600(c) of this chapter.

(1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

(2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during the treatment period.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

(a) *Chemical name.* *N'*-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range of 180° C. to 186°C.

(c) *Sponsor.* See No. 010042 in § 510.600 (c) of this chapter.

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Swine*—(i) *Amount.* 1.9 to 3.8 grams per gallon (0.05 percent to 0.1 percent).

(ii) *Indications for use.* Treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella cholerasuis* infection.

(iii) *Limitations.* Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days as sodium sulfaethoxypyridazine; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 2.5 grams per gallon (0.066 percent).

(ii) *Indications for use.* Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food.

§ 520.2240b Sulfaethoxypyridazine tablets.

(a) *Chemical name.* N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range of 180° C. to 186° C.

(c) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used for cattle as follows:

(1) *Amount.* 2.5 or 15 grams per tablet.

(i) *Indications for use.* Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(ii) *Limitations.* Administer 25 milligrams per pound of animal weight per day for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use only by or on the order of a licensed veterinarian.

(2) *Amount.* 15-gram controlled release tablets.

(i) *Indications for use.* Treatment of foot rot and respiratory infections (shipping fever and pneumonia) caused by sulfonamide-susceptible pathogens (*E. coli*, streptococci, staphylococci, *Sphaerophorus necrophorus* and Gram-negative rods including *Pasteurella*); for use prophylactically in cattle during periods of stress for reducing losses due to sulfonamide sensitive disease conditions.

(ii) *Limitations.* Administer 100 milligrams per pound of body weight; do not treat within 16 days of slaughter; as sole source of sulfonamide; not for use in lactating dairy cows; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2260 Sulfamethazine tablets and bolus.

(a) *Chemical name.* *N'*-(4,6-Dimethyl-2-pyrimidinyl) sulfanilamide.

(b) *Sponsor.* See No. 011519 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use.* It is used for oral administration to nonlactating cattle as follows:

(1) *Amount.* 22.5 grams per bolus.

(2) *Indications for use.* For treatment of infectious disease in which the causative organism is sensitive to sulfamethazine; for the prevention of bacterial infections associated with hemorrhagic septicemia (shipping fever complex).

(3) *Limitations.* One bolus per each 185 to 200 pounds of body weight; do not slaughter for food within 21 days of treatment; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2280 Sulfamethizole and methenamine mandelate tablets.

(a) *Specifications.* Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

(b) *Sponsor.* See No. 000046 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the treatment of urinary tract infections in dogs and cats such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. It is also used as an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the bladder, in ureterostomies, and in instrumentation of the urethra and bladder.

(2) It is administered at a dosage level of one tablet for each 20 pounds of body weight given three times per day. The drug should be given until all signs are alleviated. To reduce the possibility of a relapse, it is suggested that therapy be continued for a further period of a week to 10 days.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2300 Sulfamethoxypyridazine tablets.

(a) *Chemical name.* N¹-(6-methoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Each tablet contains 250 or 500 milligrams of the drug.

(c) *Sponsor.* See No. 000071 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats for sulfa-susceptible gram-positive and gram-negative bacterial infections.

(2) It is administered orally at the rate of 20 to 30 milligrams per pound of body weight daily. Doses exceeding these amounts are not recommended. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during prolonged administration. Discontinue drug if toxic reactions occur. Not for use in animals which are raised for food production.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.2301 Acetyl sulfamethoxypyridazine oral suspension.

(a) *Chemical name.* N^1-acetyl-N^1-(6-methoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Each 5 milliliters of suspension contains 250 milligrams of sulfamethoxypyridazine.

(c) *Sponsor.* See No. 000071 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats for sulfa-susceptible gram-positive and gram-negative bacterial infections.

(2) It is administered orally at the rate of 20 to 30 milligrams per pound of body weight daily. Doses exceeding these amounts are not recommended. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during prolonged administration. Discontinue drug if toxic reactions occur. Not for use in animals which are raised for food production.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.2320 Sulfanitran and aklomide in combination.

(a) *Chemical names.* (1) Sulfanitran: Acetyl-(*p*-nitrophenyl)-sulfanilamide.

(2) Aklomide: 2-Chloro-4-nitrobenzamide.

(b) *Specifications.* (1) Sulfanitran conforms to the following specifications:

(i) Melting point range: 260° C. to 261° C.

(ii) Assay (by sodium nitrite titration): 97 to 100.5 percent.

(iii) Moisture (method No. 5.96 "Official Methods of Analysis of the Association of Official Agricultural Chemists,"[1] 8th edition, 1955, p. 64): Not more than 2.0 percent.

(iv) Molecular weight: 335.34.

(v) Soluble in 0.1*N* sodium hydroxide, reprecipitating unchanged on acidification.

(2) Aklomide conforms to the following specifications:

(i) Minimum melting point: 170° C.

(ii) Moisture content: Not to exceed 1.0 percent.

(iii) Purity: Not less than 98 percent on an anhydrous basis.

(c) *Sponsor.* See No. 017210 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See §§ 556.30 and 556.680 of this chapter.

[1] Copies may be obtained: Association of official analytical chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

(e) *Conditions of use.* It is used in the drinking water of chickens as follows:

(1) *Amount.* 374–747 milligrams of sulfanitran with 477–954 milligrams of aklomide.

(2) *Indications for use.* As an aid in the treatment of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(3) *Limitations.* Administer for 2 days at 747 milligrams of sulfanitran per gallon and 954 milligrams of aklomide per gallon, followed by 5 days at 374 milligrams of sulfanitran per gallon and 477 milligrams of aklomide per gallon; do not treat birds over 6 weeks of age; do not administer within 5 days of slaughter; not for laying chickens.

§ 520.2362 Thenium closylate tablets.

(a) *Chemical name.* (N,N-Dimethyl-N-2-phenoxyethyl-N-2' - thenylammonium)-p-chlorobenzenesulfonate.

(b) *Specifications.*—Thenium closylate tablets contain thenium closylate equivalent to 500 milligrams thenium as base in each tablet.

(c) *Sponsor.* See No. 011492 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The Tablets are administered orally to dogs as a single day treatment of canine ancylostomiasis by the removal from the intestines of the adult forms of the species *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms). Dogs weighing 10 pounds and over are administered 1 tablet as a single dose. Dogs weighing 5 to 10 pounds are administered one-half tablet twice during a single day. All dosages are given for 1 day only. The treatment should be repeated after 2 or 3 weeks.

(2) Suckling puppies or recently weaned puppies weighing less than 5 pounds should not be treated with the drug. Animals that are severely infected, exhibiting evidence of intestinal hemorrhage, debilitation, and anemia, should be given supportive treatment.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2380 Thiabendazole oral dosage forms.

§ 520.2380a Thiabendazole top dressing and mineral protein feed block.

(a) *Chemical name.* 2-(4-Thiazolyl)-benzimidazole.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* (1) See No. 017800 in § 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (e)(1) of this section.

(2) See No. 000006 in § 510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e) of this section and §§ 520.2380b and 520.2380c.

(3) See No. 021930 in § 510.600(c) of this chapter for the sponsor of the usage provided for by paragraph (e)(2) of this section.

(d) *Related tolerances.* See § 556.730 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Route of administration.* In feed, as a top dressing.

(a) *Amount.* 2 grams per 100 pounds of body weight.

(b) *Indications for use.* For control of large strongyles, small strongyles, pinworms, and threadworms (including members of the genera *Strongylus, Cyathostomum, Cylicobrachytus,* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum, Oxyuris,* and *Strongyloides*).

(c) *Limitations.* Add to the usual feed of horses mixed into that amount of the feed normally consumed at one feeding. Warning: Not for use in horses intended for food.

(ii) *Route of administration.* In feed.

(a) *Amount.* 2 grams per 100 pounds of body weight.

(b) *Indications for use.* For control of large and small strongyles, *Strongyloides,* and pinworms of the genera *Strongylus, Cyathostomum, Cylicobrachytus* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum, Oxyuris, Strongyloides,* and *Parascaris.*

(c) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(b) *Amount.* 4 grams per 100 pounds of body weight.

(b) *Indications for use.* For control of ascarids of the genera *Strongylus, Cyathostomum, Cylicobrachytus* and related genera, *Craterostomum, Oesophagodontus, Poteriostomum, Oxyuris, Strongyloides,* and *Parascaris.*

(c) *Limitations.* Administer in a single dosage mixed with the normal grain ration given at one feeding. Warning: Not for use in horses intended for food.

(2) *Cattle*—(i) *Route of administration.* In feed block.

(ii) *Amount.* 3.3 percent consumed at the recommended level of 0.11 pound per 100 pounds of body weight per day.

(iii) *Indications for use.* For control of infections of gastrointestinal roundworms (members of the genera *Trichostrongylus, Haemonchus, Ostertagia* and *Cooperia* species).

(iv) *Limitations.* Administer to cattle on pasture or range accustomed to mineral protein block feeding for 3 days when 3.3 percent is consumed at the recommended level of 0.11 pound per 100 pounds of body weight per day. Milk taken from animals during treatment and within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed by a veterinarian or diagnostic laboratory prior to worming. Animals maintained under conditions of constant worm exposure may require re-treatment within 2 to 3 weeks. Animals that are severely parasitized, sick, or off feed should be isolated and a veterinarian consulted for advice concerning treatment.

§ 520.2380b Thiabendazole drench or oral paste.

(a) *Chemical name.* 2-(4-Thiazolyl) benzimidazole.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* (1) See No. 017800 in § 510.600(c) of this chapter for the sponsor of the usage provided by § 520.2380a (e) (1).

(2) See No. 000006 in § 510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e) of this section and § 520.2380c.

(3) See No. 021930 in § 510.600(c) of this chapter for the sponsor of the usage provided for by § 520.2380a(e) (2).

(d) *Related tolerances.* See § 556.730 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Horses.* As a single liquid oral dose, as a drench or administered by stomach tube.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(a) *Indications for use.* Control of infections with *Strongylus spp., Cyathostomum spp., Cylicobrachytus spp.,* and related genera; *Craterostomum spp., Oesophagodontus spp., Poteriostomum spp., Oxyuris spp.,* and *Strongyloides spp.*

(b) *Limitations.* Not for use in horses to be slaughtered for food purposes; for use only by or on the order of a licensed veterinarian.

(ii) *Amount.* 4 grams per 100 pounds of body weight.

(a) *Indications for use.* Control of infections of gastrointestinal ascarids (genera *Parascaris spp.*).

(b) *Limitations.* Not for use in horses to be slaughtered for food purposes; for use only by or on the order of a licensed veterinarian.

(2) *Pigs.* As an oral paste.

(i) *Amount.* 200 milligrams for each 5 to 7 pounds of body weight per dose.

(ii) *Indications for use.* For control of infections with *Strongyloides ransomi.* These infections are commonly found in Southeastern United States.

(iii) *Limitations.* Administer to baby pigs (1 to 8 weeks of age). Treatment may be repeated in 5 to 7 days if necessary. Before treatment, obtain an accurate diagnosis from a veterinarian or diagnostic laboratory. Do not treat within 30 days of slaughter.

(3) *Cattle.* Orally in paste form using a dosing gun designed for the product.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(a) *Indications for use.* For *Trichostrongylus spp., Haemonchus spp., Neamtodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum.*

(b) *Limitations.* For most effective results, severely parasitized animals or those constantly exposed to helminth infection should be re-treated every 2 to 3 weeks. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed prior to worming.

(ii) *Amount.* 5 grams per 100 pounds of body weight.

(a) *Indications for use.* For *Cooperia spp.* or severe infections with the other species.

(b) *Limitations.* For most effective results, severely parasitized animals or these constantly exposed to helminth infection should be re-treated every 2 to 3 weeks. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter. For a satisfactory diagnosis, a microscopic fecal examination should be performed prior to worming.

§ 520.2380c Thiabendazole bolus.

(a) *Chemical name.* 2-(4-Thiazolyl) benzimidazole.

(b) *Specifications.* Conforms to N.F. XII.

(c) *Sponsor.* (1) See No. 017800 in § 510.600(c) of this chapter for the sponsor of the usage provided for by § 520.2380a(e)(1).

(2) See No. 000006 in § 510.600(c) of this chapter for the sponsor of the usages provided for by paragraph (e) of this section and §§ 520.2380a and 520.2380b.

(3) See No. 021930 in § 510.600(c) of this chapter for the sponsor of the usage provided for by § 520.2380a(e)(2).

(d) *Related tolerances.* See § 556.730 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Cattle.* In a bolus or in liquid form.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(a) *Indications for use.* Control of infections of gastrointestinal roundworms (genera *Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum*).

(b) *Limitations.* As a single oral dose; as a drench or bolus; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 pounds of body weight.

(a) *Indications for use.* Control of severe infections of gastrointestinal roundworms (genera *Trichostrongylus spp., Haemonchus spp., Nematodirus spp., Ostertagia spp.,* and *Oesophagostomum radiatum*). Control of infections with *Cooperia spp.*

(b) *Limitations.* As a single oral dose; as a drench or bolus; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Sheep and goats.* In a bolus or in liquid form.

(i) *Amount.* 2 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms in sheep and goats (genera *Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp., and Oesophagostomum spp.*); also active from 3 hours to 3 days following treatment against ova and larvae passed by sheep (good activity against *T. colubriformis* and *axei, Ostertagia spp., Bunostomum spp., Nematodirus spp.,* and *Strongyloides spp.*; less effective against *Haemonchus* contortus and *Oesophagostomum spp.*)

(iii) *Limitations.* As a single oral dose; as a drench or bolus; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; in severe infections in sheep, treatment should be repeated in 2 to 3 weeks.

(3) *Goats.* In a bolus or in liquid form.

(i) *Amount.* 3 grams per 100 pounds of body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (genera *Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* As a single oral dose; as a drench or bolus; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food; treatment should be repeated in 2 to 3 weeks.

§ 520.2380d Thiabendazole, piperazine citrate suspension.

(a) *Specifications.* Each fluid ounce of suspension contains 2 grams of thiabendazole and 2.5 grams of piperazine (from piperazine citrate).

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is administered to horses by stomach tube or as a drench at the rate of 1 fluid ounce of suspension per 100 pounds of body weight for the control of large strongyles, small strongyles, pinworms, *Strongyloides* and ascarids (including members of the genera *Strongylus spp., Cyathostomum spp., Cylicobrachytus spp.* and related genera *Craterostomum spp., Oesophagodontus spp., Poteriostomum spp., Oxyuris spp., Strongyloides spp.,* and *Parascaris spp.*).

(2) Do not use in horses intended to be used for food purposes.

(3) For use by or on the order of a licensed veterinarian.

§ 520.2460 Ticarbodine oral dosage forms.

§ 520.2460a Ticarbodine tablets.

(a) *Specifications.* Ticarbodine tablets, veterinary contain 90, 225, or 900 milligrams of ticarbodine per tablet.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs for the removal of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).

(2) Dosage is administered at 45 milligrams of the drug per pound of body weight in a single dose. Dosage may be repeated in 21 days.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2460b Ticarbodine capsules.

(a) *Specifications.* Each capsule contains 90, 225, 450, or 900 milligrams of ticarbodine.

(b) *Sponsor.* See No. 000986 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs for removal of roundworms (*Toxocara canis*), hookworms (*Ancylostoma caninum and Uncinaria stenocephala*), and tapeworms (*Dipylidium caninum and Taenia pisiformis*).

(2) Dosage is administered orally as a single dose at 45 milligrams per lb. of body weight. Dosage may be repeated at 21-day intervals.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2480 Triamcinolone tablets.

(a) *Chemical name.* 9-Fluoro-11β,16α, 17,21 - tetrahydroxy - pregna - 1,4 - diene-3,20-dione.

(b) *Specifications.* Each tablet contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 010042 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is indicated for use in dogs and cats for its anti-inflammatory activity.

(2) The dosage range for dogs is 0.25 milligram to 2.0 milligrams per day for 7 days and the dosage range for cats is 0.25 milligram to 0.5 milligram per day for 7 days. Daily dosage may be given in two or more divided doses. Dosage must be adjusted to the response of the individual animal. Generally, initial dosages are at the higher range and when the response is satisfactory, the dosage is gradually reduced until a minimum adequate dose is obtained. Dosage may be repeated when necessary. Daily dosage may be given in two or more divided doses.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Side reactions such as weight loss, anorexia, diarrhea, polydypsia and polyuria may occur.

(4) For use only by or on the order of a licensed veterinarian.

§ 520.2481 Triamcinolone acetonide tablets.

(a) *Chemical name.* 9-Fluro-11β,16α, 17,21 - tetrahydroxypregna-1,4-diene - 3, 20-dione cyclic 16,17-acetal with acetone.

(b) *Specifications.* Each tablet contains either 0.5 milligram or 1.5 milligrams of the drug.

(c) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is indicated for use in dogs and cats for its anti-inflammatory activity.

(2) An initial daily dosage of 0.05 milligram per pound of body weight is usually sufficient to control symptoms, although up to 0.1 milligram per pound of body weight may be given daily if response to the smaller dose is inadequate. As soon as feasible, and in any case within 2 weeks, dosage should be reduced gradually to maintenance levels of 0.0125 to 0.025 milligram per pound of body weight per day. Therapy should be discontinued by a gradual reduction in dosage after the condition has been controlled for several days. Therapy may be initiated with a single dose of sterile triamcinolone acetonide suspension veterinary in which case the tablet dosage should be administered beginning 5 to 7 days after the injection or when symptoms reappear.

(3) For use only by or on the order of a licensed veterinarian.

§ 520.2520 Trichlorfon oral dosage forms.

§ 520.2520a Trichlorfon oral.

(a) *Chemical name.* Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(b) *Sponser.* See Nos. 017800, 017135, and 000859 in § 510.600(c) of this chapter.

(c) *Special considerations.* This drug is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Conditions of use.* (1) It is intended for use in horses for the removal of bots (*Gasterophilus spp.*), ascarids (*Parascaris equorum*), and pinworms (*Oxyuris equi*).

(2) Mix the drug, either dry or dissolved in water, in feed and administer at the rate of 4.5 grams of trichlorfon per 250 pounds of body weight. The drug is to be consumed at one feeding. Treatment should be repeated at 3- to 4-month intervals. Do not repeat treatment more frequently than every 30 days. Do not treat horses to be used for food. Do not treat sick or debilitated horses, colts under 4 months of age, mares in the last month of pregnancy, or animals other than horses. Do not administer intravenous anesthetics, especially muscle relaxants, for a period of 2 weeks after treatment.

§ 520.2520b Trichlorfon and atropine.

(a) *Chemical name.* (1) For trichlorfon: *O,O*-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate.

(2) For atropine: Atropine N.F.

(b) *Sponsor.* See No. 000856 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the treatment of *Syphacia obvelata* (pinworm) in laboratory mice.

(2) It is administered in distilled water as sole source of drinking water continuously for 7 to 14 days at 1.67 grams of trichlorfon and 7.7 milligrams of atropine per liter.

(3) Prepare fresh solution every 3 days. Do not use simultaneously with other drugs, insecticides, pesticides, or chemicals having cholinesterase activity, nor within 7 days before or after treatment with any other cholinesterase inhibitor.

(4) Restricted to use by or on the order of a licensed veterinarian.

§ 520.2560 Trifluomeprazine tablets.

(a) *Chemical name.* Phenothiazine, 10-[3-(dimethylamino) - 2 - methyl-propyl]-2-(trifluoromethyl), maleate.

(b) *Specifications.* Trifluomeprazine tablets, veterinary, contain 10 milligrams of trifluomeprazine in each tablet.

(c) *Sponsor.* See No. 011519 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs for tranquilization and chemical restraint at a dosage level of ¼ to 1 milligram per pound of body weight once or twice daily as required.

(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2582 Triflupromazine hydrochloride tablets.

(a) *Specifications.* Each tablet contains either 10 milligrams or 25 milligrams of triflupromazine hydrochloride.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

(2) The drug is administered orally to dogs and cats at a dosage level of 1 to 2 milligrams per pound of body weight daily; an initial dosage at the 2-milligrams level is suggested followed by daily doses at the 1-milligram level. Frequently, the drug may be withdrawn after 4 to 5 days, with drug effect continuing after withdrawal.

(3) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2604 Trimeprazine tartrate and prednisolone tablets.

(a) *Specifications.* Each tablet contains: trimeprazine tartrate, 5 milligrams; and prednisolone, 2 milligrams.

(b) *Sponsor.* See No. 011519 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered orally to dogs for the relief of itching regardless of cause; reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. It is also used in dogs as adjunctive therapy in various cough conditions including treatment of "kennel cough" or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory in-

fections and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

(2) The drug is administered orally at an initial dosage level of ½ tablet twice daily to dogs weighing up to 10 pounds, one tablet twice daily to dogs weighing 11 to 20 pounds, two tablets twice daily to dogs weighing 21 to 40 pounds, and three tablets twice daily to dogs weighing over 40 pounds. After 4 days, the dosage is reduced to approximately ½ the initial dosage or to an amount just sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.

(4) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2640 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use.* It is used in drinking water of animals as follows:

(1) *Chickens*—(i) *Amount.* 2 grams per gallon.

(ii) *Indications for use.* Aid in the treatment of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin in broiler and replacement chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* sensitive to tylosin at time of vaccination or other stress in chickens. For the control of chronic respiratory disease (CRD) caused by *Mycoplasma synoviae* sensitive to tylosin in broiler chickens.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption; administer from 1 to 5 days as sole source of drinking water; treated chickens should consume enough medicated drinking water to provide 50 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; do not administer within 24 hours of slaughter; as tylosin tartrate.

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon.

(ii) *Indications for use.* Maintaining weight gains and feed efficiency in the presence of infectious sinusitis caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption; administer from 2 to 5 days as sole source of drinking water; treated turkeys should consume enough medicated drinking water to provide 60 milligrams of tylosin per pound of body weight per day; prepare a fresh solution every 3 days; when sinus swelling is present, inject the sinus with tylosin injectable simultaneously with the drinking water treatment; do not administer within 5 days of slaughter; as tylosin tartrate.

(3) *Swine*—(i) *Amount.* 0.25 gram per gallon.

(ii) *Indications for use.* For the control and treatment of swine dysentery (bloody scours) caused by pathogens sensitive to tylosin.

(iii) *Limitations.* As only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated: mix fresh solution daily; present as tylosin base; medication must be withheld from animals 48 hours prior to slaughter.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Sec.

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522.1940 Progesterone and estradiol benzoate in combination.
522.1962 Promazine hydrochloride injection.
522.2002 Propiopromazine hydrochloride injection.
522.2022 Protokylol hydrochloride injection.
522.2063 Pyrilamine maleate injection.
522.2100 Selenium, vitamin E injection.
522.2120 Spectinomycin injection.
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522.2240 Sulfaethoxypyridazine.
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522.2424 Sodium thiamylal for injection.
522.2444 Sodium thiopental implantation or injectable dosage forms.
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522.2680 Zeranol.

AUTHORITY: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).

§ 522.23 Acepromazine maleate injectable.

(a) *Chemical name.* [10-[3-(Dimethylamino) propyl] phenothiazin-2-yl-methyl ketone] maleate.

(b) *Specifications.* Each milliliter of the drug contains 10 milligrams of ace-

promazine maleate in double distilled water.

(c) *Sponsor.* See No. 000046 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used as a tranquilizer in dogs, cats, and horses.

(2) The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. It is administered to dogs at a dosage level of 0.25 to 0.5 milligram of acepromazine maleate per pound of body weight; to cats at a dosage level of 0.5 to 1.0 milligram of acepromazine maleate per pound of body weight; and to horses at a dosage level of 2.0 to 4.0 milligrams of acepromazine maleate per 100 pounds of body weight.

(3) Do not use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.*—Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.-600(c) of this chapter.

(c) *Conditions of use.*—(1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000015 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

Weight of animal in pounds:	*Dosage in milligrams*
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use dosage may be continued by oral administration of tablets.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.82 Aminopropazine fumarate sterile solution injection.

(a) *Specifications.* Each milliliter of aminopropazine fumarate sterile aqueous solution, veterinary, contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 017220 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis in cats and dogs and in colic spasms in horses.

(2) It is administered intramuscularly or intravenously to dogs and cats at a level of 1 to 2 milligrams per pound of body weight. It is administered intramuscularly or intravenously to horses at a level of 0.25 milligrams per pound of body weight. Dosage can be repeated every 12 hours, as indicated.

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.144 Arsenamide sodium aqueous injection.

(a) *Chemical name.* [[(*p*-Carbamoylphenyl)arsylene]dithio diacetic acid, sodium salt.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains 10.0 milligrams of arsenamide sodium.

(c) *Sponsor.* See Nos. 020112, 043731, and 000859 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis.*

(2) It is administered intravenously at 0.1 milliliter per pound of body weight (1.0 milliliter for every 10 pounds) twice a day for 2 days. For dogs in poor condition, particularly those with evidence of reduced liver function, a more conservative dosage schedule of 0.1 milliliter per pound of body weight daily for 15 days is recommended.

(3) Restricted to use only by or on the order of a licensed veterinarian.

§ 522.161 Betamethasone acetate and betamethasone disodium phosphate aqueous suspension.

(a) *Chemical names.* Betamethasone acetate: 9-α-Fluoro-16-β-methylprednisolone-21-acetate ($C_{24}H_{31}F\ O_6$). Betamethasone disodium phosphate: 9-α-Fluoro-16-β-methylprednisolone-21-disodium phosphate ($C_{22}H_{29}F\ Na_2O_8P$).

(b) *Specifications.* The drug is a sterile aqueous suspension and each cubic centimeter contains: 12 milligrams of betamethasone acetate (equivalent to 10.8 milligrams of betamethasone), 3.9 milligrams of betamethasone disodium phosphate (equivalent to 3 milligrams of betamethasone), 2 milligrams of dibasic sodium phopsphate, 5 milligrams of sodium chloride, 0.1 milligram of disodium EDTA, 0.5 milligram of polysorbate 80, 9 milligrams of benzyl alcohol, 5 milligrams of sodium carboxymethylcellulose, 1.8 milligrams of methylparaben, 0.2 milligram of propylparaben, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection q.s.

(c) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* It is used or intended for use by intra-articular injection of horses for the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpel and fetlock joints. Administer from 2.5 to 5 cubic centimeters per dose. Dose may be repeated when necessary depending upon the duration of relief obtained. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

§ 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.

(a) *Specifications.* Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension is a sterile aqueous suspension. Each milliliter of the suspension contains the equivalent of 5 milligrams of betamethasone as betamethasone dipropionate and 2 milligrams of betamethasone as betamethasone sodium phosphate.

(b) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an aid in the control of pruritus associated with dermatoses.

(2) It is administered by intramuscular injection at a dosage of 0.25 to 0.5 milliliter per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. In clinical studies one dosage of the drug brought relief for 1 to 6 weeks; the average period of relief was 3 weeks, and in many cases only one injection was required. Therefore, dosage may be repeated every 3 weeks or when symptoms recur. Total dosage should not exceed four injections.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.204 Boldenone undecylenate injection.

(a) *Specifications.* Each milliliter contains 25 or 50 milligrams of boldenone undecylenate in a sesame oil base.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use as an aid in treating debilitated horses following disease or overwork and overexertion when an improvement in weight, hair coat, or general physical condition is desired. The drug is given only as adjunctive therapy to other specific and supportive therapy for diseases, surgical cases, and trau-

matic injuries. Optimal results can be expected only when good management and feeding practices are followed.

(2) It is administered intramuscularly at a dosage level of 0.5 milligram per pound of body weight. Treatment may be repeated at 3-week intervals.

(3) For use in horses only. Do not administer to horses intended for use as food. The effectiveness of the drug in stallions and pregnant mares has not been established, nor has the drug been shown not to be teratogenic in pregnant mares; therefore, this drug should not be used in stallions and pregnant mares.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.281 Calcium disodium edetate injection.

(a) *Specifications.* Calcium disodium edetate injection contains 6.6-percent calcium disodium edetate in purified water.

(b) *Sponsor.* See No. 000859 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of acute lead poisoning in horses.

(2) It is administered by slow intravenous injection at the rate of 1 milliliter per 2 pounds of body weight daily. It is best administered in divided doses 2 to 3 times daily and continued for 3 to 5 days. If additional treatment is indicated, a 2-day rest period is recommended which may be followed by another 3- to 5-day period of therapy.

(3) Do not use in horses intended for food purposes.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.340 Cephaloridine injection.

(a) *Specifications.* Cephaloridine injection is sterile; each cubic centimeter contains 100 milligrams of cephaloridine activity.

(b) *Sponsor.* See No. 000986 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs for the treatment of bacterial infections of the respiratory, enteric, and urinary tracts and soft tissue due to cephaloridine-sensitive organisms and in cats for the treatment of bacterial infections of the respiratory and enteric tracts, urinary bladder and soft tissue due to cephaloridine-sensitive organisms.

(2) It is administered by intramuscular or subcutaneous injection at a dosage level of 5 milligrams per pound of body weight. It is administered twice a day. Treatment should not exceed 7 days without reassessment of diagnosis.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

(a) (1) *Specifications.* Chloral hydrate, pentobarbital, and magnesium sulfate injection contains 42.51 mg of chloral hydrate, 9.72 mg of pentobarbital, and 21.25 mg of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 44.34 percent propylene glycol, and 11.5 percent alcohol.

(2) *Sponsor.* See No. 017220 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for general anesthesia, and as a sedative-relaxant in cattle and horses.

(ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 ml/100 lb of body weight for general anesthesia. It is administered intravenously via gravity flow until the desired effect is produced as indicated by rate and depth of respirations, muscle tone, and corneal reflex. Due to the weight of the rumen contents, cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution contains 42.5 milligrams of chloral hydrate, 8.86 milligrams of pentobarbital, and 21.2 milligrams of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 33.8 percent propylene glycol, and 14.25 percent ethyl alcohol.

(2) *Sponsor.* See No. 000856 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for general anesthesia and as a sedative-relaxant in cattle and horses.

(ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 milliliters per 100 pounds of body weight for general anesthesia until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.443 Chlorpromazine hydrochloride injection.

(a) *Specifications.* Chlorpromazine hydrochloride injection contains 25 milligrams of chlorpromazine hydrochloride in each milliliter.

(b) *Sponsor.* See No. 011716 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is administered either intramuscularly or intravenously to dogs and cats as a tranquilizer, potentiator, and antiemetic with a sedating effect.

(2) It is administered to dogs and cats intravenously at a dosage level of 25 milligrams per 12.5 to 100 pounds body weight. It is administered intramuscularly at a dosage level of 25 milligrams per 8 pounds to 50 pounds body weight. It is administered one to four times daily depending upon size of dose and the needs of the patient.

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.480 Repository corticotropin injection.

(a) *Specifications.* The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.P. (I.U.) units per cubic centimeter.

(b) *Sponsor.* See No. 000845 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The drug should be refrigerated. With prolonged use supplement daily diet with potassium chloride at one gram for small animals and from 5 to 10 grams for large animals.

(d) *Conditions of use.* (1) It is used as an intramuscular or subcutaneous injection in cattle and small animals for stimulation of the adrenal cortex where there is a general deficiency of ACTH. It is also a therapeutic agent for primary bovine ketosis.

(2) It is administered to cattle initially at 200 to 600 units followed by a dose daily or every other day of 200 to 300 units and to small animals at one unit per pound of body weight to be repeated as indicated.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.540 Dexamethasone solution.

(a) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 2 mg of dexamethasone.

(b) *Sponsor.* See Nos. 000085 and 010271 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in dogs, cats, cattle, and horses.

(2) The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(i) Canine—0.25 to 1 mg.

(ii) Feline—0.125 to 0.5 mg.

(iii) Equine—2.5 to 5 mg.

(iv) Bovine—5 to 20 mg depending on the severity of the condition.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.564 Sodium diatrizoate and meglumine diatrizoate injection.

(a) *Specifications.* Sodium diatrizoate and meglumine diatrizoate injection contains 35-percent sodium diatrizoate and 34.3-percent meglumine diatrizoate in sterile aqueous solution.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs and cats for visualization in excretion urography, including

renal angiography, uretography cystography, and urethrography, aortography; angiocardiography peripheral arteriography and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography, and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter into the urethra to provide desired contrast delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catherer or intraventricular puncture. For cerebral angiography rapid injection of 3 to 10 milliliters via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 1.0 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be delineated. For sialography slowly inject 0.5 to 1.0 milliliter into the duct to be delineated. For delineation of fistulous tracts slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias inject 0.5 to 1.0 milliliter per pound of body weight directly into the peritoneal cavity.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.640 Diethylstilbestrol.

(a) *Chemical name.* 3,4-bis(*p*-Hydroxyphenyl)-3-hexene.

(b) *Sponsor.* See No. 011801 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.190 of this chapter.

(d) *Conditions of use.* It is used as a subcutaneous ear implantation for lambs as follows:

(1) *Amount per dose.* 3 milligrams.

(2) *Indications for use.* Increase rate of gain and improve feed efficiency.

(3) *Limitations.* Not for use in breeding animals; implantation should be made at the start of the feeding period or approximately 70 days before marketing; implant one 3-milligram pellet per animal.

§ 522.723 Diprenorphine hydrochloride injection.

(a) *Chemical name.* N-Cyclopropylmethyl)-6,7,8,14-tetrahydro - 7 - alpha-(1-hydroxy-1-methylethyl)-6,14 - endoethanonororipavine hydrochloride.

(b) *Specifications.* Each milliliter of diprenorphine hydrochloride injection, veterinary, contains 2 mg of diprenorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors.* See Nos. 010042 and 000693 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(2) It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(3) Do not use in animals to be used for food. Do not use in wild animals that might be used for food during the hunting season.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs and researchers.

§ 522.740 Disophenol injection.

(a) *Chemical name.* 2,6-Diiodo-4-nitrophenol.

(b) *Specifications.* The drug is sterile and contains 4.5 percent disophenol in polyethylene glycol 400 and distilled water.

(c) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used for the treatment of both dogs infested with hookworms (including *Ancylostoma caninum, A. braziliense* and *Uncinaria stenocephala*) and cats infested with the hookworm *A. tubaeforme.*

(2) The drug is administered subcutaneously at a dosage level of 4.5 milligrams per pound of body weight. A second injection may be indicated 14 to 21 days after the initial treatment.

(3) Do not repeat treatment in less than 14 days.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.784 Doxylamine succinate injection.

(a) *Specifications.* Each milliliter of the drug contains 11.36 mg of doxylamine succinate.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.800 Droperidol and fentanyl citrate injection.

(a) *Specifications.* Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) *Sponsor.* See No. 000045 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered as follows:

(i) For analgesia and tranquilization administer according to response desired, as follows:

(*a*) Intramuscularly at the rate of 1 cubic centimeter per 15 to 20 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight, or

(*b*) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight.

(ii) For general anesthesia administer according to response desired, as follows:

(*a*) Intramuscularly at the rate of 1 cubic centimeter per 40 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight, or

(*b*) Intravenously at the rate of 1 cubic centimeter per 25 to 60 pounds of body weight in conjunction with atropine sulfate administered at the rate of 0.02 milligram per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 milligrams per pound of body weight.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.842 Estradiol benzoate and testosterone propionate in combination.

(a) *Chemical names.* (1) Estradiol benzoate: 1,3,5(10)-Estratriene-3,17 beta-diol 3-benzoate.

(2) Testosterone propionate: 17beta-Hydroxyandrost-4-en-3-one propionate.

(b) *Sponsor.* See No. 000022 in § 510.600(c of this chapter.

(c) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

(d) *Conditions of use.* It is used for implantation in heifers as follows:

(1) *Amount.* 20 milligrams of estradiol benzoate and 200 milligrams of testosterone propionate per dose.

(2) *Indications for use.* Growth promotion and feed efficiency.

(3) *Limitations.* For heifers weighing between 400 and 800 pounds; for subcutaneous ear implantation, one dose per animal; not to be used within 60 days of slaughter; not for dairy heifers.

§ 522.844 Estradiol monopalmitate.

(a) *Chemical name.* 1,3,5(10)-Estratriene-3,17beta-diol 17-palmitate.

(b) *Sponsor.* See No. 027863 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.250 of this chapter.

(d) *Conditions of use.* It is used for injection into roasting chickens as follows:

(1) *Amount.* 10 milligrams per dose.

(2) *Indications for use.* Produce more uniform fat distribution; improve finish.

(3) *Limitations.* One dose per bird by injection under skin at base of skull at not less than 5 weeks of age; not to be used within 6 weeks of slaughter.

§ 522.863 Ethylisobutrazine hydrochloride injection.

(a) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 50 milligrams of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 017220 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs as a tranquilizer.

(2) It is administered intramuscularly at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight for profound tranquilization. It is administered intravenously at a dosage level of 1 to 2 milligrams of ethylisobutrazine hydrochloride per pound of body weight to effect.

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.883 Etorphine hydrochloride injection.

(a) *Chemical name.* 6,7,8,14-tetrahydro-alpha-methyl-alpha-propyl-6,14-endo-ethenooripavine-alpha-methanol hydrochloride.

(b) *Specifications.* Each milliliter of etorphine hydrochloride injection, veterinary, contains 1 mg of etorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors.* See Nos. 010042 and 000693 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used for the immobilization of wild and exotic animals.

(2) It is administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(3) Do not use the drug unless diprenorphine hydrochloride injection, veterinary, as provided for in § 522.723, is available for use in reversing the effects of etorphine hydrochloride injection, veterinary.

(4) Do not use in animals to be used for food. Do not use in wild and exotic animals that might be used for food during the hunting season.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

§ 522.940 Colloidal ferric oxide injection.

(a) *Specifications.* Each milliliter of the drug contains colloidal ferric oxide equivalent to 100 milligrams of iron stabilized with a low-viscosity dextrin and contains 0.5 percent phenol as a preservative.

(b) *Sponsor.* See Nos. 010042, 011519, and 012481 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in baby pigs as follows:

(1) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 1 milliliter of the drug to each animal at any time between 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(2) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of from 1 to 2 milliliters of the drug to each animal at any time between 5 to 28 days of age.

§ 522.960 Flumethasone suspension.

(a) *Chemical name.* 6α,9α-Difluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione.

(b) *Specifications.* Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of flumethasone, 20 milligrams of propylene glycol, 9 milligrams of benzyl alcohol (as preservative), 8 milligrams of sodium chloride, 0.02 milligram of polysorbate-80, 0.1 milligram of citric acid, and water for injection q.s.

(c) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpitis, and osselets.

(2) The drug is administered intra-articularly at a dosage level of 6 to 10 milligrams per injection. The dosage level is dependent upon the size of the involved synovial structure and the degree of severity of the condition under treatment. The dosage is limited to a single injection per week in any one synovial structure.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally and parenterally to animals during the last trimester of pregnancy may induce the first stage of parturition and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The drug is not to be used in horses intended for slaughter for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.961 Flumethasone acetate injection.

(a) *Chemical name.* 6-alpha,9-alpha-difluoro-16-alpha-methylprednisolone 21-acetate.

(b) *Specifications.* Flumethasone injection is sterile and contains per cubic centimeter: 2 milligrams of flumethasone acetate; 20 milligrams of propylene glycol; 9 milligrams of benzyl alcohol (as preservative); 8 milligrams of sodium chloride; 1 milligram of polysorbate 80; 0.1 milligram of citric acid; water for injection q.s.

(c) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(2) The drug is administered intramuscularly at the following recommended daily dosage:

Weight of animal in pounds	*Dosage in milligrams*
Up to 10	1.0
10 to 25	2.0
25 and over	4.0

Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 milligram per animal.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.1020 Gelatin solution.

(a) *Specifications.* It is sterile and each 100 cubic centimeters contains 8 grams of gelatin in an 0.85 percent sodium chloride solution.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used to restore circulatory volume and maintain blood pressure in animals being treated for shock.

(2) The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight. It is administered intravenously at a rate of 10 cubic centimeters per minute in small animals and 20 to 30 cubic centimeters per minute in large animals. The solution is administered aseptically and must be between 50° to 70° F. when injected.

(3) A few animals will exhibit signs of allergic reaction. This solution can cause transient reversible nephrosis. This product is not intended to replace whole blood in cases of anemia and should not be used in the presence of renal dysfunction. Unused portions remaining in bottles should be discarded.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.1044 Gentamicin sulfate injection.

(a) *Specifications.* Conforms to the standards of identity, strength, quality, and purity prescribed by § 444.220 of this chapter, except that each milliliter of the drug contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base if intended for use in dogs and cats or gentamicin sulfate equivalent to 5 milligrams of gentamicin base if intended for use in turkeys.

(b) *Sponsor.* (1) See No. 000085 in § 510.600(c) of this chapter for condi-

tions of use provided for in paragraph (c) of this section.

(2) See No. 000138 in § 510.600(c) of this chapter for conditions of use provided for in paragraph (d) of this section.

(c) *Conditions of use in dogs and cats.* (1) It is used or intended for use:

(i) In dogs for the treatment of urinary tract infections (cystitis, nephritis), and respiratory tract infections (tonsillitis, pneumonia, tracheobronchitis).

(ii) In cats for the treatment of urinary tract infections (cystitis, nephritis), and respiratory tract infections (pneumonitis, pneumonia, upper respiratory infections).

(2) It is administered intramuscularly or subcutaneously at a rate of 2 milligrams per pound of body weight, twice on the first day of treatment and once daily thereafter. If response is not noted after 7 days, the antibiotic sensitivity of the infecting organism should be retested.

(d) *Conditions of use in turkeys.* (1) It is used in 1- to 3-day-old turkey poults as an aid in the prevention of early mortality due to Arizona paracolon infections susceptible to gentamicin sulfate.

(2) It is administered subcutaneously in the neck of 1- to 3-day-old turkey poults at a rate of 1 milligram per poult.

(3) For use in 1- to 3-day-old turkey poults only. Injected poults must not be slaughtered for food for at least 9 weeks following treatment.

§ 522.1060 Glyceryl guaiacolate sterile powder.

(a) *Specifications.* Complies with N.F. XIII.

(b) *Sponsor.* See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for intravenous use as a muscle relaxant in horses.

(2) A 5 percent solution is prepared by dissolving 50 grams of the drug in sterile water for injection to make 1 liter of solution. It is administered by rapid intravenous infusion at a fixed dosage of 1 milliliter of prepared solution per pound of body weight.

(3) Not to be used in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.

(a) (1) *Specifications.* Chorionic gonadotropin for injection, when reconstituted with appropriate diluent, provides 1,000 U.S.P. units of chorionic gonadotropin per milliliter.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for parenteral use in the treatment of cows for nymphomania (frequent of constant heat) due to cystic ovaries.

(ii) It is administered at a recommended dose of 10,000 U.S.P. units by deep intramuscular injection or 2,500 to 5,000 U.S.P. units intravenously or by intrafollicular injection of 500 to 2,500 U.S.P. units. Dosage may be repeated in 14 days if necessary.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Chorionic gonadotropin suspension, veterinary contains in each milliliter, 750 I.U. of chorionic gonadotropin suspended in white wax and sesame oil.

(2) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used as an aid in increasing pregnancy rate of estrus synchronized and normal cycling heifers.

(ii) It is administered at the rate of 2 milliliters (1,500 I.U.) subcutaneously at the time of insemination in the neck or shoulder region.

(iii) The drug is not to be used to induce multiple ovulations. Doses higher than recommended may reduce pregnancy rate.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1143 Hexylcaine hydrochloride injection.

(a) *Specifications.* Hexylcaine hydrochloride injection contains 1 percent or 5 percent hexylcaine hydrochloride in a sterile aqueous solution.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used as a long-lasting anesthetic for epidural anesthesia of mature cattle, of horses, and of dogs; for infiltration anethesia (field blocking) of cattle, of horses, and of dogs; and for nerve block anesthesia of cattle and of horses.

(2) The drug is administered by injection. For epidural anesthesia, it is administered to mature cattle at a dosage level of 0.2 to 0.6 milligram per pound of body weight to effect, to horses at a dosage level of 0.2 to 0.4 milligram per pound of body weight to effect, and to dogs at a dosage level of 0.5 to 1 milligram per pound of body weight to effect. For infiltration anesthesia (field blocking) and for nerve block anesthesia, either the 1 percent solution or a 2 percent solution prepared from the 5 percent solution is administered to effect.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1182 Iron dextran complex injection.

(a) *Specifications.* Iron dextran complex injection contains ferric hydroxide dextran complex with 0.5 percent phenol as a preservative. It is sterile and each cubic centimeter contains 100 milligrams of elemental iron.

(b) *Sponsor.* (1) See No. 010271 in § 510.600(c) of this chapter for the sponsor of the usages provided by paragraph (c) (1) and (2) of this section.

(2) See No. 000856 in § 510.600(c) of this chapter for the sponsor of usages provided by paragraph (c) (3) and (4) of this section.

(c) *Conditions of use.* It is used in baby pigs as follows:

(1) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 75 to 150 milligrams of elemental iron to each animal at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(2) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 100 to 200 milligrams of elemental iron.

(3) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(4) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron.

§ 522.1183 Iron hydrogenated dextran injection.

(a) (1) *Specifications.* Iron hydrogenated dextran injection contains in each milliliter 100 milligrams of elemental iron stabilized with a low molecular weight hydrogenated dextran with 0.5 percent phenol as a preservative.

(2) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(3) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 milligrams of elemental iron to each animal at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 100 milligrams of elemental iron to each animal when indicated between 5 and 28 days of age.

(b) (1) *Specifications.* Iron hydrogenated dextran injection contains in each milliliter 100 milligrams of elemental iron stabilized with a low molecular weight hydrogenated dextran with 0.5 percent phenol as a preservative.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use.* It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron to each animal at 2 to 4 days of age.

(ii) For the treatment of anemia due to iron deficiency, administer by intramuscular or subcutaneous injection of 100 milligrams of elemental iron in baby pigs up to 4 weeks of age.

§ 522.1204 Kanamycin sulfate injection.

(a) *Specifications.* Kanamycin sulfate injection veterinary conforms to the standards of identify, strength, quality, and purity prescribed by § 444.230(a) of this chapter, except that each milliliter contains either 50 or 200 milligrams of kanamycin.

(b) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in the treatment of bacterial infections due

to kanamycin sensitive organisms in dogs and cats.

(2) It is administered subcutaneously or intramuscularly at 5 milligrams per pound of body weight per day in equally divided doses at 12-hour intervals.

(3) Its label shall bear an appropriate expiration date.

(4) Restricted to use by or on the order of a licensed veterinarian.

§ 522.1222 Ketamine hydrochloride injection.

(a) *Chemical name.* 2-(o-Chlorophenyl) - 2 - (methylamino) cyclohexanone hydrochloride.

(b) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains: Ketamine hydrochloride equivalent to 100 milligrams ketamine base activity and 1:10,000 benzethonium chloride.

(c) *Sponsors.* (1) See No. 000015 in § 510.600(c) of this chapter.

(2) See No. 000071 in § 510.600(c) of this chapter.

(d) *Special considerations.* Store in a cool place. Protect from light. Do not use if precipitate appears.

(e) *Conditions of use.* (1) In cats: (i) It is used for restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(ii) It is administered intramuscularly at a recommended dose that ranges from 5 to 15 milligrams per pound of body weight depending on the effect desired.

(2) In subhuman primates: (i) It is used for restraint.

(ii) It is administered intramuscularly at a recommended dose that ranges from 3 to 15 milligrams per kilogram of body weight depending upon the species, general condition, and age of the subject.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1244 Levamisole phosphate injection.

(a) *Specifications.* Each milliliter of levamisole phosphate injection veterinary contains levamisole phosphate equivalent to 182 milligrams of levamisole hydrochloride in sterile aqueous solution.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered by subcutaneous injection to cattle as an anthelmintic against the following nematode infections: stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*) and lungworms (*Dictyocaulus*).

(2) It is administered subcutaneously in the mid-neck region at the rate of 2 milliliters per 100 pounds of body weight. Cattle maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

(3) Consult veterinarian before using in severely debilitated animals.

(4) Do not administer to cattle within 7 days of slaughter for food. Do not administer to dairy animals of breeding age.

§ 522.1260 Lincomycin injection.

(a) *Specifications.* Meets the specifications in § 453.230(a)(1) of this chapter, except that each immediate container may contain 20 or 50 milliliters of solution containing 100 milligrams of lincomycin per milliliter or that each immediate container may contain 50 milliliters of solution containing 50 milligrams of lincomycin per milliliter.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Special considerations.* When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to the labeling requirements of § 201.105 of this chapter.

(d) *Related tolerances.* See § 556.360 of this chapter.

(e) *Conditions of use.* It is used for animals as follows:

(1) *Dogs and cats*—(i) *Amount.* 5 to 10 milligrams per pound of body weight per day.

(ii) *Indications for use.* Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) *Limitations.* Administer intramuscularly 10 milligrams per pound of body weight once a day or 5 milligrams per pound of body weight twice daily or intravenously 5 to 10 milligrams per pound of body weight one or two times daily by slow injection. May be diluted with 5 percent glucose in water or normal saline and given as an infusion; as lincomycin hydrochloride monohydrate; for use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 5 milligrams per pound of body weight per day.

(ii) *Indications for use.* Treatment of infectious arthritis and mycoplasma pneumonia.

(iii) *Limitations.* Administer intramuscularly as a single daily dose for 3 to 7 days; as lincomycin hydrochloride monohydrate: do not treat within 48 hours of slaughter.

§ 522.1362 Meglumine diatrizoate and sodium diatrizoate injection.

(a) *Specifications.* Meglumine diatrizoate and sodium diatrizoate injection contains 66 percent meglumine diatrizoate and 10 percent sodium diatrizoate in sterile aqueous solution.

(b) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs and cats for visualization in excretion urography, including renal angiography, uretography, cystography and urethrography; aortography; angiocardiography; peripheral arteriography and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter into the urethra to provide desired contrast delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catheter or intraventricular puncture. For cerebral angiopraphy rapid injection of 3 to 10 milliliters via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 1.0 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be delineated. For sialography slowly inject 0.5 to 1.0 milliliter into the duct to be delineated. For delineation of fistulous tracts slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias inject 0.5 to 1.0 milliliter per pound of body weight directly into the peritoneal cavity.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1380 Methocarbamol injection.

(a) *Chemical name.* 3-(*0*-Methyoxyphenoxy)-1,2-propanediol 1-carbamate.

(b) *Specifications.* Methocarbamol injection contains per milliliter: 100 milligrams of methocarbamol, 0.1 percent of sodium bisulfite U.S.P., 50 percent of polyethylene glycol 300, and water for injection q.s. Its pH is 5.2–5.6. It is sterile and pyrogen-free.

(c) *Sponsor.* See No. 000031 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is administered to dogs, cats, and horses as an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles and to reduce muscular spasms and in horses to effect striated muscle relaxation.

(2) The drug is administered intravenously. For relief of moderate conditions in dogs and cats, a dose of 20 milligrams per pound of body weight may be adequate. An initial dose in dogs and cats of 25 to 100 milligrams per pound of body weight is suggested for controlling the severe effects of strychnine poisoning and tetanus. Additional amounts may be needed in dogs and cats for relieving residual effects and for preventing the recurrence of symptoms. A total cumulative dose in dogs and cats of 150 milligrams per pound of body weight should not be exceeded. For relief of moderate conditions, in horses, a dose of 2 to 10 milligrams per pound of body weight to effect is recommended; and for severe conditions (tetanus), a dose of 10 to 25 milligrams per pound of body weight to effect is recommended.

(3) Not to be used in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1404 Sodium methohexital for injection.

(a) *Specifications.* Sodium methohexital for injection is a sterile dry powder containing a mixture of sodium methohexital and anhydrous sodium carbonate. It is packaged in sterile vials with directions for adding the necessary amount of either sterile water for injection or sterile normal saline solution to produce a 2.5 percent solution of sodium methohexital. Five percent solutions may be prepared if desired by halving the amount of diluent.

(b) *Sponsor.* See No. 000986 § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats as a general anesthetic.

(2) It is injected intravenously in the average animal at 1 milliliter of a 2.5 percent solution per 5 pounds of animal weight. Approximately half the estimated dose is administered during a period of approximately 30 to 60 seconds; the remainder of the dose is then administered at the rate of 1 milliliter per 60 seconds. To maintain anesthesia for longer periods of time after the initial injection, inject 0.5 milliliter (12.5 milligrams) to 1 milliliter (25 milligrams) of the 2.5 percent solution per 5 pounds of body weight intermittently as required. Continuous drip anesthesia may also be employed after the initial injection by diluting the drug to 0.1 or 0.2 percent levels and adjusting the flow rate to approximately 0.15 milligram of the drug per minute for each pound of body weight to maintain continuous anesthesia.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1462 Naloxone hydrochloride injection.

(a) *Specifications.* Naloxone hydrochloride injection is an aqueous sterile solution containing 0.4 milligram of naloxone hydrochloride per milliliter.

(b) *Sponsor.* See No. 000056 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as a narcotic antagonist in dogs.

(2) It is administered by intravenous, intramuscular, or subcutaneous injection at an initial dose of 0.04 milligram per kilogram of body weight. When given intravenously, the dosage may be repeated at 2- to 3-minute intervals as necessary. Onset of action by intramuscular or subcutaneous injection is slightly longer than it is by intravenous injection, and repeated dosages must be administered accordingly.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.1484 Neomycin sulfate sterile solution.

(a) *Specifications.* Neomycin sulfate sterile solution contains 50 milligrams of neomycin sulfate in each milliliter of solution (equivalent to 35 milligrams neomycin base). The neomycin sulfate used in preparing the drug conforms to the standards of identity, strength, quality, and purity prescribed by § 444.42a(a)(1) of this chapter.

(b) *Sponsor.* See No. 000009 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats in the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.

(2) It is administered intramuscularly or intravenously for a period of 3 to 5 days in a total daily dosage of 5 milligrams per pound of body weight. The total daily dosage is divided into portions that are administered every 6 to 8 hours.

(3) Its label shall bear an appropriate expiration date and the statement that neomycin must not be used parenterally in food-producing animals because of prolonged residues of the antibiotic in edible tissues.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.1503 Neostigmine methylsulfate injection.

(a) *Specifications.* Neostigmine methylsulfate injection contains two milligrams of neostigmine methylsulfate in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 011716 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use for treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions. It is a curare antagonist.

(2) It is administered to cattle and horses at a dosage level of 1 milligram per 100 pounds of body weight subcutaneously. It is administered to sheep at a dosage level of 1 to 1½ milligrams per 100 pounds body weight subcutaneously. It is administered to swine at a dosage level of 2 to 3 milligrams per 100 pounds body weight intramuscularly. These doses may be repeated as indicated.

(3) The drug is contraindicated in mechanical, intestinal or urinary obstruction, late pregnancy, and in animals treated with other cholinesterase inhibitors.

(4) Not for use in animals producing milk, since this use will result in contamination of the milk.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1563 Nitrofurantoin sodium injection.

(a) *Specifications.* It is sterile and packaged so that each vial contains sufficient drug to permit withdrawal of 180 milligrams of nitrofurantoin sodium. The nitrofurantoin sodium used is the sodium salt of nitrofurantoin U.S.P.

(b) *Sponsor.* See No. 000947 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used only in bacterial infections of the urinary tract of dogs when the oral forms are not feasible.

(2) It is administered intramuscularly at the rate of 1.5 milligrams of nitrofurantoin sodium per pound of body weight twice daily (total daily dose: 3 milligrams per pound) for a maximum of 10 days.

(3) For use by or on the order of a licensed veterinarian.

§ 522.1620 Orgotein for injection.

(a) *Specifications.* Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor.* See No. 024991 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses in the treatment of soft tissue inflammation associated with the musculoskeletal system.

(2) It is administered by deep intramuscular injection at a dosage level of 5 milligrams every other day for 2 weeks and twice weekly for 2 to 3 more weeks. In severe cases, both acute and chronic may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not yet been achieved.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1642 Oxymorphone hydrochloride injection.

(a) *Specifications.* The drug contains 1 or 1.5 milligrams of oxymorphone hydrochloride per milliliter of aqueous solution containing 0.8 percent sodium chloride.

(b) *Sponsor.* See No. 000056 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is a narcotic analgesic, preanesthetic, anesthetic, and substitute anesthetic adjuvant for intramuscular, subcutaneous or intravenous administration to cats and dogs as follows:

Animal	Body weight (pounds)	Dosage (milligram)
Dogs	2 to 5	0.75
	5 to 15	0.75–1.5
	15 to 30	1.5–2.5
	30 to 60	2.5–4.0
	Over 60	4.0
Cats	Small	0.4–0.75
	Large	0.75–1.5

(2) Do not mix with a barbiturate in the same syringe to preclude precipitation.

(3) It tends to depress respiration. Naloxone hydrochloride and other narcotic antagonists are used to counter over-dosing.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.

§ 522.1662a Oxytetracycline hydrochloride injection.

(a)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline

hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 025001 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.; Hemophilis spp.; Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresi*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as streptococcal and staphylococcal organisms)).

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b) (1) *Specifications.* The drug contains 50 milligrams of oxytetracycline base as oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 000010 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in the treatment of diseases due to oxytetracycline-susceptible organisms in beef cattle and nonlactating dairy cattle. It is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp., Hemophilus spp., Klebsiella spp.,* footrot and diphtheria caused by *Spherophorus necrophorus,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresi,* acute metritis, and wound infections caused by Staphylococcal and Streptococcal organisms. The drug is intended for use in sows to aid in control of infections enteritis (baby pig scours, colibacillosis) in sucking pigs caused by *Escherichia coli.*

(ii) It is administered by intramuscular or intravenous injection to beef cattle and non-lactating dairy cattle at a level of 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In severe foot-rot and severe forms of the indicated diseases treat at 5 milligrams per pound of body weight. When administered intramuscularly no more than 0.5 to 2 milliliters should be injected in each site in the case of smaller animals and no more than 10 milliliters should be injected in each site in adult cattle. Treatment in cattle should be continued for 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 days. It is administered to sows intramuscularly at a level of 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing. No more than 5 milliters should be injected intramuscularly per site in sows.

(iii) Not for use in lactating dairy animals. Discontinue use 18 days before slaughter. When administered to animals within 20 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) If the product contains the statement, "Federal law restricts this drug to use by or on the order of a licensed veterinarian" it may contain additional directions for use in beef cattle and nonlactating dairy cattle for use in the treatment of anaplasmosis caused by *Anaplasma marginale.* It is administered to beef cattle and nonlactating dairy cattle as described in subdivision (ii) of this subparagraph at the dosage level of 5 milligrams of oxytetracycline per pound of body weight.

(c) (1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 000196 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle and non-lactating dairy cattle. It is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella sp., Hemophilus sp., Klebsiella sp.,* foot rot and diphtheria caused by *Spherophorus necrophorus,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresi,* acute metritis, and wound infections caused by staphylococcal and streptococcal organisms.

(ii) It is administered to cattle at a dosage level of 3 to 5 milligrams per pound of body weight per day intramuscularly or intravenously. Severe foot rot and the severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight. Treatment should be continued 24 to 48 hours following remission of disease symptoms, however, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 hours, consult a veterinarian. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the amount injected at each site according to the size of the animal. For very small calves do not use more than 2 milliliters per injection site.

(iii) Not for use in lactating dairy cattle. Discontinue treatment at least 19 days prior to slaughter. When administered intramuscularly within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site and surrounding tissues.

(d) (1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 000069 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) In beef cattle and non-lactating dairy cattle as follows:

(*a*) It is used for the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Hemophilus spp;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresi;* leptospirosis caused by *Leptospira pomona;* wound infections and acute metritis caused by staphyl ococcal and streptococcal organisms.

(*b*) Administer by intravenous or intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and severe forms of the indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended.

(*c*) If the labeling of the drug bears the statement "Federal law restricts this drug to use by or on the order of a licensed veterinarian", it may include additional directions for use in beef cattle and non-lactating dairy cattle for the treatment of anaplasmosis caused by *Anaplasma marginale,* and anthrax caused by Bacillus anthracis in which case the drug is given at 3 to 5 milligrams of oxytetracycline per pound of body weight per day for anthrax, and at 5 milligrams per pound of body weight per day for anaplasmosis.

(ii) In swine as follows:

(*a*) It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona.* Administered to sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(*b*) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day to swine. Administered to sows at 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after farrowing.

(iii) In poultry (broilers, turkeys, and breeding chickens) as follows:

(*a*) It is used for the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli;* fowl cholera caused by *Pasteurella multocida;* infectious sinusitis caused by *Mycoplasma gallisepticum;* and infectious synovitis caused by *Mycoplasma synoviae.*

(b) Administered subcutaneously to chickens 1 day to 2 weeks of age at 6.25 milligrams of oxytetracycline per bird per day diluted with 1 part of the drug to 3 parts of sterile water; to chickens 2 to 4 weeks of age using the same diluted product at 12.5 milligrams of oxytetracycline per bird; to chickens 4 to 8 weeks of age without dilution at 25 milligrams of oxytetracycline per bird; to chickens 8 weeks of age (broilers and light pullets) at 50 milligrams of oxytetracycline per bird; to adult chickens at 100 milligrams of oxytetracycline per bird.

(c) Administered subcutaneously to turkeys 1 day to 2 weeks of age and 2 to 4 weeks of age at the same dosage as chickens; to turkeys 4 to 6 weeks of age at 50 milligrams of oxytetracycline as the undiluted product per bird; to turkeys 6 to 9 weeks of age at 100 milligrams of oxytetracycline per bird; to turkeys 9 to 12 weeks of age at 150 milligrams of oxytetracycline per bird; to turkeys 12 weeks of age and older at 200 milligrams of oxytetracycline per bird. In light turkey breeds, no more than 25 milligrams per pound of body weight is administered. For the treatment of infectious sinusitis in turkeys, ¼ to ½ milliliter of the drug is injected directly into each swollen sinus depending upon the age of the bird and the severity of the condition. At the time that the sinuses are treated, the drug should also be administered subcutaneously to the birds according to the dosage schedule given in paragraph (d) (3) (iii) (c) of this section. If refilling of the sinuses occurs, the treatment may be repeated in 5 to 7 days.

(iv) Treatment of all diseases should be instituted early. Treatment should continue for 24 to 48 hours beyond the remission of disease symptoms, but not exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, diagnosis and therapy should be reevaluated.

(v) When injecting intramuscularly in adult livestock, do not inject more than 10 milliliters at any one site. The volume administered per injection site should be reduced according to age and body size so that 1 or 2 milliliters are injected in smaller animals such as small calves and young pigs. Intravenous administration is recommended in cattle when daily dosage exceeds 50 milliliters.

(vi) Treatment must be discontinued at least 5 days prior to slaughter for chickens and turkeys and at least 22 days prior to slaughter for cattle and swine. When administered intramuscularly to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

(vii) Not for use in lactating dairy animals. Do not administer to laying hens unless the eggs are used for hatching only.

(e) (1) *Specifications.* The drug contains 100 milligrams of oxytetracycline base as oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See code No. 000069 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) For beef cattle and nonlactating dairy cattle in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Hemophilus spp.;* foot-rot and diptheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresi;* leptospirosis caused by *Leptospira pomona;* and wound infections and acute metritis caused by strains of *Staphylococci* and *Streptococci* sensitive to oxytetracycline. If the labeling of the drug bears the statement "Federal law restricts this drug to use by or on the order of a licensed veterinarian", it may include additional uses in beef cattle and nonlactating dairy cattle for the treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(ii) Administer by intramuscular injection at a dosage level of 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of anaplasmosis, foot-rot, and advanced cases of other indicated diseases, 5 milligrams per pound of body weight per day is recommended.

(iii) Treatment of all diseases should be instituted early and should continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, diagnosis and therapy should be reevaluated.

(iv) When injecting intramuscularly in adult cattle, do not inject more than 10 milliliters at any one site. The volume administered per injection site should be reduced according to age and body size so that 1 to 2 milliliters are injected in smaller animals such as small calves.

(v) Treatment must be discontinued at least 15 days prior to slaughter. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time.

(vi) Not for use in lactating dairy animals.

(f) (1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 010271 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) Use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Hemophilus spp;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresi;* leptospirosis caused by *Leptospira pomona;* wound infections, acute metritis, and traumatic injury caused by staphylococcal and streptococcal organisms.

(ii) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of leptospirosis, severe foot-rot, and severe forms of the indicated diseases, administer 5 milligrams per pound of body weight per day.

(iii) Treatment should continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Treat at the first clinical signs of disease. If no improvement is noted within 48 hours, consult a veterinarian for diagnosis and therapy.

(iv) In adult livestock, do not inject more than 10 milliliters at any one site. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less inject only 2 milliliters per site.

(v) Discontinue treatment at least 22 days prior to slaughter. Exceeding the recommended dosage level or duration of treatment may result in antibiotic residues beyond the withdrawal time.

(vi) Not for use in lactating dairy animals.

§ 522.1662b Oxytetracycline hydrochloride with lidocaine injection.

(a) *Specifications.* The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride and 2 percent lidocaine in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See Nos. 000069 and 000196 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for use in the treatment of diseases of dogs caused by pathogens sensitive to oxytetracycline hydrochloride including treatment for the following conditions in dogs caused by susceptible microorganisms: Bacterial infections of the urinary tract caused by *Hemolytic staphylococcus, Streptococcus spp.,* Bacterial pulmonary infections caused by *Brucella bronchiseptica, Streptococcus pyogenes. Staphylococcus aureus,* secondary bacterial infections caused by *Micrococcus pyogenes var. albus, Brucella bronchiseptica, Streptococcus spp.*

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 h intervals. Therapy should be continued for at least 24 h after all symptoms have subsided.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1680 Oxytocin injection.

(a) *Specifications.* Each milliliter of oxytocin injection contains 20 U.S.P. units of oxytocin.

(b) *Sponsor.* See Nos. 000845, 012481, 011811 and 010469 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) (i) The drug is administered for obstetrical use by intravenous, intramuscular, or subcutaneous injection under aseptic conditions as indicated. The following dosages

are recommended and may be repeated as conditions require:

Cats	0.25 to 0.5 ml	5 to 10 U.S.P. units.
Dogs	0.25 to 1.5 ml	5 to 30 U.S.P. units.
Ewes, sows	1.5 to 2.5 ml	30 to 50 U.S.P. units.
Cows, horses	5.0 ml	100 U.S.P. units.

(ii) The drug is also used for augmenting the letdown of milk, and for this purpose intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

Cows	0.5 to 1.0 ml	10 to 20 U.S.P. units.
Sows	0.25 to 1.0 ml	5 to 20 U.S.P. units.

(2) Do not use in dystocia due to abnormal presentation of fetus until correction is accomplished.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1704 Sodium pentobarbital injection.

(a) (1) *Specifications.* Sodium pentobarbital injection is sterile and contains in each milliliter 64.8 milligrams of sodium pentobarbital.

(2) *Sponsor.* See No. 011716 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anesthetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(ii) The drug is administered intravenously "to effect". For general surgical anesthesia, the usual dose is 11 to 13 milligrams per pound of body weight. For sedation, the usual dose is approximately 2 milligrams per pound of body weight. For relieving convulsive seizures in dogs, when caused by strychnine, the injection should be administered intravenously "to effect". The drug may be given intraperitoneally if desired. However, the results of such injections are less uniform. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration. The dose must be reduced for animals showing undernourishment, toxemia, shock and similar conditions.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Sodium pentobarbital injection is sterile and contains in each milliliter 65 milligrams of sodium pentobarbital.

(2) *Sponsor.* See Nos. 000845 and 000381 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for use as a general anesthetic in dogs and cats.

(ii) The drug is administered intravenously "to effect." For general anesthesia, the usual dose is 13 milligrams per pound of body weight.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1720 Phenylbutazone injection.

(a) *Specifications.* The drug contains 100 or 200 milligrams of phenylbutazone in each milliliter of sterile aqueous solution.

(b) *Sponsors.* (1) Approval for use of the 200 milligrams per milliliter drug in dogs and horses: See sponsor Nos. 017220, 011757, and 010719 in § 510.600(c) of this chapter.

(2) Approval for use of the 200 milligrams per milliliter drug in horses: See sponsor Nos. 010271, 000010, 011398, 000864, and 000381 in § 510.600(c) of this chapter.

(3) Approval for use of the 100 milligrams per milliliter drug in dogs and horses: See sponsor No. 000856 in § 510.-600(c) of this chapter.

(c) *Conditions of use for dogs.* (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered intravenously at a dosage level of 10 milligrams per pound of body weight daily in 3 divided doses, not to exceed 800 milligrams daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use for horses.* (1) It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(2) It is administered intravenously at a dosage level of 1 to 2 grams per 1,000 pounds of body weight daily in 3 divided doses, not to exceed 4 grams daily. Limit intravenous administration to not more than 5 successive days.

(3) Not for use in animals intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1800 Piperacetazine injection.

(a) *Specifications.* The drug is a sterile aqueous solution and each milliliter contains piperacetazine hydrochloride equivalent to 2 milligrams of piperacetazine.

(b) *Sponsor.* See No. 011716 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for use in dogs and cats as a tranquilizer, sedative, and antiemetic agent and for the symptomatic relief of pruritis.

(2) It is administered intramuscularly, intravenously, or subcutaneously; method of administration depends upon the effect desired. It is administered at a recommended average dose that ranges from 0.5 to 2 milligrams per 10 pounds of body weight, depending on the effect desired and the response of the patient. Subsequent doses are adjusted as indicated. Treatment is repeated as necessary. Parenteral treatment may be followed by administration of the drug in tablet form, as indicated.

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(4) For use only by or on the order of a licensed veterinarian.

§ 522.1820 Pituitary luteinizing hormone for injection.

(a) *Specifications.* The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.

(b) *Sponsor.* No. 000845 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

(2) Preferably given by intravenous injection, it may be administered subcutaneously; dosage is as follows: Cattle and horses, 25 mg; swine, 5 mg; sheep, 2.5 mg, and dogs, 1.0 mg. Treatment may be repeated in 1 to 4 weeks, or as indicated.

(c) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1862 Sterile pralidoxime chloride.

(a) *Chemical name.* 2-Formyl-1-methylpyridinium chloride oxime.

(b) *Specifications.* Sterile pralidoxime chloride is packaged in vials. Each vial contains 1 gram of sterile pralidoxime chloride powder and includes directions for mixing this gram with 20 cubic centimeters of sterile water for injection prior to use.

(c) *Sponsor.* See No. 000046 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.

(2) It is administered as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 milligram per pound of body weight, followed by administration of an additional 0.15 milligram of atropine per pound of body weight administered intramuscularly. Then the appropriate dosage of sterile pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when administered to horses is 2 grams per horse. When administered to dogs and cats, it is 25 milligrams per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime

chloride may be given after 1 hour if muscle weakness has not been relieved.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.1880 Sterile prednisolone suspension.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 or 25 milligrams of prednisolone.

(b) *Sponsor.* See No. 010719 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated in the treatment of dogs, cats, and horses for use as an anti-inflammatory agent.

(2) The drug is administered as follows and treatment may be repeated when necessary:

Species	Intramuscular	Intra-articular
Horse	50-200 milligrams	40-80 milligrams.
Dog	10-30 milligrams	10-20 milligrams.
Cat	5-10 milligrams	10-20 milligrams.

(3) Corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1881 Sterile prednisolone acetate aqueous suspension.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 25 mg of prednisolone acetate.

(b) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations such as bursitis, carpitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and post-operatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered to horses intra-articularly at a dosage level of 50–100 mg. The dose may be repeated when necessary. If no response is noted after 3 or 4 days, the possibility must be considered that the condition is unresponsive to prednisolone therapy. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 mg. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 mg. The dose may be repeated when necessary after 7 days for two or three doses.

(3) Corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1885 Prednisolone tertiary butylacetate suspension.

(a) *Specifications.* Prednisolone *tertiary* butylacetate (Pregna-1,4-diene-3, 20-dione-11B, 17α 21-triol 21-(3,3, dimethyl butyrate) suspension contains 20 milligrams of prednisolone tertiary butylacetate per milliliter. It is sterile.

(b) *Sponsor.* See No. 000006 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anti-inflammatory agent in horses, dogs, and cats.

(2) It is administered to horses intramuscularly at a dosage level of 100 to 300 milligrams and intrasynovially at a dosage level of 50 to 100 milligrams. It is administered intramuscularly to dogs and cats at a dosage level of 1 milligram per 5 pounds of body weight and intrasynovially at a dosage level of 10 to 20 milligrams. Intramuscular retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered late in pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1884 Prednisolone sodium succinate injection.

(a) *Chemical name.* 11 beta, 17, 21-Trihydroxypregna-1, 4-diene-3, 20-dione 21-succinate sodium salt.

(b) *Specifications.* Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10 milligrams of prednisolone.

(c) *Sponsor.* See No. 000009 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for the treatment of horses, dogs, and cats.

(2) (i) The dosage for horses is 50 to 100 milligrams as an initial dose given intravenously over a period of one-half to 1 minute, or intramuscularly, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the size of the animal, the severity of the condition and the response to treatment.

(ii) In dogs, the drug is administered intravenously at a range of 2.5 to 5 milligrams per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6 or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) In dogs and cats, the drug may be given intramuscularly for treatment of inflammatory, allergic and less severe stress conditions, where immediate effect is not required, at 1 to 5 milligrams ranging upwards to 30 to 50 milligrams in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to 5 days if necessary. If permanent corticosteroid effect is required oral therapy with prednisolone tablets may be substituted.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 552.1920 Prochlorperazine, isopropamide for injection.

(a) *Specifications.* Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milligrams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to 0.28 milligrams of isopropamide) in buffered aqueous solution.

(b) *Sponsor.* See No. 011519 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(2) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	*Dosage in Milliliters*
Up to 4	0.25
5 to 14	0.5–1
15 to 30	2–3
30 to 45	3–4
45 to 60	4–5
Over 60	6

Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.1940 Progesterone and estradiol benzoate in combination.

(a) *Chemical names.* (1) Progesterone: 4-Pregnene-3,20-dione.

(2) Estradiol benzoate: 1,3,5(10)-Estratriene-3,17beta-diol 3-benzoate.

(b) *Sponsor.* See No. 000033 in § 510.-600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

(d) *Conditions of use.* It is used for implantation in animals as follows:

(1) *Lambs*—(i) *Amount.* 25 milligrams of progesterone and 2.5 milligrams of estradiol benzoate per dose.

(ii) *Indications for use.* Growth promotion and feed efficiency.

(iii) *Limitations.* For animals weighing between 60 and 85 pounds; for subcutaneous ear implantation, one dose per animal; not to be used within 60 days of slaughter.

(2) *Steers*—(i) *Amount.* 200 milligrams of progesterone and 20 milligrams of estradiol benzoate per dose.

(ii) *Indications for use.* Growth promotion and feed efficiency.

(iii) *Limitations.* For animals weighing between 400 and 1,000 pounds; for subcutaneous ear implantation, one dose per animal; not to be used within 60 days of slaughter.

§ 522.1962 Promazine hydrochloride injection.

(a) *Chemical name.* 10-[3-(Dimethylamino) propyl] phenothiazine monohydrochloride.

(b) *Specifications.* The product contains 50 milligrams of promazine hydrochloride in each milliliter of sterile aqueous solution.

(c) *Sponsor.* See No. 000008 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) It is administered either intramuscularly or intravenously to horses at a dosage level of 0.2 milligram to 0.5 milligram per pound of body weight and to dogs and cats at 1 milligram to 3 milligrams per pound of body weight every 4 to 6 hours as a tranquilizer or preanesthetic.

(2) It is not to be used in conjunction with organophosphates because their toxicity may be potentiated, nor with procaine hydrochloride as its activity may be increased.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2002 Propiopromazine hydrochloride injection.

(a) *Chemical name.* 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications.* Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) *Sponsor.* See No. 013947 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05–0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.

§ 522.2022 Protokylol hydrochloride injection.

(a) *Specifications.* Protokylol hydrochloride injection contains 0.5 milligram of protokylol hydrochloride per cubic centimeter of sterile aqueous solution.

(b) *Sponsors.* See No. 000859 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats for relief of bronchial spasm.

(2) It is administered subcutaneously or intramuscularly at a dosage level of 0.125 to 0.5 milligram to dogs and at a level of 0.125 to 0.25 milligram to cats.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2063 Pyrilamine maleate injection.

(a) *Specifications.* The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.

(b) *Sponsor.* See No. 011519 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease, such as equine laminitis or insect stings.

(2) It is administered intramuscularly, subcutaneously, or intravenously. Local injection at the site of insect bites may be indicated in severe cases. Intravenous injections must be given slowly to avoid symptoms of overdosage. Dosage may be repeated every 6 to 12 hours whenever necessary. Horses, 40 to 60 milligrams per 10 pounds body weight; foals, 20 milligrams per 100 pounds body weight.

(3) Do not use in horses intended for food purposes.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2100 Selenium, vitamin E injection.

(a) (1) *Specifications.* The drug is an emulsion containing in each milliliter, 5.48 milligrams sodium selenite (equivalent to 2.5 milligrams selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 250 milligrams polyoxyethylated vegetable oil, and 0.1 milligram thimerosal, and water for injection.

(2) *Sponsor.* See No. 000845 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use for the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(ii) The drug is administered by intravenous or deep intramuscular injection in divided doses in 2 or more sites in the gluteal or cervical muscles at a dosage level or 1 milliliter per 100 pounds of body weight and may be repeated at 5 to 10 day intervals.

(iii) Do not use in horses intended for food.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* The drug contains in each milliliter 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium), 50 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate), 100 milligrams of polyoxyethylated vegetable oil, 1:10,000 thimerosal, and water for injection.

(2) *Sponsor.* See No. 000845 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use as an aid in alleviating and controlling inflammation, pain and lameness associated with certain arthropathies in dogs.

(ii) The drug is administered subcutaneously or intramuscularly in divided doses in 2 or more sites at a dosage level of 1 milliliter per 20 pounds of body weight with a minimum dosage of ¼ millitter and a maximum dosage of 5 milliliters. The dosage is repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 milliliter per 40 pounds of body weight with a minimum dosage of ¼ milliliter which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2120 Spectinomycin injection.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. Each milliliter of the drug contains the following amount of spectinomycin activity from spectinomycin dihydrochloride pentahydrate:

(1) 5 milligrams when used as provided in paragraph (d) (1) of this section.

(2) 25 milligrams when used as provided in paragraph (d) (2) of this section.

(3) 100 milligrams when used as provided in paragraph (d) (3) of this section.

(b) *Sponsor.* See No. 043731 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The quantity of spectinomycin referred to in this section refers to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* It is administered as spectinomycin dihydrochloride pentahydrate as follows:

(1) Subcutaneously in the treatment of 1-to-3-day-old turkey poults at the rate of 1 to 2 milligrams per poult as an aid in the prevention of mortality associated with Arizona group infection.

(2) Subcutaneously in the treatment of 1-to-3-day old:

(i) Turkey poults at the rate of 5 milligrams per poult as an aid in the control of chronic respiratory disease (CRD) associated with *E. coli.*

(ii) Baby chicks at the rate of 2.5 to 5 milligrams per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae, S. typhimurium, S. infantis,* and *E. coli.*

(3) Intramuscularly in the treatment of dogs:

(i) At a dosage level of 2.5 milligrams to 5.0 milligrams per pound of body weight twice daily. Treatment may be

continued for 4 days. For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

(ii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2200 Sulfachlorpyridazine.

(a) *Chemical name.* N^1-(6-Chloro-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range 190° C. to 191° C.

(c) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(d) *Related tolerances.* See § 556.630 of this chapter.

(e) *Conditions of use.* It is used for injection into calves as follows:

(1) *Amount.* 30 to 45 milligrams per pound of body weight per day.

(2) *Indications for use.* Treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(3) *Limitations.* Administer as the sodium salt of sulfachlorpyridazine intravenously in aqueous solution for 1 to 5 days in divided doses twice daily; treated calves must not be slaughtered for food during treatment or for 5 days after the last treatment.

§ 522.2220 Sulfadimethoxine injection.

(a) (1) *Specifications.* Sulfadimethoxine injection containing 400 milligrams per milliliter.

(2) *Sponsor.* See No. 000004 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used or intended for use in dogs and cats as follows:

(*a*) For the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by Streptococci, Staphylococci, Escherichia, Salmonella, Klebsiella, Proteus, or Shigella organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.

(*b*) It is administered by intravenous or subcutaneous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours.

(*c*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) It is used or intended for use in horses as follows:

(*a*) For the treatment of respiratory disease caused by Streptococcus equi (strangles).

(*b*) It is administered by intravenous injection at an initial dose of 55 milligrams per kilogram of body weight followed by 27.5 milligrams per kilogram of body weight every 24 hours until the patient is asymptomatic for 48 hours.

(*c*) Not for use in horses intended for food.

(*d*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) It is used or intended for use in cattle as follows:

(*a*) For the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

(*b*) It is administered by intravenous injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

(*c*) Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter.

(*d*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Sulfadimethoxine injection containing 100 milligrams per milliliter.

(2) *Sponsors.* See No. 011825 in § 510.-600(c) of this chapter for use in cats and dogs and No. 000859 in § 510.600(c) of this chapter for use in dogs only.

(3) *Conditions of use.* (i) It is used or intended for use in the treatment of sulfadimethoxine-susceptible bacterial infections in cats and dogs.

(ii) It is administered by intravenous or intramuscular injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight daily thereafter for 3 to 5 days.

(iii) For use by or on the order of a licensed veterinarian.

(c) (1) *Specifications.* Sulfadimethoxine containing 100 milligrams per milliliter.

(2) *Sponsor.* See No. 011716 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used or intended for use in the treatment of sulfadimethoxine-susceptible bacterial infections in dogs, cats and horses.

(ii) It is administered by subcutaneous, intramuscular or intravenous injection to dogs and cats and by intravenous injection only to horses at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours thereafter. Continue treatment until the animal is free from symptoms for 48 hours.

(iii) Not to be administered to horses intended for use as food.

(iv) For use by or on the order of a licensed veterinarian.

(d) *Related tolerances.* See § 556.640 of this chapter.

§ 522.2240 Sulfaethoxypyridazine.

(a) *Chemical name.* N^1-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

(b) *Specifications.* Melting point range of 180° C. to 186° C.

(c) *Sponsor.* See No. 010042 in § 510.-600(c) of this chapter.

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used for injection into cattle as follows:

(1) *Amount.* 2.5 grams per 100 pounds of body weight per day.

(2) *Indications for use.* Treatment of respiratory infection (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(3) *Limitations.* Administer intravenously for not more than 4 days; or first treatment may be followed by 3 days of treatment with sulfaethoxypyridazine in drinking water, feed, or tablet in accordance with § 121.280(b) or § 520.2240(e) of this chapter; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use by or on the order of a licensed veterinarian.

§ 522.2340 Sulfomyxin.

(a) *Specifications.* Sulfomyxin for injection is sterile. It is derived from the antibiotic substance produced by the growth of *Bacillus polymyxa* or is the same substance produced by any other means.

(b) *Sponsor.* See No. 000069 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.700 of this chapter.

(e) *Conditions of use.* (1) It is used or intended for use in chickens and turkeys as an aid in the treatment of disease caused or complicated by *E. coli*, such as colibacillosis and complicated chronic respiratory disease.

(2) It is administered by subcutaneous injection as follows:

Age of birds in days	Antibiotic activity	
	Chickens	Turkeys
	Units	*Units*
1 to 14	12,500	12,500
15 to 28	25,000	25,000
29 to 63	50,000	50,000
Over 63	50,000	100,000

(3) A second injection may be given 3 days later if symptoms persist.

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter; do not treat turkeys within 7 days of slaughter.

§ 522.2350 Testosterone and diethylstilbestrol in combination.

(a) *Chemical names.* (1) Diethylstilbestrol: 3,4-bis,(*p*-Hydroxyphenyl)-3-hexene.

(2) Testosterone: 1-beta-Hydroxyandrost-4-en-3-one.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.190 and 556.708 of this chapter.

(d) *Conditions of use.* It is used as a subcutaneous ear implantation for beef cattle as follows:

(1) *Amount per dose.* Testosterone, 120 milligrams plus diethylstilbestrol, 24 milligrams.

(2) *Indications for use.* Stimulation of growth and of rate of finishing of beef cattle.

(3) *Limitations.* One dose per animal; may be repeated after 60 days; do not

use within 21 days of slaughter; may be administered to cattle being fed diethylstilbestrol in accordance with table 1, item 1, of § 121.241(b) of this chapter.

§ 522.2404 Thialbarbitone sodium for injection.

(a) *Specifications.* Thialbarbitone sodium for injection when reconstituted with sterile distilled water provides 94 milligrams of thialbarbitone sodium per milliliter of solution.

(b) *Sponsor.* See No. 000856 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered as a general anesthetic in surgical procedures on dogs, cats, swine, sheep, cattle, and horses. The drug is used for procedures of relatively short duration. However, the period of anesthesia can be lengthened by slower initial injection and supplemental administration during surgery.

(2) It is administered intravenously. The drug is injected slowly to dogs, cats, cattle, sheep, and swine. For horses, it is recommended that a pre-anesthetic sedation be administered to the horse 30 minutes before the drug is administered. The drug is then injected rapidly and completely. The drug is used at the following dosage levels:

Species	Weight of animal in pounds	Dosage in milligrams per pound
Dog	Over 50	14.1
Do	30-50	18.8
Do	10-30	23.5
Do	Under 10	28.2
Cat		31.3-37.6
Horse		6.3-7.8
Cattle and swine		6.7-9.4
Calves and sheep		9.4-11.8

(3) Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2424 Sodium thiamylal for injection.

(a) (1) *Specifications.* Sodium thiamylal for injection is a sterile dry powder containing a mixture of sodium thiamylal and anhydrous sodium carbonate. It is contained in vials with directions for adding the necessary amount of water for injection or of sodium chloride for injection in order to produce a 0.5 to 4.0 percent solution of sodium thiamylal.

(2) *Sponsor.* See No. 000010 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* It is used in dogs, as follows:

(*i*) (*a*) To induce anesthesia,

(*b*) For short periods of anesthesia (10 to 15 minutes), and

(*c*) As an additional dosage of anesthetic when needed in major surgery.

(ii) An initial dose of approximately 8 milligrams per pound of body weight is administered. Additional dosages are given at approximately one-fourth of the initial dose.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) (1) *Specifications.* Sodium thiamylal for injection is a sterile dry powder containing a mixture of sodium thiamylal and anhydrous sodium carbonate. It includes directions for adding the necessary amount of sterile distilled water to produce a 0.5 to 4 percent solution of sodium thiamylal.

(2) *Sponsor.* See No. 000071 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* The drug is used either as the sole intravenous anesthetic agent for major and minor surgery or for intubation and induction of anesthesia prior to the administration of a volatile anesthetic as follows:

(i) The drug is administered to initially anesthetize an average-sized dog or cat in an approximate quantity calculated on the basis of 40 milligrams per 5 pounds of body weight. Young animals may require a larger dose than do older animals. Lower dosage is generally applicable to larger and older animals, those in poor physical condition, and brachiocephalic breeds.

(ii) It is administered to horses directly into the jugular vein for light anesthesia, it is administered at 1 gram to animals weighing from 500 to 1,100 pounds. For deeper anesthesia, it is administered at a dosage of 40 milligrams per 12 pounds of body weight; supplemental volatile liquid or gas may be used if desired to prolong anesthesia.

(iii) It is administered to swine at 40 milligrams per 5 pounds of body weight. It is administered either into the anterior vena cava or into the external ear vein, depending upon the size of the animal.

(iv) It is administered to cattle intravenously either at 20 milligrams per 5 pounds of body weight from a 2 percent solution or at 40 milligrams per 7 pounds of body weight from a 4 percent solution.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2444 Sodium thiopental implantation or injectable dosage forms.

§ 522.2444a Sodium thiopental for injection.

(a) *Specifications.* The drug contains sodium thiopental sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 000856 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(2) It is administered as follows:

(i) For brief anesthesia (6 to 10 minutes) a dosage of 6 to 9 milligrams per pound of body weight is suggested.

(ii) To obtain anesthesia of 15 to 25 minutes duration the suggested dosage is 10 to 12 milligrams per pound of body weight.

(iii) Use of a preanesthetic tranquilizer or morphine will decrease the dosage of sodium thiopental required, provide for smoother induction and smoother recovery, and sometimes prolong the recovery period. If morphine is used as a preanesthetic agent the dose of the barbiturate can be reduced as much as 40 to 50 percent. When a tranquilizer is administered the barbiturate dosage can be reduced 10 to 25 percent.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2444b Sodium thiopental, sodium pentobarbital for injection.

(a) *Specifications.* Each gram of the drug contains 750 milligrams of sodium thiopental and 250 milligrams of sodium pentobarbital sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 043731 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(2) It is administered as follows:

(i) For total anesthesia, it is given at approximately 10 to 12 milligrams per pound of body weight over a period of 3.5 to 5 minutes.

(ii) When preanesthetic medication is used, it is important to wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually ½ to ⅔ the normal amount is adequate.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2480 Triamcinolone injection.

(a) *Chemical name.* 9-Fluro-11β,16α, 17,21 - tetrahydroxypregna - 1,4 - diene-3,20-dione.

(b) *Specifications.* Each cubic centimeter of triamcinolone injection contains: 2.5 milligrams of triamcinolone and 10 milligrams of procaine hydrochloride with 0.1 percent of sodium bisulfite and 84.4 percent of polyethylene glycol 400.

(c) *Sponsor.* See No. 010042 in § 510.-600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is indicated for use in dogs and cats for its anti-inflammatory activity.

(2) (i) In dogs, the drug may be given by intramuscular or subcutaneous injection at 0.625 milligram for each 10 pounds of body weight, and, if only one or two injections are anticipated, the dosage may be doubled. It may also be given to dogs by intra-articular administration at from 0.625 milligram to 1.25 milligrams per dose. Repeat dosage as indicated.

(ii) In cats, the drug may be given by intramuscular or subcutaneous injection at 0.625 milligram for each 10 pounds of body weight. It may also be given by intra-articular administration at from 0.31 milligram to 0.625 milligram per dose. Repeat dosage as indicated.

(iii) Since requirements vary with the individual animal, recommended dosage is approximate and must be adjusted to the response of the individual animal. Generally, initial dosages are at a higher range. When response is satisfactory, gradually reduce dosage until a minimum dose is obtained. This is particularly important for long-term medication. If additional treatment or a long-term

treatment is necessary, triamcinolone tablets may be used as a maintenance dosage.

(3) For use by or on the order of a licensed veterinarian.

§ 522.2582 Triflupromazine hydrochloride injection.

(a) *Specifications.* Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

(2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body weight daily to a maximum dose of 100 milligrams.

(3) Not for use in horses intended for food.

(4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentitate the toxicity of organophosphates and the activity of procaine hydrochloride.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2640 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 000986 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use.* It is used for injection into animals as follows:

(1) *Cattle*—(i) *Amount.* 100 to 200 milligrams per 100 pounds of body weight per day.

(ii) *Indications for use.* Treatment of contagious calf pneumonia (pneumoenteritis), diphtheria, foot rot (necrotic pododermatitis), metritis, and pneumonia.

(iii) *Limitations.* Administer intramuscularly for not more than 5 days; do not administer within 8 days of slaughter; when used in milk-producing animals, milk that has been taken during treatment and for 96 hours (8 milkings) after the latest treatment must not be used for food; as tylosin base.

(2) *Chickens*—(i) *Amount.* 25 milligrams per 2 pounds of body weight.

(ii) *Indications for use.* As an aid in the control and treatment of chronic respiratory disease caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Not for use in laying chickens producing eggs for human consumption; inject 25 milligrams per 2 pounds of body weight under the loose skin of the neck behind the head; if no improvement is noted within 5 days, the diagnosis should be reconfirmed; do not inject within 3 days of slaughter; as tylosin tartrate.

(3) *Swine*—(i) *Amount.* 100 to 400 milligrams per 100 pounds of body weight per day.

(ii) *Indications for use.* Treatment of erysipelas, pneumonia, dysentery (vibrionic), arthritis due to pleuro-pneumonia-like organisms.

(iii) *Limitations.* Administer intramuscularly for not more than 3 days, do not administer within 4 days of slaughter; as tylosin base.

(4) *Turkeys*—(i) *Amount.* 6.25 to 12.5 milligrams per sinus.

(ii) *Indications for use.* As an aid in the control and treatment of infectious sinusitis caused by *Mycoplasma gallisepticum* sensitive to tylosin.

(iii) *Limitations.* Do not use in laying turkeys producing eggs for human consumption; inject 6.25 milligrams or 12.5 milligrams per sinus, depending on severity of condition, treatment may be repeated in 10 days if the swelling persists; do not inject within 5 days of slaughter; as tylosin tartrate; may be used in conjunction with tylosin in drinking water as indicated in § 520.2640(e)(2) of this chapter.

§ 522.2662 Xylazine hydrochloride injection.

(a) *Specifications.* Xylazine hydrochloride injection is a sterile aqueous solution containing xylazine hydrochloride equivalent to 100 milligrams of xylazine in each milliliter of solution when intended for use in horses and containing 20 milligrams of xylazine per milliliter of solution when intended for use in dogs and cats.

(b) *Sponsor.* See No. 000859 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in horses, dogs, and cats to produce sedation, as an analgesic, and a preanesthetic to local or general anesthesia.

(2) It is administered as follows:

(i) To horses from a solution containing 100 milligrams of xylazine hydrochloride per milliliter intravenously at 0.5 mg. per 100 pounds of body weight or intramuscularly at 1.0 mg. per 100 pounds of body weight.

(ii) To dogs and cats from a solution containing 20 milligrams of xylazine hydrochloride per milliliter intravenously at 0.5 mg. per pound of body weight or intramuscularly or subcutaneously at 1.0 mg. per pound of body weight. In dogs over 50 pounds, a dosage of 0.5 mg. per pound administered intramuscularly may provide sufficient sedation and/or analgesia for most procedures.

(3) Not to be administered to food-producing animals.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.2680 Zeranol.

(a) *Chemical name.* 6 - (6,10 - Dihydroxyundecyl) - β - resorcylic acid - μ - lactone ($C_{18}H_{26}O_5$).

(b) *Specifications.* (1) Melting point range 181°–185° C.

(2) Ultraviolet absorbance: A solution of zeranol in methanol having a concentration of 10 micrograms per milliliter exhibits three maxima at approximately 218, 265, and 304 μ.

(c) *Sponsor.* See No. 012769 in § 510.-600(c) of this chapter.

(d) [Reserved]

(e) *Related tolerances.* See § 556.760 of this chapter.

(f) *Conditions of use.* It is used for subcutaneous ear implantation in animals as follows:

(1) *Beef cattle*—(i) *Amount.* Three 12-milligram implants per dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* For beef cattle (including weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers); do not implant animals within 65 days of slaughter.

(2) *Feedlot lambs*—(i) *Amount.* One 12-milligram implant per dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* Do not implant animals within 40 days of slaughter.

(3) *Suckling beef calves*—(i) *Amount.* Three 12-milligram implants per dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Do not implant animals within 65 days of slaughter.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Sec.

524.321 Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment.
524.402 Chlorhexidine diacetate ointment.
524.463 Copper naphthenate solution.
524.520 Cuprimyxin cream.
524.541 Dexamethasone acetate, nitrofurathiazide, grisofulvin, undecylenic acid, tetracaine hydrochloride otic suspension.
524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.
524.660a Dimethyl sulfoxide solution.
524.660b Dimethyl sulfoxide gel.
524.900 Famphur.
524.920 Fenthion.
524.960 Flumethasone, neomycin sulfate and polymyxin B sulfate ophthalmic solution.
524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.
524.981a Fluocinolone acetonide cream.

Sec.
524.981b Fluocinolone acetonide solution.
524.981c Fluocinolone acetonide, neomycin sulfate cream.
524.981d Fluocinolone acetonide, dimethyl sulfoxide solution.
524.981e Fluocinolone acetonide, dimethyl sulfoxide otic solution.
524.1000 Flurandrenolide with neomycin sulfate ointment.
524.1044 Gentamicin sulfate, betamethasone valerate otic solution.
524.1200 Kanamycin ophthalmic and topical dosage forms.
524.1200a Kanamycin ophthalmic ointment.
524.1200b Kanamycin ophthalmic aqueous solution.
524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.
524.1301 Mafenide acetate and nitrofurazone aerosol powder.
524.1443 Miconazole nitrate cream; miconazole nitrate lotion.
524.1484 Neomycin sulfate ophthalmic and topical dosage forms.
524.1484a Neomycin sulfate ophthalmic ointment.
524.1484b Neomycin sulfate, 9-fluoroprednisolone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.
524.1484c Neomycin sulfate, 9-fluoroprednisolone acetate, tetracaine hydrochloride ointment.
524.1484d Neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride ear ointment.
524.1484e Neomycin sulfate and polymyxin B sulfate ophthalmic solution.
524.1484f Neomycin sulfate, prednisolone acetate, tetracaine hydrochloride eardrops.
524.1484g Neomycin sulfate-thiabendazole-dexamethasone solution.
524.1580 Nitrofurazone - nifuroxime diperodon hydrochloride ear solution.
524.1600 Nystatin ophthalmic and topical dosage forms.
524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.
524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ophthalmic ointment.
524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.
524.1662a Oxytetracycline hydrochloride and hydrocortisone spray.
524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.
524.1695 Pancreatic dornase.
524.1742 N-(Mercaptomethyl) phthalimide S-(0,0-dimethyl phosphorodithioate) emulsifiable liquid.
524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.
524.1881 Prednisolone acetate ophthalmic and topical dosage forms.
524.1881a Prednisolone acetate, sodium sulfacetamide, neomycin ointment.
524.1881b Prednisolone acetate - neomycin sulfate sterile suspension.
524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.
524.1982 Proparacaine hydrochloride ophthalmic solution.
524.2140 Squalane, pyrethrins and piperonyl butoxide.
524.2481 Triamcinolone acetonide cream.
524.2542 Triethanolamine polypeptide oleate-condensate otic solution.
524.2620 Liquid crystalline trypsin, peru balsam, castor oil.
524.2640 Tylosin, neomycin eye powder.

AUTHORITY: Sec. 512(i), (n), 82 Stat. 347, 350–351 (21 U.S.C. 360b(i), (n)).

§ 524.321 Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment.

(a) *Specifications.* Each gram of the drug contains 10 milligrams cephalonium, 5,000 units polymyxin B sulfate, 0.25 milligram flumethasone, 30 milligrams iodochlorhydroxyquin, and 40 milligrams piperocaine hydrochloride in a suitable and harmless ointment base.

(b) *Sponsor.* See No. 000986 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* The drug is recommended for dermal and otic use on dogs and cats for the treatment of the following conditions when complicated by bacteria, yeast, or fungus: Pyodermatitis, allergic dermatitis, dermatophytosis, nonspecific pruritus, and external otitis. For mild inflammations a periodic treatment of applying from once daily to twice weekly may be indicated. In severe conditions apply once or twice daily when continuous treatment may be indicated. Dosage per treatment should not exceed 300 milligrams of the ointment. For otic use treatment should not exceed a total of 12 days. For use only by or on the order of a licensed veterinarian.

§ 524.402 Chlorhexidine diacetate ointment.

(a) *Specifications.* The product contains 1 percent of chlorhexidine diacetate in an ointment base.

(b) *Sponsor.* See No. 000856 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used as a topical antiseptic ointment for surface wounds on dogs, cats, and horses.

(2) The wound area is carefully cleansed and the drug is applied daily.

(3) The drug is not to be used in horses intended for use as food.

§ 524.463 Copper naphthenate solution.

(a) *Specification.* The drug contains 37.5 percent copper naphthenate in a suitable solute.

(b) *Sponsor.* See No. 000046 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in the treatment of lesions in horses, cattle, swine, sheep, goats, and dogs including footrot, ringworm, wounds, for drying up superficial sores, for drying necrotic material for subsequent removal, to keep open lesions clean, and for treating udder sores. It is used in cattle for treating heal cracks, hoof punctures, and dehorning wounds. It is used in horses for treating thrush, scratches, and for toughening hooves (spongy). It is used in dogs for treating cracked skin over elbows and for toughening foot pads.

(2) Necrotic material should be removed prior to application if damage is extensive. The drug is applied daily. If a scab is present, the drug should be applied once a day until the scab is easily removed; then the drug is applied every other day until fully healed. After dehorning, the drug is applied to the open wound with a swab.

(3) Do not use on teats of lactating dairy animals.

§ 524.520 Cuprimyxin cream.

(a) *Specifications.* The drug contains 0.5 percent cuprimyxin (6-methoxy-1-phenazinol 5, 10-dioxide, cupric complex) in an aqueous cream base.

(b) *Sponsor.* See No. 000004 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) Cuprimyxin is a broad spectrum antibacterial and antifungal cream for the topical treatment of superficial infections in dogs and cats caused by bacteria, dermatophytes (*Trichophyton spp.; Microsporum spp.*) and yeast (*Candida albicans*) affecting skin, hair, and external mucosae.

(2) The cream is applied twice daily to affected areas by rubbing into lesions. Treatment should be continued for a few days after clinical recovery to avoid possible relapses.

(3) After application to cutaneous areas, a change in color from dark green to pink is due to the liberation of free myxin from its copper complex.

(4) If no response is seen within seven days, diagnosis and therapy should be reevaluated. If any adverse local reaction is observed after topical application, discontinue treatment.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.541 Dexamethasone acetate, nitrofurathiazide, griseofulvin, undecylenic acid, tetracaine hydrochloride otic suspension.

(a) *Specifications.* Dexamethasone acetate, nitrofurathiazide, griseofulvin, undecylenic acid, tetracaine hydrochloride otic suspension contains in each milliliter 0.25 milligram dexamethasone acetate (equivalent to 0.226 milligram dexamethasone alcohol), 2 milligrams nitrofurathiazide, 15 milligrams griseofulvin, 10 milligrams undecylenic acid, 10 milligrams tetracaine hydrochloride.

(b) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the treatment of acute otitis externa and as adjunctive therapy in the treatment of chronic otitis externa complicated by organisms sensitive to griseofulvin, undecylenic acid or nitrofurathiazide in cats.

(2) Four to 10 drops of the drug are instilled into the ear canal. Treatment should be repeated 2 or 3 times daily.

(3) The drug should not be used in conditions where corticosteroids are contraindicated. Do not administer parenteral corticosteroids during treatment with the drug.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

§ 524.660a Dimethyl sulfoxide solution.

(a) *Specifications.* Dimethyl sulfoxide contains 90 percent of dimethyl sulfoxide and 10 percent of water.

(b) *Sponsor.* See No. 000033 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used or intended for use as a topical application to reduce acute swelling due to trauma:

(i) In horses administered 2 or 3 times daily in an amount not to exceed 100 milliliters per day. Total duration of therapy should not exceed 30 days.

(ii) In dogs administered 3 or 4 times daily in an amount not to exceed 20 milliliters per day. Total duration of therapy should not exceed 14 days.

(2) Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food. Other topical medications should only be used when the dimethyl sulfoxide treated area is thoroughly dry. Do not administer by any other route.

(3) For use by or on the order of a licensed veterinarian.

§ 524.660b Dimethyl sulfoxide gel.

(a) *Specifications.* Dimethyl sulfoxide gel, veterinary contains 90 percent dimethyl sulfoxide in an aqueous gel.

(b) *Sponsor.* See No. 000033 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is recommended for use on horses as a topical application to reduce acute swelling due to trauma.

(2) It is administered topically to the skin over the affected area. Liberal application should be administered 2 to 3 times daily. Total daily dosage should not exceed 100 grams. Total duration of therapy should not exceed 30 days.

(3) Not to be administered to horses that are to be slaughtered for food or intended for breeding purposes. For topical application only. Do not administer by any other route. No other medications should be present on the skin prior to application of the drug.

(4) Federal law restricts this drug to used by or on the order of a licensed veterinarian.

§ 524.900 Famphur.

(a) *Chemical name.* *O,O*-Dimethyl *O*-[*p*-(dimethylsulfamoyl)phenyl] phosphorothioate.

(b) *Specifications.* The drug is in liquid form containing 13.2 percent famphur.

(c) *Sponsor.* See No. 010042 in § 510.-600(c) of this chapter.

(d) *Special considerations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(e) *Related tolerances.* See 40 CFR 180.233 under the chemical name.

(f) *Conditions of use.* (1) The drug is used as a pour-on formulation for the control of cattle grubs and to reduce cattle lice infestations.

(2) It is used at the rate of 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, applied from the shoulder to the tail head as a single treatment. It is applied as soon as possible after heel fly activity ceases. Do not use on lactating dairy cows or dry dairy cows within 21 days of freshening, calves less than 3 months old, animals stressed from castration, overexcitement or dehorning, sick or convalescent animals. Animals may become dehydrated and under stress following shipment. Do not treat until they are in good condition. Brahman and Brahman crossbreeds are less tolerant of cholinesterase-inhibiting insecticides than other breeds. Do not treat Brahman bulls.

(3) Do not slaughter within 35 days after treatment. Swine should be eliminated from area where run-off occurs.

§ 524.920 Fenthion.

(a) *Chemical name.* O,O-Dimethyl O-[4-(methylthio)-*m*-tolyl] phosphorothioate.

(b) *Specifications* (1) The drug is in a liquid form containing 3 percent of fenthion.

(2) *Sponsor.* See No. 000859 in § 510.-600(c) of this chapter.

(3) *Special considerations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(4) *Related tolerances.* See 40 CFR 180.214.

(5) *Conditions of use.* (i) The drug is used as a pour-on formulation for the control of grubs and lice in beef and nonlactating cattle.

(ii) It is used at the rate of one-half fluid ounce per 100 pounds of body weight placed on the backline of the animal. Only one application per season should be made for grub control and this will also provide initial control of lice. A second application for lice control may be made if animals become reinfested, but no sooner than 35 days after the first treatment. Proper timing of treatment is important for grub control; cattle should be treated as soon as possible after heelfly activity ceases. Cattle should not be slaughtered within 35 days following a single treatment. If a second application is made for lice control, cattle should not be slaughtered within 45 days of the second treatment. The drug must not be used within 28 days of freshening of dairy cattle. If freshening should occur within 28 days after treatment, do not use milk as human food for the balance of the 28-day interval. Do not treat lactating dairy cattle; calves less than 3 months old; or sick, convalescent, or stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, or dehorning or after exposure to contagious infectious diseases.

(c) *Specifications.* (1) The drug is in a liquid form containing 20 percent fenthion.

(2) *Sponsor.* See No. 000859 in § 510.-600(c) of this chapter.

(3) *Special considerations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(4) *Related tolerances.* See 40 CFR 180.214.

(5) *Conditions of use.* (i) The drug is applied using an automatic syringe for the control of grubs in beef and nonlactating dairy cattle.

(ii) It is used on the backline of the animals at the following rate per animal:

Weight range	*Dosage*
150–300 lbs	4 ml.
301–600 lbs	8 ml.
601–900 lbs	12 ml.
901–1,200 lbs	16 ml.
1,201 lbs. and above	20 ml.

Only one application should be made per season, and it should be made as soon as possible after heelfly activity has ceased and at least 6 weeks prior to appearance of grubs in the back. Do not slaughter within 45 days of treatment. Do not treat dairy cattle of breeding age; calves less than 3 months old; or sick, convalescent, or severely stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, or dehorning or after exposure to contagious or infectious diseases.

§ 524.960 Flumethasone, neomycin sulfate and polymyxin B sulfate ophthalmic solution.

(a) *Specifications.* Each milliliter of the ophthalmic preparation contains 0.10 milligram flumethasone, 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 units of polymyxin B sulfate.

(b) *Sponsor.* See No. 000033 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for the treatment of the inflammation, edema and secondary bacterial infections associated with topical ophthalmological conditions of the eye such as corneal injuries, incipient pannus, superficial keratitis, conjunctivitis, acute nongranulomatous anterior uveitis, keratoconjunctivitis, and blepharitis in the dog.

(2) The recommended dosage is 1 to 2 drops in each eye every 6 hours.

(3) In treating ophthalmological conditions associated with bacterial infections, the drug is contraindicated in those cases in which microorganisms are not susceptible to the antibiotics incorporated in the drug.

(4) The drug is contraindicated in infectious tuberculous lesions of the eye, early acute stages of viral diseases of the cornea and conjunctiva, herpes simplex lesions of the eye, and fungal infections of the conjunctiva and eyelids.

(5) The usual precautions and contraindications for corticosteroids and adrenocorticoids are applicable with this drug. Corticosteroids may inhibit essential inflammatory responses intrinsic to the fundamental healing mechanism. Adrenocorticoid compounds have been reported to cause an increase in intraocular pressure. Intraocular pressure should be checked frequently. Ocular reexaminations should be made at frequent intervals during long-term therapy.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.

§ 524.981a Fluocinolone acetonide cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the relief of pruritus and inflamation associated with certain superficial acute and chronic dermatoses in dogs. It is used in the treatment of allergic and acute moist dermatitis and for the relief of superficial inflammation caused by chemical and physical abrasions and burns.

(2) A small amount is applied to the affected area two or three times daily.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.981b Fluocinolone acetonide solution.

(a) *Specifications.* The drug contains 0.01 percent fluocinolone acetonide in propylene glycol with citric acid.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the relief of pruritus and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses in the dog. It is also indicated for the relief of pruritus and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses in the cat.

(2) A small amount of solution is applied to the affected area 2 or 3 times daily.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.981c Fluocinolone acetonide, neomycin sulfate cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide and 0.5 percent neomycin sulfate (0.35 percent neomycin base).

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in the relief of pruritis and inflammation associated with superficial acute and chronic dermatoses in dogs. It is used in the treatment of such conditions as allergic and acute moist dermatoses and nonspecific dermatoses in dogs. It is used in the treatment of wound infections in dogs and cats.

(2) A small amount is applied to the infected area two or three times daily.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.981d Fluocinolone acetonide, dimethyl sulfoxide solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent fluocinolone acetonide and 20 percent dimethyl sulfoxide with propylene glycol and citric acid.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs for the relief of impaction commonly present in apparently normal anal sacs, for the reversal of inflammatory changes associated with abnormal anal sacs, and to counteract the offensive odor of anal sac secretions.

(2) It is administered by instillation of 1 to 2 milliliters into each anal sac following expression of anal sac contents. It may be necessary to repeat treatment at 60-day intervals to maintain an odor-free state. The total dosage used should not exceed 2 milliliters per anal sac per treatment.

(3) For use only by or on the order of a licensed veterinarian.

§ 524.981e Fluocinolone acetonide, dimethyl sulfoxide otic solution.

(a) *Specifications.* Each milliliter of solution contains 0.01 percent of fluocinolone acetonide in 60 percent dimethyl sulfoxide with propylene glycol and citric acid.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs for the relief of pruritis and inflammation associated with acute and chronic otitis.

(2) It is administered at 4 to 6 drops (0.2 milliliter) twice daily into the ear canal for a maximum period of 14 days. The total dosage used should not exceed 17 milliliters. The ear canal should be cleansed by some appropriate method prior to instillation of the solution and the ear should be massaged gently following instillation.

(3) There should be careful initial evaluation and followup of infected ears. Incomplete response or exacerbation of corticosteroid-responsive lesions may be due to the presence of an infection which requires identification or antibiotic sensitivity testing, and the use of the appropriate antimicrobial agent. As with any corticosteroid, animals with a generalized infection should not be treated with this product without proper supportive antimicrobial therapy. Preparations with dimethyl sulfoxide should not be used in pregnant animals. For use by or on the order of a licensed veterinarian.

§ 524.1000 Flurandrenolide with neomycin sulfate ointment.

(a) *Specifications.* Each gram of flurandrenolide with neomycin sulfate ointment contains: 0.5 milligram of flurandrenolide and 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base) in a bland hydrophilic ointment base.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use on dogs for the topical management of allergic dermatitis, otitis externa, and superficial pyoderma which may be expected to respond to corticosteroids and which may be threatened or complicated by bacterial infections. The drug is applied to the affected areas 2 or 3 times daily until all evidence of infection has disappeared.

(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1044 Gentamicin sulfate, betamethasone valerate otic solution.

(a) *Specifications.* Each cubic centimeter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin base and betamethasone valerate equivalent to 1 milligram of betamethasone alcohol.

(b) *Sponsor.* See No. 000085 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used or indicated for use in dogs in the treatment of acute and chronic otitis externa caused by bacteria sensitive to gentamicin; the drug is also used or indicated for use in dogs and cats in the treatment of superficial infected lesions caused by bacteria sensitive to gentamicin.

(2) (i) For the treatment of acute and chronic canine otitis externa caused by bacteria sensitive to gentamicin, the drug is administered by instillation of 3 to 8 drops of solution into the ear canal twice daily for 7 to 14 days. Duration of treatment will depend upon the severity of the condition and the response obtained. The duration of treatment and/or frequency of the dosage may be reduced but care should be taken not to discontinue therapy prematurely. The external ear and ear canal should be properly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area of the external ear.

(ii) For the treatment of canine and feline superficial infected lesions caused by bacteria sensitive to gentamicin, the lesion and adjacent area should be properly cleaned before treatment. Excessive hair should be removed. A sufficient amount of the drug should be applied to cover the treatment area. The drug should be administered twice daily for 7 to 14 days.

(3) If hypersensitivity to any of the components occurs treatment with this product should be discontinued and appropriate therapy instituted. Concomitant use with other drugs known to induce ototoxicity is not recommended. This preparation should not be used in conditions where corticosteroids are contraindicated. Do not administer parenteral corticosteroids during treatment with this drug. The antibiotic sensitivity of the pathogenic organism should be determined prior to use of this preparation.

(4) For use by or on the order of a licensed veterinarian.

§ 524.1200 Kanamycin ophthalmic and topical dosage forms.

§ 524.1200a Kanamycin ophthalmic ointment.

(a) *Specifications.* (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by § 444.30 of this chapter.

(2) The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

(b) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used treating conditions such as conjunctivitis, blepharitis, dacryocystitis,

keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued for at least 48 hours after the eye appears normal. For use only by or on the order of a licensed veterinarian.

§ 524.1200b Kanamycin ophthalmic aqueous solution.

(a) *Specifications.* (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by § 444.30 of this chapter.

(2) The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10.0 milligrams of kanamycin activity (as the sulfate) per cubic centimeter of solution.

(b) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used in treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Instill a few drops into the affected eye every 3 hours or more frequently if deemed advisable. Administer as frequently as possible for the first 48 hours, after which the frequency of applications may be decreased. Treatment should be continued for at least 48 hours after the eye appears normal. For use only by or on the order of a licensed veterinarian.

§ 524.1204 Kanamycin sulfate, calcium amphomycin, and hydrocortisone acetate.

(a) *Specifications.* (1) The kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by § 444.30(a)(1) of this chapter.

(2) The calcium amphomycin used conforms to the standards of identity, strength, quality, and purity prescribed by § 455.3(a)(1) of this chapter.

(3) The drug is in a water-miscible ointment or cream base and each gram of ointment or cream contains: 5.0 milligrams of kanamycin activity as the sulfate, 5.0 milligrams of amphomycin activity as the calcium salt, and 10.0 milligrams of hydrocortisone acetate.

(b) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs in the following conditions associated with bacterial infections caused by organisms susceptible to one or both antibiotics: Acute otitis externa, furunculosis, folliculitis, pruritus, anal gland infections, erythema, decubital ulcer, superficial wounds, and superficial abscesses.

(2) The ointment should be applied to the affected areas of the skin at least twice daily. In severe or widespread lesions it may be desirable to apply the ointment more than twice daily. After some improvement is observed, treatment can usually be reduced to once daily. Before application, hair in the affected area should be closely clipped and the area should be thoroughly cleansed of crusts, scales, dirt, or other detritus. When treating infections of the anal gland, the drug should be introduced into the orifice of the gland and not through any fistulous tract. If no response is evident in 7 days, diagnosis and therapy should be reevaluated.

(3) For use only by or on the order of a licensed veterinarian.

§ 524.1301 Mafenide acetate and nitrofurazone aerosol powder.

(a) *Specifications.* The product is in an aerosol preparation which contains 6.61 percent of mafenide acetate and 0.12 percent of nitrofurazone as active ingredients.

(b) *Approvals.* To No. 000024 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is intended for topical application to dogs for the prophylactic and therapeutic treatment of wound infections and pyogenic dermatitis caused by a variety of gram-positive and gram-negative bacteria including *Staphylococcus sp., Streptococcus sp., Proteus sp., Pseudomonas sp., Escherichia coli* and *Aerobacter aerogenes,* and virulent strains of *Pseudomonas aeruginosa.*

(2) After cleansing the area to be treated, apply a light coat of the drug. Use once or twice daily, usually for up to 5 days.

(3) Avoid application to eyes.

(4) Occasional transitory local reactions (irritation) may occur.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1443 Miconazole nitrate cream; miconazole nitrate lotion.

(a) *Specifications.* (1) Miconazole is 1-[2,4-dichloro-β-(2,4-dichlorobenzyloxy) phenethyl]imidazole.

(2) The cream contains 23 milligrams of miconazole nitrate (equiv. to 20 mg of miconazole base) per gram.

(3) The lotion contains 1.15 percent of miconazole nitrate (equiv. to 1 percent miconazole base).

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Miconazole nitrate is an antifungal agent for topical treatment of infections in dogs and cats caused by *Microsporum canis, Microsporum gypseum,* and *Trichophyton mentagrophytes.*

(2) Apply once daily by rubbing into infected site and into immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is completely eradicated as determined by appropriate laboratory examination.

(3) Accurate diagnosis of infecting organism is essential. Identify by microscopic examination of a mounting of infected tissue in potassium hydroxide solution or by culture on an appropriate medium.

(4) If no improvement is observed in 2 weeks, reevaluate diagnosis and therapy.

(5) Avoid contact with eyes since irritation may result.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use in dogs and cats for the treatment of superficial ocular bacterial infections limited to the conjunctival or the anterior segment of the eye.

(2) The drug is applied four times each day.

(3) The drug is applied by inserting the tip of the tube beneath the lower lid and by expressing a small quantity of ointment into the conjunctival sac. The tip of the tube should not come in contact with the eye surface.

(4) Severe infections should be supplemented by systemic therapy.

(5) Prolonged administration of the drug may permit overgrowth of organisms that are not susceptible to neomycin. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken.

§ 524.1484b Neomycin sulfate, 9-fluoroprednisolone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 1 milligram of 9-fluoropredniscione acetate, 5 milligrams of tetracaine hydrochloride and .2 milligram of myristyl-gamma-picolinium chloride in each gram of the product in a special adherent powder base.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses, dogs, and cats in the treatment or adjunctive therapy of certain ear and skin conditions when such conditions are caused by or associated with neomycin-susceptible organisms and/or allergy. In addition the product is indicated as superficial dressing applied to minor cuts, wounds, lacerations, abrasions, and for postsurgical application where reduction of pain and inflammatory response is deemed desirable. The product may be used as a dusting powder following amputation of tails, claws, and dewclaws and following ear trimming, castrating, and such surgical procedures as ovariohysterectomies. The product may also be used in the treatment of acute otitis externa in dogs, acute moist dermatitis and interdigital dermatitis in dogs.

(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1484c Neomycin sulfate, 9-fluoroprednisolone acetate, tetracaine hydrochloride ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base), 1 milligram of 9-fluoroprednisolone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in treating such conditions as acute otitis externa in dogs and to a lesser degree, chronic otitis externa in dogs. It also is effective in treating anal gland infections and moist dermatitis in the dog and is a useful dressing for minor cuts, lacerations, abrasions, and post-surgical therapy in the horse, cat, and dog. It may also be used following amputation of dewclaws, tails and claws, following ear trimming and castrating operations.

(2) In treatment of otitis externa and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal may be applied one to three times daily. When used on the skin or mucous membranes, the affected area should be cleansed, and a small amount of the ointment applied and spread or rubbed in gently. The involved area may be treated one to three times a day and these daily applications continued in accordance with the clinical response.

(3) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the drug. If such signs are noted, therapy with the drug should be stopped. Treatment should be limited to the period when local anesthesia is essential to control self-inflicted trauma.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1484d Neomycin sulfate, hydrocortisone acetate, tetracaine hydrochloride ear ointment.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 5 milligrams of hydrocortisone acetate, and 5 milligrams of tetracaine hydrochloride in each gram of ointment.

(b) *Sponsor.* See Nos. 011904 and 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for treating acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats. In treatment of ear canker and other inflammatory conditions of the external ear canal, a quantity of ointment sufficient to fill the external ear canal may be applied one to three times daily.

(2) Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy to the product. If such signs are noted, therapy with the product should be stopped. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1484e Neomycin sulfate and polymyxin B sulfate ophthalmic solution.

(a) *Specifications.* Each milliliter of the ophthalmic preparation contains 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 Units of polymyxin B sulfate.

(b) *Sponsor.* See No. 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for the treatment of bacterial infections associated with topical ophthalmological conditions such as corneal injuries, superficial keratitis, conjunctivitis, keratoconjunctivitis, and blepharitis in the dog.

(2) The recommended dosage is 1 to 2 drops per eye every 6 hours.

(3) In treating ophthalmological conditions associated with bacterial infections the drug is contraindicated in those cases in which microorganisms are nonsusceptible to the antibiotics incorporated in the drug.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1484f Neomycin sulfate, prednisolone acetate, tetracaine hydrochloride eardrops.

(a) *Specifications.* The product contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, 2.5 milligrams of prednisolone acetate, and 5 milligrams of tetracaine hydrochloride in each milliliter of sterile suspension.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is useful in treating such conditions as acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats. It is indicated as treatment or adjunctive therapy of certain ear conditions in dogs and cats caused by or associated with neomycin-susceptible organisms and/or allergy. In otitis externa, 2 to 6 drops may be placed in the external ear canal two or three times daily.

(2) Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use of antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly Monilia. Thus, if improvement is not noted within 2 or 3 days, or if redness, irritation, or swelling persists or increases, the diagnosis should be redetermined and appropriate therapeutic measures initiated. Tetracaine and neomycin have the potential to sensitize. Care should be taken to observe animals being treated for evidence of hypersensitivity or allergy. If such signs are noted, therapy should be stopped.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1484g Neomycin sulfate-thiabendazole-dexamethasone solution.

(a) *Specifications.* Each cubic centimeter of neomycin sulfate-thiabendazole-dexamethasone solution contains: 40 milligrams of thiabendazole, 3.2 milligrams of neomycin (from neomycin sulfate), and 1 milligram of dexamethasone.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use as an aid in the treatment of bacterial, mycotic, and inflammatory dermatoses and otitis externa in dogs and cats.

(2) In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (two to four drops per square inch) twice daily. In treating otitis externa, five to 15 drops of the drug should be instilled in the ear twice daily. The drug is limited to 7 days maximum duration of administration.

(3) For use only by or on order of a licensed veterinarian.

§ 524.1580 Nitrofurazone - nifuroxime-diperodon hydrochloride ear solution.

(a) *Specifications.* Nitrofurazone-nifuroxime-diperodon hydrochloride ear solution contains on a weight-in-weight basis 0.2 percent nitrofurazone; 0.375 percent nifuroxime, and 2 percent diperodon hydrochloride in a water soluble vehicle.

(b) *Sponsor.* See No. 000035 in § 510.600(c) of this chapter.

(c) *Conditions of use.* The drug is recommended for use in dogs in the treatment of bacterial ear infections caused by organisms sensitive to nitrofurazone and/or nifuroxime. It is administered two or three times daily. The drug is not intended for prolonged use. Sensitivity to the drug may develop. If redness, irritation, or swelling persists or increases, use of the drug should be discontinued and a veterinarian consulted.

§ 524.1600 Nystatin ophthalmic and topical dosage forms.

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units thiostrepton, and 1.0 milligram of triamcinolone acetonide.

(b) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for local therapy as an anti-inflammatory, antipruritic, antifungal, and antibacterial ointment for the topical therapy of cutaneous disorders in cats and dogs. It is used in the treatment of acute and chronic otitis of varied etiologies, in interdigital cysts in

cats and dogs, and in anal gland infections in dogs. It is also indicated in the management of dermatologic disorders characterized by inflammation and dry or exudative dermatitis particularly those caused, complicated, or threatened by bacterial or candidal (Candida albicans) infections. It is also used in eczematous dermatitis, contact dermatitis, and seborrheic dermatitis and as an adjunct in the treatment of dermatitis due to parasitic infestation.

(2) It is to be administered as follows:

(i) For otitis: Clean ear canal of impacted cerumen. Inspect canal and remove any foreign bodies such as grass, awns, ticks, etc. Instill three to five drops of ointment. Preliminary use of a local anesthetic may be advisable.

(ii) For infected anal glands, cystic areas, etc.: Drain gland or cyst and then fill with ointment.

(iii) For other dermatologic disorders: Clean affected areas and remove any encrusted discharge or exudate. Apply ointment sparingly in a thin film.

(iv) Frequency of administration is dependent upon the severity of the condition. For mild inflammations, application may range from once daily to once a week; for severe conditions the ointment may be applied as often as two to three times daily. Frequency of treatment may be decreased as improvement occurs.

§ 524.1600b Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ophthalmic ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thiostrepton, and 1.0 milligram of triamcinolone acetonide.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for ophthalmic use as an anti-inflammatory, antipruritic, antifungal (Candida albicans), and antibacterial ointment for local therapy in keratitis and conjunctivitis in cats and dogs and for infectious keratoconjunctivitis (pink eye) in cattle.

(2) It is to be administered as follows:

(i) For conjunctivitis and keratitis: Apply one drop of ointment to the affected eye(s) two or three times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) For bovine infectious keratoconjunctivitis: Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iii) Frequency of administration is dependent on the severity of the condition. For mild inflammations, applications may range from once daily to once a week; for severe conditions the drug may be applied as often as two to three times daily. Frequency of treatment may be decreased as improvement occurs.

(3) For use only by or on the order of a licensed veterinarian.

§ 524.1662 Oxytetracycline hydrochloride ophthalmic and topical dosage forms.

§ 524.1662a Oxytetracycline hydrochloride and hydrocortisone spray.

(a) *Specifications.* Each 3-ounce unit of oxytetracycline hydrochloride and hydrocortisone spray contains 300 milligrams of oxytetracycline hydrochloride and 100 milligrams of hydrocortisone with an inert freon propellant such that a 1-second spray treatment will deliver approximately 2.5 milligrams of oxytetracycline hydrochloride and 0.8 milligram of hydrocortisone.

(b) *Sponsor.* See No. 000069 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for relief of discomfort and continued treatment of many allergic, infectious, and traumatic skin conditions. The indications include prevention of bacterial infections in superficial wounds, cuts, and abrasions, treatment of allergic dermatoses, including urticaria, eczemas, insect bites, and cutaneous drug reactions, infections associated with minor burns and wounds, and nonspecific pruritus in dogs and cats.

(2) A small quantity should be sprayed on the affected surface by holding the container about 6 inches from the area to be treated and pressing the nozzle for 1 or 2 seconds. Only sufficient spray to coat the skin thinly is necessary. The application of small amounts at frequent intervals will give best results. Before treating animals with long or matted hair, it may be necessary to clip the affected area or spread the hairs to allow the medication to contact the skin surface. Relief may be noted following the first or second treatment; however, treatment should not be discontinued too soon after the initial favorable response has been obtained.

(3) Keep away from eyes or other mucous membranes; avoid inhaling; use with adequate ventilation; in case of deep or puncture wounds or serious burns, consult a veterinarian.

§ 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracyline and 10,000 units of polymyxin B sulfate.

(b) *Sponsor.* See No. 000069 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae, *E. coli*, and *A. aerogenes* (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in dogs, cats, cattle, sheep, and horses); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other infectious diseases in dogs, cats, cattle, sheep, and horses.

(2) It is administered topically to the eye two to four times daily.

(3) Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

§ 524.1695 Pancreatic dornase.

(a) *Specifications.* Pancreatic dornase is the enzyme desoxyribonuclease extracted from beef pancreas and lyophilized. It is sterile and packaged in vials containing 100,000 units of the drug.

(b) *Sponsor.* See No. 000006 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The drug should be maintained under refrigeration and used immediately upon reconstitution.

(d) *Conditions of use.* (1) It is used for enzymatic debridement of pathologic conditions in animals.

(2) The drug is reconstituted with sterile water for injection or with sodium chloride injection. The usual dosage is 50,000 to 100,000 units of reconstituted pancreatic dornase alone or with an antibiotic. It is administered as an irrigation or as a wet dressing or is injected directly into the infected area.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1742 *N*-(Mercaptomethyl) phthalimide *S*-(*O*,*O*-dimethyl phosphorodithioate) emulsifiable liquid.

(a) *Specifications.* The emulsifiable liquid contains 11.6 percent *N*-(mercaptomethyl) phthalimide *S*-(*O*,*O*-dimethyl phosphorodithioate).

(b) *Sponsor.* See No. 017032 in § 510.-600(c) of this chapter.

(c) *Conditions of use*—(1) *Methods of application.* Methods of application to control the following conditions on beef cattle:

To control:	*Method of use*
Grubs	Dip, pour-on, or spray.
Lice	Dip, pour-on, or spray.
Hornflies	Spray.
Cattle ticks	Dip or spray.
Southern cattle ticks.	Dip or spray.

(i) *Dip vat procedure.* (*a*) Prior to charging vat, empty old contents and thoroughly clean the vat. Add water to the vat. Add the drug at a rate of 1 gallon to each 60 gallons water. Add triple super phosphate at a rate of 100 pounds per 1,000 gallons of vat solution. Super phosphate is added to control the pH of the solution and insure vat stability. Super phosphate is usually available at most fertilizer dealers as 0–45–0, or 0–46–0. Stir the vat thoroughly, preferably with a compressed air device; however, any form of thorough mixing is adequate. Re-stir vat contents prior to each use. During the dipping operation, each time the vat's volume is reduced by ¼ of its initial volume, replenish the vat with

water and add the drug at a rate of 1 gallon for each 50 gallons water added. Also add super phosphate at a rate of 10 pounds per 100 gallons of additional solution. Stir well and resume dipping. Repeat replenishment process as necessary. For evaporation, add additional water accordingly. For added water due to rainfall, merely replenish vat with the product according to directions.

(b) Vat should be emptied, cleaned, and recharged each time one of the following occurs: When the vat has been charged for 60 days. When the dip becomes too foul for satisfactory use, within the 60-day limit. If the number of animals dipped equals the number of gallons of the initial bath volume, within the 60-day limit.

(ii) *Spray method.* To prepare the spray, mix 1 gallon of the drug with 49 gallons of water and stir thoroughly. Apply the fresh mixture as a high-pressure spray, taking care to wet the skin, not just the hair. Apply to the point of "runoff", about 1 gallon of diluted spray per adult animal. Lesser amounts will permit runoff for younger animals.

(iii) *Pour-on method.* Dilute 1 part of the drug with 2 parts of water by slowly adding the water to the product while stirring. Apply 1 ounce of the diluted mixture per 100 pounds of body weight (to a maximum of 8 ounces per head) down the center line of the back.

(2) *Timing of applications for cattle grub control.* For optimum cattle grub control, it is important to treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal, as the rapid kill of large numbers of larvae in these tissues may cause toxic side effects such as bloat, salivation, staggering, and paralysis.

(3) *Warnings.* The drug is a cholinesterase inhibitor. Do not use this drug on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not apply within 21 days of slaughter. For use on beef cattle only. Do not treat sick, convalescent, or stressed cattle, or calves less than 3 months old except in Federal or State eradication programs where immediate treatment of all animals in an infested herd is mandatory. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip excessively thirsty animals. Do not dip animals when overheated. Repeat treatment as necessary but not more often than every 7 to 10 days. Treatment for lice, ticks, and hornflies may be made any time of the year except when cattle grub larvae are in the gullet or spinal canal. Treatment for lice and ticks may be made any time 7 to 10 days following treatment for grubs. Do not treat grubs when the grub larvae are in the gullet or spinal canal. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear rubber gloves, goggles, and protective clothing. In case of skin contact, wash immediately with soap and water; for eyes, flush with water. Wash all contaminated clothing with soap and hot water before re-use.

(d) *Related tolerances.* See 40 CFR § 180.261.

§ 524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Prednisolone-neomycin sulfate ophthalmic ointment contains 2 milligrams prednisolone and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

(b) *Sponsor.* See No. 017030 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* The drug is recommended for use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye of cats and dogs, such as those associated with allergic reactions or gross irritants. A small quantity of the ointment should be expressed into the conjunctival sac four times a day for 7 days. After 7 days, if clinical improvement is not noted, reevaluation of the diagnosis should be considered. All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. For use only by or on the order of a licensed veterinarian.

§ 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.

§ 524.1881a Prednisolone acetate, sodium sulfacetamide, neomycin ointment.

(a) *Specifications.* Each gram of ointment contains 5 milligrams of prednisolone acetate, 100 milligrams of sodium sulfacetamide, and 2.5 milligrams of neomycin sulfate (equivalent to 1.75 milligrams of neomycin base) in a white petrolatum and mineral oil base.

(b) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for treating external eye and ear infections caused by bacteria sensitive to neomycin or sodium sulfacetamide and the inflammation, edema, and allergy which often accompany these conditions in dogs and cats.

(2) Application of the drug for eye and ear purposes should be made frequently, a thin film should be applied three or four times daily. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of application.

(3) All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and regeneration is well underway.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.

(a) *Specifications.* Prednisolone acetate-neomycin sulfate sterile suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base) in each milliliter of sterile suspension.

(b) *Sponsor.* See No. 000009 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa in dogs and cats.

(2) For beginning treatment of acute ocular inflammations 1 or 2 drops may be placed in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, the dosage may be reduced to 1 drop 2 to 4 times daily. In otitis externa, 2 to 6 drops may be placed in the external ear canal 2 or 3 times daily.

(3) All topical ophthalmic preparations containing corticosteroids with or without an anti-microbial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment contains prednisolone sodium phosphate equivalent to 2.5 milligrams prednisolone 21-phosphate and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

(b) *Sponsor.* See No. 000006 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye of cats and dogs, such as those associated with allergic reactions or gross irritants.

(2) A small quantity of the ointment should be expressed into the conjunctival sac 4 times a day (at intervals of 1 to 8 hours) for a few days until there is a favorable response, then the frequency of application may be reduced to twice daily as long as the condition remains under control. Treatment may require from a few days to several weeks.

(3) All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway.

(4) For use only by or on the order of a licensed veterinarian.

§ 524.1982 Proparacaine hydrochloride ophthalmic solution.

(a) *Specifications.* The drug is an aqueous solution containing 0.5 percent proparacaine hydrochloride, 2.45 percent glycerin as a stabilizer, and 0.2 percent chlorobutanol (choral derivative) and 1:10,000 benzalkonium chloride as preservatives.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Special considerations.* The long-term toxicity of proparacaine is unknown. Prolonged use may possibly delay wound healing.

(d) *Conditions of use.* (1) The drug is indicated for use as a topical ophthalmic anesthetic in animals. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected. Local applications may also be used as an aid in the removal of foreign bodies from the nose and ear canal, as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(2) It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to 10 drops in the ear; for nasal use, instill five to 10 drops in each nostril every 3 minutes for three doses.

(iii) For tonometry: Instill one to two drops immediately before measurement.

(iv) As an aid intreatment of otitis: Instill two drops into the ear every 5 minutes for three doses.

(v) For minor surgery: Instill one or more drops as required.

(vi) For catheterization: Instill two to three drops with a blunt 20-gauge needle immediately before inserting catheter.

(3) For use only by or on the order of a licensed veterinarian.

§ 524.2140 Squalane, pyrethrins and piperonyl butoxide.

(a) *Specifications.* The drug contains 25 percent squalane (hexamethyltetracosane), 0.05 percent pyrethrins and 0.50 percent technical piperonyl butoxide.

(b) *Sponsor.* See No. 017030 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the treatment of ear mites in dogs and cats.

(2) It is administered as follows: Cats and dogs 5–15 pounds body weight, 4 to 5 drops in each ear daily. Dogs 16–30 pounds body weight, 5 to 10 drops in each ear daily. Dogs 30 pounds body weight and over 10 to 15 drops in each ear daily. The recommended treatment is for 7 to 10 days with repeated treatment in 2 weeks if necessary.

§ 524.2481 Triamcinolone acetonide cream.

(a) *Specifications.* Triamcinolone acetonide cream contains 0.1 percent triamcinolone acetonide in an aqueous vanishing cream base.

(b) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use on dogs as an anti-inflammatory, antipruritic, and antiallergic agent for topical treatment of allergic dermatitis and summer eczema.

(2) The drug is applied by rubbing into affected areas two to four times daily for 4 to 10 days.

(3) For use only by or on the order of a licensed veterinarian.

§ 524.2542 Triethanolamine polypeptide oleate-condensate otic solution.

(a) *Specifications.* The drug contains 10 percent triethanolamine polypeptide oleate-condensate in propylene glycol with 0.5 percent chlorobutanol.

(b) *Sponsor.* See No. 000034 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats to help remove excess or impacted earwax.

(2) Tilt the animal's head to the side and fill the external auditory canal with the drug. Allow the drug to remain in contact for 15 to 30 minutes; then gently flush the ear with warm water. Repeat if needed.

(3) A veterinarian should be consulted if the animal has a history of allergy including skin sensitivity or if ear irritation occurs or if earwax remains after three instillations of the drug.

§ 524.2620 Liquid crystalline trypsin, peru balsam, castor oil.

(a) *Specifications.* The drug is a liquid for direct application or as an aerosol preparation formulated so that each gram delivered to the wound site contains 0.12 milligram of crystalline trypsin, 87.0 milligrams of peru balsam, and 788.0 milligrams of castor oil.

(b) *Sponsor.* See No. 000514 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* The drug is used as an aid in the treatment of external wounds and assists healing by facilitating the removal of necrotic tissue, exudate and organic debris.

§ 524.2640 Tylosin, neomycin eye powder.

(a) *Specifications.* Tylosin, neomycin eye powder contains 2 percent tylosin activity (as base), neomycin sulfate equivalent to 0.25 percent neomycin base, 1 percent piperocaine hydrochloride, 0.5 percent acriflavine neutral, and boric acid q.s.

(b) *Sponsor.* See No. 000986 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in cattle for the treatment of pinkeye (infectious keratoconjunctivitis).

(2) It is administered by holding the eyelids open and dusting powder into both eyes. The treatment is repeated daily for up to 7 days depending on the severity of the infection. Affected animals should be protected from direct sunlight, dust, and files. In an affected herd, all animals with or without signs of the disease should receive at least one treatment.

(3) If there is severe eye damage or if the condition persists or increases, discontinue administering the drug and consult a veterinarian.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Sec.

529.360 Cephalothin discs.
529.1044 Gentamicin sulfate in certain other dosage forms.
529.1044a Gentamicin sulfate intrauterine solution.
529.1044b Gentamicin sulfate solution.
529.2503 Tricaine methanesulfonate.

AUTHORITY: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).

§ 529.360 Cephalothin discs.

(a) *Specifications.* Cephalothin discs, comply with the requirements of § 460.1 of this chapter.

(b) *Sponsor.* See No. 000986 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The discs are used for determining the in vitro susceptibility of bacteria to cephaloridine and cephalonium.

(2) For veterinary laboratory diagnosis only.

§ 529.1044 Gentamicin sulfate in certain other dosage forms.

§ 529.1044a Gentamicin sulfate intrauterine solution.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for use for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(2) It is administered at a dosage level of 2 to 2.5 grams per day for 3 to 5 days during estrus, each dose being diluted with 200 to 500 milliliters of sterile physiological saline before aseptic infusion into the uterus.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) Not for use in horses intended for food.

§ 529.1044b Gentamicin sulfate solution.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) *Sponsor.* See No. 000085 in § 510.-600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended as an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii (paracolon), Salmonella st. paul,* and *Mycoplasma meleagridis.*

(2) The drug is added to clean water to provide a dip solution with a gentamicin concentration of 250 to 1,000 parts per million. A concentration of 500 parts per million is recommended. Clean eggs should be held submerged in the genta-

micin solution under a vacuum of about 27.5 to 38 centimeters of mercury for 5 minutes followed by additional soaking in gentamicin solution for approximately 10 minutes at atmospheric pressure. Eggs can also be treated by warming them for 3 to 6 hours at approximately 100° F. then immediately submerging them in gentamicin solution maintained at about 40° F., keeping the eggs submerged for 10 to 15 minutes.

(3) For use in the dipping treatment of turkey-hatching eggs only. Eggs which have been dipped in the drug shall not be used for food.

§ 529.2503 Tricaine methanesulfonate.

(a) *Chemical name.* Ethyl-*m*-aminobenzoate methanesulfonate.

(b) *Sponsor.* See No. 000046 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the temporary immobilization of fish, amphibians, and other aquatic cold-blooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(2) It is used as follows:

(i) For fish the drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) For amphibians and other aquatic cold-blooded animals, the drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(iii) Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature should exceed 10° C. (50° F.). In other fish and in cold-blooded animals, the drug should be limited to hatchery or laboratory use.

PART 536—TESTS FOR SPECIFIC ANTIBIOTIC DOSAGE FORMS

Sec.
536.500 Penicillin bougies.
536.501 Penicillin-streptomycin ointment; penicillin - dihydrostreptomycin ointment.
536.502 Penicillin-streptomycin bougies; penicillin - dihydrostreptomycin bougies.
536.503 Penicillin-bacitracin ointment.
536.504 Crystalline penicillin and bacitracin.
536.505 Penicillin - streptomycin - bacitracin ointment; penicillin-dihydrostreptomycin-bacitracin ointment; penicillin - streptomycin - bacitracin methylene disalicylate ointment; penicillin - dihydrostreptomycin-bacitracin methylene disalicylate ointment.
536.506 Penicillin-bacitracin-neomycin ointment; penicillin-bacitracin-neomycin in oil.
536.507 Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution (procaine penicillin and benzathine penicillin G in crystalline dihydrostreptomycin sulfate solution).
536.508 Procaine penicillin - streptomycin-polymyxin in oil; procaine penicillin - dihydrostreptomycin - polymyxin in oil; procaine penicillin-streptomycin - polymyxin ointment; procaine penicillin-dihydrostreptomycin - polymyxin ointment.
536.509 Penicillin-streptomycin-erythromycin ointment; penicillin-dihydrostreptomycin-erythromycin ointment.
536.510 Penicillin - tetracycline phosphate complex-novobiocin-nystatin capsules.
536.511 Penicillin - streptomycin - bacitracin methylene disalicylate-neomycin ointment; penicillin-dihydrostreptomycin-bacitracin methylene disalicylate-neomycin ointment.
536.512 Procaine penicillin G-novobiocin-neomycin-dihydrostreptomycin in oil.
536.513 Streptomycin / dihydrostreptomycin for inhalation therapy.
536.514 Streptomycin sulfate/dihydrostreptomycin sulfate oral powder.
536.515 Dihydrostreptomycin - neomycin-polymyxin aerosol solution.
536.516 Chlortetracycline - neomycin-streptomycin/dihydrostreptomycin penicillin ointment; tetracycline hydrochloride-neomycin-streptomycin/dihydrostreptomycin penicillin ointment.
536.517 Calcium chlortetracycline-neomycin sulfate mastitis suspension.
536.518 Bacitracin-neomycin in oil.

AUTHORITY: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).

§ 536.500 Penicillin bougies.

(a) *Potency.* Proceed as directed in § 440.180a(b)(1) of this chapter.

(b) *Moisture.* Proceed as directed in § 436.500(c) of this chapter, using 1.0 to 2.0 grams of bougies dissolved in 10 milliliters of dry chloroform if it contains the excipient polyethylene glycol. If it does not contain the excepient polyethylene glycol, proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 536.501 Penicillin-streptomycin ointment; penicillin-dihydrostreptomycin ointment.

(a) *Potency*—(1) *Total penicillin content.* Proceed as directed in § 540.380a(b)(1) or § 440.80a(b)(5)(iv)(a) of this chapter, except that if the iodometric chemical assay described in § 440.80a(b)(5)(iv)(*a*) of this chapter is used prepare the sample as follows: Accurately measure two representative portions of the sample, each equivalent to about 20,000 units. Place one portion in a centrifuge tube containing 10.0 milliliters of 1 percent phosphate buffer, pH 6.0, and 10.0 milliliters of chloroform for each 5 milliliters or grams of sample. Shake the tube for 1 minute and centrifuge to obtain a substantially clear buffer layer. Use 2.0 milliliters of this solution as the blank. Add one drop of 1.2 *N* HCl to the blank immediately before the addition of the 10.0 milliliters of 0.01 *N* I_2. Immediately titrate with 0.01 *N* $Na_2S_2O_3$. Place the second portion of the sample in a centrifuge tube containing 10.0 milliliters of 1 *N* $NaHCO_3$ (previously adjusted to a pH of 9.3±0.2 with 1.0 *N* NaOH) and 10.0 milliliters of chloroform for each 5 milliliters or grams of sample. Shake the tube for 1 minute and centrifuge to obtain a substantially clear aqueous layer. To 2.0 milliliters of the aqueous layer, add 2.0 milliliters of 1 *N* NaOH and allow to stand for 15 minutes. Add sufficient 1.2 *N* HCl to obtain a pH of 1.0; then add 10.0 milliliters of 0.01 *N* I_2. Allow to stand for 15 minutes and then titrate with 0.01 *N* $Na_2S_2O_3$. From the titration data calculate the amount of penicillin in the sample. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Crystalline sodium penicillin or potassium penicillin content*—(i) *Direct method*—(*a*) *Preparation of the solution for assay.* Accurately measure a representative portion of the sample equivalent to about 20,000 units of crystalline sodium penicillin or potassium penicillin and place it in a centrifuge tube containing 10.0 milliliters of 20 percent sodium sulfate solution and 10.0 milliliters of chloroform for each 5 milliliters or grams of sample. Shake the tube for 1 minute and then centrifuge to obtain a substantially clear aqueous layer. This is used as the solution for assay.

(*b*) *Iodometric assay for total penicillin in the solution for assay.* Determine the quantity of penicillin in the solution for assay by the iodometric assay procedure described in § 440.80a(b)(5)(iv)(a), of this chapter.

(*c*) *Colorimetric determination of procaine penicillin in the solution for assay.* (*1*) If the sample does not contain sulfonamides, determine the procaine penicillin in the solution for assay by the colorimetric procedure described in § 436.503(b)(3) of this chapter.

(2) If the sample contains sulfonamides, proceed as follows: Place 10.0 milliliters of the solution for assay in a separatory funnel containing 2 milliliters of 1 *N* NaOH and 10.0 milliliters of chloroform and shake for 1 minute. Allow the layers to separate and collect the lower chloroform layer in a cylinder containing 10.0 milliliters of 4 *N* HCl. Shake for 1 minute and allow the layers to separate. Using the upper acid layer as the solution for assay, determine the procaine penicillin content by the colorimetric procedure described in § 436.503(b)(3) of this chapter.

(*d*) The content of crystalline sodium or potassium penicillin in the sample is calculated as follows:

$$A=(B-C)F$$

where:

A=crystalline sodium penicillin or potassium penicillin content of the sample.

B=total number of units of penicillin per milliliter as determined in paragraph (a)(2)(i)(*b*) of this section.

C=number of units of procaine penicillin per milliliter as determined in paragraph (a) (2) (i) (c) of this section.
F=appropriate dilution factor depending on the dilution made in the preparation of the solution for assay and the size of the representative portion of the sample tested.

(ii) *Indirect method.* The content of crystalline sodium or potassium penicillin is the difference between the total penicillin content determined in paragraph (a) (1) of this section and the procaine penicillin determined in paragraph (a) (3) (i) of this section. Its content of crystalline sodium penicillin or potassium penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) *Procaine penicillin content*—(i) *Direct method.* Using the stock solution prepared for bioassay in paragraph (a) (1) of this section, determine the procaine penicillin content colorimetrically as directed in paragraph (a) (2) (i) (c) (2) of this section.

(ii) *Indirect method.* The procaine penicillin content of the sample is the difference between the total penicillin content determined in paragraph (a) (1) of this section and the crystalline sodium penicillin or potassium penicillin content determined in paragraph (a) (2) of this section. Its content of procaine penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(4) *Streptomycin content.* Proceed as directed in § 444.70a(b).(1) of this chapter, except paragraph (b) (1) (xi) of that section, and in lieu of the directions in § 444.70a(b) (1) (v) and (x) (c), test a representative portion of the sample (usually approximately 1 gram, accurately weighed) or the entire contents of a single-dose container prepared by one of the following methods:

(i) *To assay by the cup-plate method.* Use either extraction or blending.

(a) *Extraction.* Place the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of ether. Shake the sample and ether until homogeneous. Add 20 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0. and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of buffer. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of buffer at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives and make up to an appropriate measured volume with buffer. To a suitable aliquot add sufficient penicillinase and let stand for 30 minutes at 37° C. to inactivate the penicillin. After inactivation, make the proper estimated dilution with buffer at pH 8.0.

(b) *Blending.* Place the sample in a blending jar containing 1.0 milliliter of 10-percent aqueous solution of polysorbate 80 and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to give a final volume of 500 milliliters. Using a high-speed blender, blend the mixture for 3 minutes. To a suitable aliquot, add sufficient penicillinase and let stand for 30 minutes at 37° C. to inactivate the penicillin. After inactivation, make the proper estimated dilutions with buffer at pH 8.0.

(ii) *To assay by the turbidimetric method.* Place the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of ether. Shake the sample and ether until homogeneous. Add 20 milliliters of distilled water, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of water. Allow the layers to separate. Remove the aqueous layer and repeat the extraction with new portions of water at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives, and make to an appropriate measured volume with water. Remove the aliquot and, if the ratio of the content of penicillin to the content of streptomycin is equal to or greater than one unit for each microgram, add sufficient penicillinase and let stand for 30 minutes at 37° C. to inactivate the penicillin. Make the proper estimated dilutions with distilled water. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(5) *Dihydrostreptomycin content.* Proceed as directed in paragraph (a) (4) of this section, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 540.380a(b) (2) of this chapter.

§ 536.502 Penicillin-streptomycin bougies; penicillin-dihydrostreptomycin bougies.

(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 440.180a(b) (1) of this chapter, except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Using 12 bougies, proceed as directed in § 444.70a (b) (1) of this chapter, except paragraph (b) (1) (xi) of that section, and if the cup-plate method is used, use potassium phosphate buffer (pH 7.8–8.0) for dissolving the sample in lieu of sterile distilled water as directed in § 444.70a(b) (1) (v) of this chapter and add sufficient penicillinase to the solution under test to completely inactivate the penicillin present. If the turbidimetric method is used, inactivation with penicillinase is not necessary unless the ratio of the content of penicillin to the content of streptomycin is equal to or greater than 1.0 unit for each microgram. Its content of sterptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in paragraph (a) (2) of this section, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 536.500(b).

§ 536.503 Penicillin-bacitracin ointment.

The requirements for certification and the tests and methods of assay for penicillin-bacitracin ointment are described under § 436.504 of this chapter.

§ 536.504 Crystalline penicillin and bacitracin.

The requirements for certification and the tests and methods of assay for crystalline penicillin and bacitracin are described under § 440.280c of this chapter.

§ 536.505 Penicillin-streptomycin-bacitracin ointment; penicillin-dihydrostreptomycin-bacitracin ointment; penicillin - streptomycin - bacitracin methylene disalicylate ointment; penicillin - dihydrostreptomycin-bacitracin methylene disalicylate ointment.

The requirements for certification and the tests and methods of assay for penicillin - streptomycin - bacitracin ointment; penicillin dihydrostreptomycin-bacitracin ointment; penicillin-streptomycin-bacitracin methylene disalicylate ointment; penicillin-dihydrostreptomycin-bacitracin methylene disalicylate ointment are described under § 436.505 of this chapter.

§ 536.506 Penicillin-bacitracin-neomycin ointment; penicillin-bacitracin-neomycin in oil.

The requirements for certification and the tests and methods of assay for penicillin-bacitracin-neomycin ointment; penicillin-bacitracin-neomycin in oil are described under § 436.508 of this chapter.

§ 536.507 Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution (procaine penicillin and benzathine penicillin G in crystalline dihydrostreptomycin sulfate solution).

(a) *Potency*—(1) *Total potency and procaine penicillin content.* Proceed as directed in § 436.507(a) (1) and (2), except that in the iodometric assay one drop of 1.2 *N* HCl is added to the blank immediately, before the addition of the 0.01 *N* iodine.

(2) *Benzathine penicillin G content.* The difference between the total penicillin potency and the procaine penicillin content determined under paragraph (a) (1) of this section represents the benzathine penicillin G content. The benzathine penicillin G content is satisfactory if it is not less than 85 percent

of that which it is represented to contain.

(3) *Streptomycin content.* Proceed as directed in § 444.70a(b)(1)(x) and (xi) of this chapter.

(4) *Dihydrostreptomycin content.* Proceed as directed in § 444.10a(b)(1) of this chapter.

(b) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, and medium F in lieu of medium E. During the period of incubation, shake the tubes at least once daily.

(c) *Toxicity.* Proceed as directed in § 540.250(b)(3) of this chapter.

(d) *Pyrogens.* Proceed as directed in § 540.250(b)(4) of this chapter.

(e) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using the undiluted aqueous suspension.

§ 536.508 Procaine penicillin-streptomycin-polymyxin in oil; procaine penicillin-dihydrostreptomycin-polymyxin in oil; procaine penicillin-streptomycin-polymyxin ointment; procaine penicillin-dihydrostreptomycin-polymyxin ointment.

The requirements for certification and the tests and methods of assay for procaine penicillin-streptomycin-polymyxin in oil; procaine penicillin-dihydrostreptomycin-polymyxin in oil; procaine penicillin-streptomycin-polymyxin ointment; procaine penicillin-dihydrostreptomycin-polymyxin ointment are described under § 436.509 of this chapter.

§ 536.509 Penicillin-streptomycin-erythromycin ointment; penicillin-dihydrostreptomycin-erythromycin ointment.

The requirements for certification and the tests and methods of assay for penicillin - streptomycin - erythromycin ointment; penicillin-dihydrostreptomycin-erythromycin ointment are described under § 436.510 of this chapter.

§ 536.510 Penicillin-tetracycline phosphate complex - novobiocin-nystatin capsules.

(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 440.180d(b)(1)(i)(*a*), except in lieu of the directions prescribed in § 440.180d(b)(1)(i)(a)(1) of this chapter, prepare the stock solution by blending 3 capsules in 100 milliliters of potassium phosphate buffer, pH 8.0, using a glass jar and a high-speed blender. Its penicillin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Novobiocin content.* Use a suitable aliquot of the stock solution prepared as directed in paragraph (a)(1) of this section and proceed as directed in § 440.180d(b)(1)(ii) of this chapter. Its content of novobiocin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Tetracycline phosphate complex content.* Proceed as directed in § 436.515(a)(1) of this chapter. Its potency is satisfactory if it contains the equivalent of not less than 85 percent of the number of milligrams of tetracycline hydrochloride that it is represented to contain.

(4) *Nystatin content.* Proceed as directed in § 446.181b(b)(1)(i)(*b*) of this chapter. Its nystatin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 536.511 Penicillin-streptomycin-bacitracin methylene disalicylate-neomycin ointment; penicillin-dihydrostreptomycin - bacitracin methylene disalicylate-neomycin ointment.

The requirements for certification and the tests and methods of assay for penicillin-streptomycin-bacitracin methylene disalicylate-neomycin ointment; penicillin -dihydrostreptomycin-bacitracin methylene disalicylateneomycin ointment are described under § 436.511 of this chapter.

§ 536.512 Procaine penicillin G-novobiocin - neomycin - dihydrostreptomycin in oil.

The requirements for certification and the tests and methods of assay for procaine penicillin G-novobiocin-neomycin-dihydrostreptomycin in oil are described under § 436.512 of this chapter.

§ 536.513 Streptomycin/dihydrostreptomycin for inhalation therapy.

(a) *Potency*—(1) *Streptomycin content.* Proceed as directed in § 444.70a(b)(1) of this chapter, except if it is packaged with inert gases proceed as follows: Use not less than 6 immediate containers. Place one-half the number of such containers in a suitable sharp freezing unit having a temperature not higher than —30° C. After freezing, cut open the containers and transfer the contents of each to a suitable beaker and allow gas to evaporate. After gas has evaporated, wash and ry the residue remaining in the container into the beaker with sterile distilled water, after which wash the entire contents of the beaker into a 500-milliliter volumetric flask and make to mark with sterile distilled water. Use an appropriate aliquot of each of these solutions and proceed as directed in § 444.70a(b)(1) of this chapter to determine the average total quantity of streptomycin in each container. Expel the drug from each of the remaining containers as directed in its labeling. After all gas (with drug) has been expelled, cut open the containers and place each in a large beaker containing 500 milliliters of sterile distilled water. Let stand for not less than 15 minutes, with frequent agitation. Remove an aliquot and proceed as directed in § 444.70a(b)(1) of this chapter, to determine the quantity of streptomycin that remains in each container. The quantity of streptomycin expelled is determined by subtracting the average amount of the residue found from the average total amount contained in the containers. Its potency is satisfactory if it contains not less than 90 percent, or 85 percent if it is packaged with inert gases, of the number of milligrams of streptomycin that it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in paragraph (a)(1) of this section, except use the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 90 percent, or 85 percent if it is packaged with insert gases, of the number of milligrams of dihydrostreptomycin that it is represented to contain.

(b) *Unless it is packaged with inert gases, toxicity, histamine, moisture, pH, streptomycin content (if it is dihydrostreptomycin), crystallinity (if it is crystalline dihydrostreptomycin).* Proceed as directed in §§ 444.10a(b)(2), 444.70a(b)(3), (5), and (6), and 440.80a(b)(5)(iii) of this chapter.

(c) *If it is packaged with inert gases, moisture.* Proceed as directed in § 436.500(c) of this chapter, but in lieu of the directions for preparing the sample in § 436.500(c)(3) of this chapter prepare the sample and calculate as follows: Freeze the container as described in paragraph (a) of this section. After freezing, open the container and remove a representative 10-milliliter aliquot. Place this sample in a dry titrating vessel, immediately add an excess of Karl Fischer reagent, and back-titrate with water-methanol solution until the endpoint is reached.

$$\text{Percent moisture} = \frac{(v_1 - V_2 f) \times c}{100}$$

§ 536.514 Streptomycin sulfate/dihydrostreptomycin sulfate oral powder.

(a) *Potency*—(1) *Total potency.* Using the dihydrostreptomycin working standard as the standard of comparison, proceed as directed in § 444.70a(b)(1)(x) of this chapter. Its total potency is satisfactory if it contains not less than 90 percent of the combined number of milligrams of streptomycin and dihydrostreptomycin that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 544.211b(b)(2) of this chapter. Its content of streptomycin is satisfactory if it contains not less than 45 percent and not more than 55 percent of the total potency as determined under paragraph (a)(1) of this section.

(b) *Moisture.* Using a 1-gram sample, proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 536.515 Dihydrostreptomycin-neomycin-polymyxin aerosol solution.

(a) *Potency.* (1) Using a separate graduate for each container to be tested, eject the drug as directed in its labeling. Measure the volume of each dose until the total contents are expelled. Remove appropriate aliquots and proceed as follows:

(i) *Dihydrostreptomycin content.* Using the dihydrostreptomycin working standard as the standard of comparison, proceed as directed in § 444.70a(b)(1)(i) through (ix) of this chapter. Its content of dihydrostreptomycin is satisfac-

tory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(ii) *Neomycin content.* Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(iii) *Polymyxin content.* Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *pH.* Using the undiluted solution, proceed as directed in § 440.80a(b)(5)(ii) of this chapter.

§ 536.516 Chlortetracycline - neomycin-streptomycin / dihydrostreptomycin penicillin ointment; tetracycline hydrochloride -neomycin-streptomycin/ dihydrostreptomycin penicillin ointment.

(a) *Potency*—(1) *Penicillin content.* Place an accurately weighed sample of approximately 1 gram in an extraction funnel prepared by fusing a ground-glass joint to the top of a medium-porosity sintered-glass filter funnel (30-millimeter diameter). Wash with five 10-milliliter portions of warm iso-octane and draw off the ointment base under vacuum. Discard the iso-octane washings. Wash the residue with three 10-milliliter portions of chloroform and draw off under vacuum, combine the extracts, and make to mark in a 250-milliliter volumetric flask with absolute alcohol. Make the proper estimated dilutions in 1-percent phosphate buffer, at pH 6.0, and proceed as directed in § 440.80a(b)(1) of this chapter. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per gram of ointment that it is represented to contain.

(2) *Chlortetracycline content.* Wash the residue in the funnel four times with 10-milliliter portions of 0.3 percent piperidine in acetone solution. Withdraw each washing under vacuum. Combine the four washings in a 100-milliliter volumetric flask and make to mark with 0.1 *M* monopotassium phosphate buffer, pH 4.5. The sample may also be prepared by placing a representative portion (usually 1.0 gram, accurately weighed) in a glass blending jar containing 199 milliliters of 0.01 *N* HCl and 1.0 milliliter of polysorbate 80. Using a high-speed blender, blend the mixture for 2 to 3 minutes and make proper estimated dilutions in 0.1 *M* monopotassium phosphate buffer, pH 4.5, adding sufficient penicillinase to inactivate the penicillin. Proceed as directed in § 446.10a(b)(1)(viii) of this chapter. Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(3) *Tetracycline hydrochloride content.* Prepare the sample as directed in paragraph (a)(2) of this section and proceed as directed in § 446.81a(b) of this chapter. Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(4) *Neomycin content.* The residue remaining in the funnel after the extraction described in paragraph (a)(2) of this section contains the neomycin and streptomycin or dihydrostreptomycin. Wash this residue five times, using 10-milliliter aliquots of 0.1 *M* phosphate buffer, pH 8.0, drawing each washing off under vacuum. Combine the washings in a 100-milliliter volumetric flask and make to mark with 0.1 *M* phosphate buffer, pH 8.0. Using an aliquot of this aqueous solution, proceed as directed in § 436.105 of this chapter. The content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(5) *Streptomycin content.* Using an aliquot of the aqueous solution prepared in paragraph (a)(4) of this section, proceed as directed in § 444.70a(b)(1)(i) through (ix) of this chapter. The content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(6) *Dihydrostreptomycin content.* Using an aliquot of the aqueous solution prepared in paragraph (a)(4) of this section, and the dihydrostreptomycin working standard as a standard of comparison, proceed as directed in § 444.70a(b)(1)(i) through (ix) of this chapter. The content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 540.380a(b)(2) of this chapter.

§ 536.517 Calcium chlortetracycline-neomycin sulfate mastitis suspension.

(a) *Potency*—(1) *Chlortetracycline content.* Proceed as directed in § 446.10a(b)(1)(viii) of this chapter, except prepare the sample as follows: Discharge a dose of the product completely into a glass blending jar. Add sufficient 0.01*N* hydrochloric acid to give a total volume of 500 milliliters. Using a high-speed blender, blend the mixture for 2 to 3 minutes. Dilute an aliquot with 0.1*M* phosphate buffer, pH 4.5, to the proper prescribed reference concentration. The chlortetracycline content of a single dose is satisfactory if it is equivalent to not less than 90 percent and not more than 125 percent of the number of milligrams of chlortetracycline hydrochloride that it is represented to contain.

(2) *Neomycin content.* Proceed as directed in § 444.42a(b)(1)(i) of this chapter, except prepare the sample as follows: Discharge a dose of the product completely into a glass blending jar. Add sufficient 0.1*M* potassium phosphate buffer, pH 8.0, to give a total of 500 milliliters. Using a high-speed blender, blend the mixture for 2 to 3 minutes. Dilute an aliquot with 0.1*M* potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration. The neomycin content of a single dose is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 540.380a(b)(2) of this chapter.

§ 536.518 Bacitracin-neomycin in oil.

(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 448.510a(b)(1) of this chapter. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) *Neomycin content.* Prepare the sample as directed in § 540.380a(b)(1) of this chapter, except in lieu of 1 percent potassium phosphate buffer use 0.10 *M* potassium phosphate buffer (pH 7.8–8.0) and proceed as directed in § 436.517(b)(1) of this chapter. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 540.380a(b)(2) of this chapter.

PART 539—BULK ANTIBIOTIC DRUGS SUBJECT TO CERTIFICATION

Subpart A—[Reserved]

Subpart B—Bulk Provisions for Oligosaccaride Antibiotic Drugs for Animal Use

Sec.

539.170 Streptomycin sulfate veterinary grade; dihydrostreptomycin sulfate veterinary grade; dihydrostreptomycin hydrochloride veterinary grade.

Subpart C—Bulk Provisions for Tetracycline Antibiotic Drugs for Animal Use

539.210 Chlortetracycline bulk provisions.
539.210a Chlortetracycline.
539.210b Chlortetracycline bisulfate.

Subpart D—Bulk Provisions for Peptide Antibiotics for Animal Use

539.310 Bacitracin methylene disalicylate.

AUTHORITY: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).

Subpart A—[Reserved]

Subpart B—Bulk Provisions for Oligosaccaride Antibiotic Drugs for Animal Use

§ 539.170 Streptomycin sulfate veterinary grade; dihydrostreptomycin sulfate veterinary grade; dihydrostreptomycin hydrochloride veterinary grade.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate veterinary grade is the sulfate salt of a kind of streptomycin or a mixture of two or more such salts. Dihydrostreptomycin sulfate veterinary grade and dihydrostreptomycin hydrochloride veterinary grade are the hydrogenated sulfate or hydrochloride salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug may contain a suitable and harmless lubricant. Each such drug is so purified and dried that:

(i) Its potency is not less than 450 micrograms per milligram.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 14.0 percent.

(iv) Its pH in aqueous solution of 0.2 gram per milliliter is not less than 3.0 and not more than 7.0.

(v) If it is dihydrostreptomycin sulfate veterinary grade or dihydrostreptomycin hydrochloride veterinary grade, its content of streptomycin is not more than 5 percent when calculated as streptomycin base.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin or dihydrostreptomycin per gram and the number of grams of the drug in the immediate container; and if the batch contains a lubricant, the name of such ingredient.

(iii) The statement "Expiration date _____", the blank being filled in with the date which is 36 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 48 months or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) (1) of this section.

(iv) The statement "For use only in the manufacture of nonsterile veterinary drugs".

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 431.1 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams of streptomycin or dihydrostreptomycin per gram, and the total number of grams of streptomycin or dihydrostreptomycin in each package. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, and streptomycin content if it is dihydrostreptomycin.

(ii) Such person shall submit with his request an accurately representative sample of the batch, consisting of 6 packages each containing approximately 1.0 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (a) (2) of this section.

(b) *Tests and methods of assay*—(1) *Potency.* If it is streptomycin sulfate veterinary grade, proceed as directed in § 444.70a(b) (1) of this chapter. If it is dihydrostreptomycin sulfate veterinary grade or dihydrostreptomycin hydrochloride veterinary grade, proceed as directed in § 444.70a(b) (1) (x) of this chapter, using the dihydrostreptomycin working standard as the standard of comparison.

(2) *Toxicity.* Proceed as directed in § 444.70a(b) (3) of this chapter.

(3) *Moisture.* Using a 1-gram sample, proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(4) *pH.* Proceed as directed in § 444.70a(b) (6) (ii) of this chapter.

(5) *Streptomycin content (if it is dihydrostreptomycin).* Proceed as directed in § 444.10a(b) (2) of this chapter.

Subpart C—Bulk Provisions for Tetracycline Antibiotic Drugs for Animal Use

§ 539.210 Chlortetracycline bulk provisions.

§ 539.210a Chlortetracycline.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chlortetracycline is a golden-yellow crystalline powder with the chemical structure 7-chloro-4-dimethylamino - 1,4,4a,5,5a,6,11,12a - octahydro - 3,6,10,12,12a - pentahydroxy-6-methyl - 1,11-dioxo-2 - naphthacenecarboxamide. It is so purified and dried that:

(i) Its potency is equivalent to not less than 968 micrograms of chlortetracycline hydrochloride per milligram when calculated on an anhydrous basis.

(ii) It passes the toxicity test.

(iii) Its moisture content is not more than 5.0 percent.

(iv) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 4.0 and not more than 7.0.

(v) Its absorptivity at 445 mμ is 107.2±4.0 percent of the chlortetracycline hydrochloride working standard similarly treated and both calculated on the anhydrous basis.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U.S.P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package of chlortetracycline shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(i) The batch mark.

(ii) The number of micrograms of chlortetracycline hydrochloride equivalent per milligram and the total number of grams in the immediate container.

(iii) The statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which it was certified.

(iv) The statement "For use only in the manufacture of nonsterile veterinary drugs".

(v) The statement "Caution: Federal law prohibits dispensing without prescription".

(4) *Request for certification, check tests and assays; samples.* (i) In addition to complying with the requirements of § 431.1 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, crytallinity, and absorptivity.

(ii) Such person shall submit with his request an accurately representative sample of the batch consisting of 10 packages, each containing approximately 300 milligrams taken from a different part of such batch and each packaged in accordance with the requirements of paragraph (a) (2) of this section.

(iii) In connection with contemplated requests for certification of batches of another drug in the manufacture of which chlortetracycline is to be used, the manufacturer of the batch that is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by paragraph (a) (4) (ii) of this section. From the information required by paragraph (a) (4) (i) of this section may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer the results of such check tests and assays as are so requested.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 446.10a (b) (1) of this chapter.

(2) *Toxicity.* Proceed as directed in § 440.80a(b) (4) of this chapter, using as a test dose 0.5 milliliter of an aqueous solution containing the equivalent of 2.0 milligrams of chlortetracycline hydrochloride per milliliter, prepared by dissolving approximately 40 milligrams of the sample in 2.0 milliliters of 0.1*N* hydrochloric acid and diluting with the required amount of water.

(3) *Moisture.* Proceed as directed in § 440.74a(b) (5) of this chapter.

(4) *pH.* Proceed as directed in § 440.80a(b) (5) (ii) of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(5) *Microscopical test for crystallinity.* Mount a few particles of the sample in mineral oil and examine by means of a polarizing miscroscope. The particles reveal the phenomena of birefringence and extinction positions on revolving the microscope stage.

(6) *Absorptivity*—(i) *Reagents*—(a) *Hydrochloric acid.* 5*N* and 1*N* aqueous solutions.

(b) *Sodium bisulfite.* 10 grams per 100 milliliters of water. This reagent must be freshly prepared.

(c) *Buffer solution, pH 7.5.* 178 grams of anhydrous K_2HPO_4 and 22 grams of anhydrous KH_2PO_4 per liter of water. Filter the solution before using.

(d) *Stock standard solution.* Weigh exactly 100.0 milligrams of chlortetracycline hydrochloride working standard and transfer to a 100-milliliter volumet-

ric flask. Dilute to mark with water and mix well. Store in refrigerator (5° C. to 8° C.) in an amber bottle. The solution is stable and may be used for 1 week.

(e) *Working standard solution.* Pipet 10.0 milliliters of the stock standard solution into a 100-milliliter volumetric flask. Dilute to mark with water and mix well. Each milliliter contains 0.1 milligram of chlortetracycline hydrochloride. (Prepare just before using.)

(ii) *Preparation of sample.* Weigh accurately about 100 milligrams of sample and transfer to a 1-liter volumetric flask with the aid of water. Add 10 milliliters of 1*N* hydrochloric acid and 100 milliliters of water. Mix until solution is complete. Make to mark with water and mix thoroughly.

(iii) *Procedure.* (a) Pipet two 10.0-milliliter portions of the final dilution of the sample into each of two 50-milliliter volumetric flask, referred to in paragraph (b) (6) (iii) of this section as sample and sample blank, respectively.

(b) Pipet two 10.0-milliliter portions of the working standard into each of two 50-milliliter volumetric flasks, referred to in paragraph (b) (6) (iii) of this section as standard and standard blank, respectively.

(c) To the sample and the standard add in this order: 12 milliliters of 5*N* hydrochloric acid; 15 milliliters of buffer solution, pH 7.5; and 2 milliliters of sodium bisulfite solution. Suspend in a boiling water bath for exactly 7 minutes, and swirl occasionally. (It is essential that the water boils throughout the entire heating period.)

(d) To the sample blank and standard blank, add 15 milliliters of buffer solution, pH, 7.5, and 2 milliliters of sodium bisulfite solution. Suspend in a boiling water bath for 5 minutes with occasional swirling. After exactly 5 minutes has elapsed add 12 milliliters of 5*N* hydrochloric acid and heat for an additional 2 minutes.

(e) After the completion of the heat treatment, immediately cool all the flasks under tap water. Fill each flask to mark with water and mix well.

(f) Read the absorbances of the standard and sample against their respective blanks at a wavelength of 445 mμ in a suitable spectrophotometer.

(iv) *Calculation.*

$$\frac{(A_{445}\text{ sample})\ (0.02)\ (1000)\ (50)\ (100)\ (100)}{(A_{445}\text{ standard})\ (\text{sample wt. in mg.})\ (10)\ (100\text{-percent moisture in sample})}$$

=percent of absorptivity compared to the chlortetracycline hydrochloride working standard

§ 539.210b Chlortetracycline bisulfate.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Chlortetracycline bisulfate is the crystalline acid sulfate salt of chlortetracycline, containing butyl alcohol bound to or complexed with it. It is so purified and dried that:

(i) Its potency is equivalent to not less than 760 micrograms of chlortetracycline hydrochloride per milligram when corrected for the moisture and butyl alcohol content.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 2.0 percent.

(iv) Its butyl alcohol content is not more than 15 percent.

(v) Its sulfate content is not less than 15 percent when corrected for moisture and butyl alcohol content.

(vi) Its absorptivity, when corrected for its moisture and butyl alcohol content, is 89 percent ±6 percent of that of the chlortetracycline hydrochloride working standard similarly treated and calculated on the anhydrous basis.

(2) *Packaging.* In all cases, the immediate containers shall be tight containers as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of chlortetracycline hydrochloride equivalent per gram and the number of grams in the immediate container.

(iii) The statement "Expiration date ----------", the blank being filled in with the date that is 48 months after the month during which the batch was certified.

(iv) The statement "For use only in the manufacture of nonsterile veterinary drugs".

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 431.1 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams of chlortetracycline hydrochloride equivalent per gram, and the total number of grams in each package. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, butyl alcohol content, sulfate content, absorptivity, and crystallinity.

(ii) Such person shall submit with his request an accurately representative sample of the batch, consisting of 10 packages each containing approximately 0.5 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (a) (2) of this section.

(b) *Tests and Methods of assay—*(1) *Potency.* Using a 3.0-gram sample, proceed as directed in § 446.10a(b) (1) of this chapter, except § 446.10a(b) (1) (ix) of this chapter.

(2) *Toxicity.* Proceed as directed in § 440.80a(b) (4) of this chapter, using as a test dose 0.4 milliliter of an aqueous solution containing 2 milligrams of chlortetracycline hydrochloride equivalent per milliliter.

(3) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(4) *Butyl alcohol content—*(i) *Ceric nitrate reagent.* Dissolve 20 grams of ceric ammonium nitrate ($(NH_4)_2Ce(NO_3)_6 \cdot 2H_2O$) in 4 *M* HNO_3 and make up to 100 milliliters with 4 *M* HNO_3.

(ii) *Sample.* Accurately weigh an amount of sample calculated to contain approximately 30 milligrams of butyl alcohol and transfer it to a 50-milliliter round-bottom distillation flask. Dissolve the sample in 25 milliliters of distilled water, add a small amount of antifoam agent, and connect to a condenser terminating in an adapter. The end of the adapter is inserted deep into a 25-milliliter graduated cylinder, which stands in an ice water bath. Distill slowly until 7 to 8 milliliters have collected. Warm the distillate to room temperature, transfer to a 10-milliliter volumetric flask, using not more than 1 milliliter of water to rinse out the graduate, and make up to 10 milliliters. Pipette 5 milliliters of this into a test tube, add 2 milliliters of the ceric nitrate reagent, and mix.

(iii) *Standard.* Prepare a standard made by diluting 3 milliliters of reagent grade *n*-butyl alcohol with about 800 milliliters of distilled water in a 1,000-milliliter volumetric flask, shaking until solution is complete, then diluting to the mark with water. Use 5 milliliters of this plus 2 milliliters of ceric nitrate reagent as the standard.

(iv) *Blank solution.* Prepare a blank made by mixing 5 milliliters of distilled water with 2 milliliters of the ceric nitrate reagent.

(v) *Procedure.* Use a suitable spectrophotometer and 1-centimeter cells. Adjust the instrument to zero absorbance with the blank solution. Immediately read the absorbancies of the sample and the standard at 475 millimicrons. Calculate the percent butyl alcohol as follows:

$$\text{Percent butyl alcohol} = \frac{A_{\text{sample}} \times 0.003 \times 10 \times 0.81 \times 100}{A_{\text{standard}} \times 0.98 \times w},$$

Where:

A sample is the absorbance of the sample at 475 millimicrons;

A standard is the absorbance of the butyl alcohol standard containing 0.003 milliliter/milliliter;

w is the weight of sample in grams;

0.81 is the density of butyl alcohol; and

The factor 0.98 corrects for incomplete recovery of butyl alcohol in the distillation step.

(5) *Percent sulfate.* Transfer an accurately weighed sample of approximately 1.0 gram to a 250-milliliter beaker. Add about 100 milliliters of distilled water and stir to dissolve. Neutralize the solution to litmus paper with 1:1 ammonium hydroxide, and warm. If precipitation occurs, filter and wash the filter paper with warm water. Neutralize the filtrate to litmus with 1:1 HCl and add 4 milliliters excess. Bring

the solution to a boil and add, with constant stirring, sufficient boiling 10 percent barium chloride solution to precipitate all the sulfate, and a slight excess. Digest on a steam bath for 1 hour. Filter through Whatman No. 40 filter paper or equivalent. Wash the precipitate with hot water until the washings give no test for chloride with 0.1*N* silver nitrate solution. Transfer the filter paper and precipitate to a tared porcelain crucible. Dry over a low flame; then carefully burn off the filter paper. Finally, heat strongly but do not blast. Cool the crucible and weight. After subtracting the weight of the crucible, the residue is barium sulfate. By use of the following formula, calculate the percent sulfate in sample.

$$\frac{\text{Weight } BaSO_4 \times 0.4115 \times 100}{\text{Weight of sample}} = \text{percent sulfate.}$$

(6) *Absorptivity.* Accurately weigh approximately 100 milligrams of the sample and place in a 100-milliliter volumetric flask. Dissolve the sample in approximately 40 milliliters of distilled water by mixing thoroughly. Dilute to exactly 100 milliliters with distilled water and mix thoroughly. Transfer a 10.0 milliliter aliquot of this solution to a 250-milliliter volumetric flask, dilute to mark with 0.1 *N* hydrochloric acid, and mix thoroughly. Determine the absorbance of the solution at 368 millimicrons compared with distilled water as a blank. Use a suitable spectrophotometer for the absorbance measurements.

$$\text{Absorptivity (1\%, 1 cm.)} = \frac{\text{Absorbance at 368 m}\mu \times 2{,}500 \times 10}{\text{Weight of sample in milligrams} \times (100 - M - B)}$$

Where:
M=percent moisture in the sample;
B=percent butyl alcohol in the sample.

(7) *Crystallinity.* Proceed as directed in § 440.80a(b) (5) (iii) of this chapter.

Subpart D—Bulk Provisions for Peptide Antibiotics for Animal Use

§ 539.310 Bacitracin methylene disalicylate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin methylene disalicylate is the methylene disalicylate salt of a kind of bacitracin. It is so purified and dried that:

(i) Its potency is not less than 14 units per milligram on an anhydrous basis.

(ii) It is nontoxic.

(iii) Its moisture content is not more than 7 percent.

(iv) Its pH in a saturated aqueous solution is not less than 3.5 and not more than 5.0.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package of bacitracin methylene disalicylate shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of units of bacitracin per gram, the number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(*c*) The statement "Expiration date _____", the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time.

(*d*) The statement "For veterinary use only".

(ii) On the circular or other labeling within or attached to the package:

(*a*) Adequate directions and warnings for the veterinary use of the drug by the laity.

(*b*) If it is intended for use in animals raised for food production, labeling in accordance with the requirements of regulations in Part 121 of this chapter and this Subchapter E.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 431.1 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units of bacitracin activity per gram, and the number of grams of bacitracin activity per pound. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, and pH.

(ii) Such person shall submit with his request an accurately representative sample of the batch, consisting of 5 packages each containing approximately 5 grams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(b) *Tests and Methods of assay*—(1) *Potency.* Proceed as directed in § 448.10a(b) (1) (i), except in lieu of the directions for preparing the sample in § 448.10a(b) (1) (i) (*b*) of this chapter prepare the sample as follows: Place an accurately weighed sample of approximately 1 gram in a blending jar, add 99 milliliters of an aqueous solution of 2-percent sodium bicarbonate and 1 milliliter of polysorbate 80 and blend for 3 minutes in a high-speed blender. Allow the foam to subside, remove an aliquot of the solution, and dilute to 1 unit per milliliter with 1-percent phosphate buffer.

(2) *Toxicity.* Proceed as directed in § 436.33 of this chapter.

(3) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(4) *pH.* Proceed as directed in § 440.80a(b) (5) (ii) of this chapter, using a saturated aqueous solution containing approximately 50 milligrams per milliliter.

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

Subpart A—Oral Dosage Forms

Sec.
540.105 Ampicillin capsules.
540.107 Ampicillin trihydrate oral dosage forms.
540.107a Ampicillin trihydrate tablets.
540.107b Ampicillin trihydrate capsules.
540.107c Ampicillin trihydrate for oral suspension.
540.107d Ampicillin trihydrate soluble powder.
540.107e Ampicillin trihydrate boluses.
540.114 Benzathine cloxacillin.
540.114a Sterile benzathine cloxacillin.
540.119 Sodium dicloxacillin monohydrate capsules.
540.129 Potassium hetacillin oral dosage forms.
540.129a Potassium hetacillin tablets.
540.129b Potassium hetacillin capsules.
540.129c Potassium hetacillin oral suspension.
540.153 Aluminum penicillin tablets.
540.155 Benzathine penicillin G oral suspension, benzathine penicillin G for oral suspension (benzathine penicillin G powder).
540.160 Dibenzylamine penicillin and potassium penicillin powder, buffered.
540.163 Ephedrine penicillin tablets.
540.166 Hydrabamine penicillin G oral suspension.
540.173 Potassium phenoxymethyl penicillin oral dosage forms.
540.173a Potassium phenoxymethyl penicillin for oral solution; potassium phenoxymethyl penicillin for oral solution.
540.173b Penicillin tablets.
540.174 Procaine penicillin oral dosage forms.
540.174a Buffered penicillin powder, penicillin powder with buffered diluent.
540.174b Penicillin streptomycin powder; penicillin dihydrostreptomycin powder.
540.174c Procaine penicillin in oil capsules.
540.180 Penicillin oral dosage forms.
540.180a Penicillin and novobiocin capsules.
540.180b Penicillin-streptomycin tablets; penicillin - dihydrostreptomycin tablets.
540.181 Crystalline penicillin oral dosage forms.
540.181a Crystalline penicillin G oral suspension; crystalline penicillin G sodium oral suspension; potassium penicillin G oral suspension.
540.181b Potassium penicillin G in drinking water.

Subpart B—Implantation or Injectable Dosage Forms

540.207 Sterile ampicillin trihydrate implantation and injectable dosage forms.
540.207a Sterile ampicillin trihydrate suspension.
540.207b Sterile ampicillin trihydrate for suspension
540.250 Penicillin-streptomycin; penicillin-dihydrostreptomycin.
540.253 Aluminum penicillin in oil.
540.255 Benzathine penicillin G implantation and injectable dosage forms.

Sec.
540.255a Benzathine penicillin G suspension.
540.255b Benzathine penicillin G in oil.
540.255c Sterile benzathine penicillin G and procaine penicillin G for aqueous injection.
540.259 Chloroprocaine penicillin O for aqueous injection.
540.260 Dibenzylamine penicillin and streptomycin in oil; dibenzylamine penicillin and dihydrostreptomycin in oil.
540.261 Diethylaminoethyl ester penicillin G hydriodide for aqueous injection (penicillin G diethylaminoethyl ester hydriodide for aqueous injection).
540.265 *l*-Ephenamine penicillin G implantation and injectable dosage forms.
water.
540.265a *l*-Ephenamine penicillin G in oil.
540.265b *l*-Ephenamine penicillin G for aqueous injection.
540.274 Procaine penicillin G implantation and injectable dosage forms.
540.274a Procaine penicillin for aqueous injection.
540.274b Procaine penicillin G aqueous suspension.
540.274c Procaine penicillin G in oil.
540.274d Procaine penicillin in streptomycin sulfate solution; procaine penicillin in dihydrostreptomycin sulfate solution.
540.274e Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil.
540.274f Penicillin and dihydrostreptomycin-streptomycin sulfates; procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution.
540.280 Sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt), crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, crystalline penicillin O sodium, crystalline penicillin O sodium salt, crystalline penicillin O potassium, crystalline penicillin O potassium salt).
540.281 Crystalline penicillin implantation and injectable dosage forms.
540.281a Crystalline penicillin and epinephrine in oil.
540. 281b Buffered crystalline penicillin.

Subpart C—Ophthalmic and Topical Dosage Forms

540.380 Penicillin ophthalmic and topical dosage forms.
540.380a Penicillin ointment.
540.380b Procaine penicillin-neomycin-polymyxin in oil; procaine penicillin-neomycin-polymyxin ointment.

Subparts D–G [Reserved]

Subpart H—Intramammary Dosage Forms

540.814 Benzathine cloxacillin for intramammary infusion.
540.814a Sterile benzathine cloxacillin for intramammary infusion.
540.829 Potassium hetacillin intramammary infusion.
540.874 Procaine penicillin G intramammary dosage forms.
540.874a Procaine penicillin G in oil.
540.874b Procaine penicillin G-sodium novobiocin in oil.
540.874c Procaine penicillin G-neomycin in oil.
540.874d Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil.
540.874e Procaine penicillin and dihydrostreptomycin in oil.
540.874f Procaine penicillin G-novobiocin for intramammary infusion.
540.881 Crystalline penicillin-streptomycin-polymyxin - oxytetracycline - carbomycin powder; crystalline penicillin - dihydrostreptomycin-polymyxin - oxytetracycline-carbomycin powder.

AUTHORITY: Secs. 507, 512, 59 Stat. 463 as amended, 82 Stat. 343–351 (21 U.S.C. 360b, 357), unless otherwise noted.

Subpart A—Oral Dosage Forms

§ 540.105 Ampicillin capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Ampicillin capsules are composed of ampicillin with or without one or more buffer substances, diluents, binders, lubricants, vegetable oils, colorings, and flavorings, enclosed in a gelatin capsule. Each capsule contains 125 milligrams or 250 milligrams of ampicillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. The loss on drying is not more than 4.0 percent. The ampicillin used conforms to the standards prescribed by § 440.5(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin used in making the batch for potency, safety, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The ampicillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with sufficient 0.1M potassium phosphate buffer, pH 8.0 (solution 3), to give a convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Place the contents of a representative number of capsules into a high-speed glass blender jar, and add sufficient distilled water to give a convenient concentration. Blend 3 to 5 minutes. Filter through Whatman No. 2 filter paper. Further dilute an aliquot of the filtrate with distilled water to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000008 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is administered orally as follows:

(*a*) To dogs:

(*1*) In the treatment of urinary tract infections (cystitis) due to *Proteus spp.*, hemolytic and non-hemolytic streptococci, beta hemolytic streptococci and *E. coli.*

(*2*) In upper respiratory tract infections tracheobronchitis (kennel cough), tonsillitis due to alpha and beta hemolytic streptococci, hemolytic positive *Staphylococci, E. coli* and *Proteus spp.*

(*3*) In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus spp. and Streptococcus spp.*

(*b*) To cats:

(*1*) In respiratory tract infections (bacterial pneumonia) due to alpha and beta hemolytic streptococci, hemolytic positive *staphylococci, E. coli,* and *Proteus spp.*

(*2*) In infections associated with abscesses, lacerations, and wounds due to *Staphylococcus spp. and Streptococcus spp.*

(ii) Dosage is recommended as follows:

(*a*) In dogs 5 to 10 milligrams per pound of body weight, e.g., one 125 milligram capsule per 14 to 25 pounds, given 2 to 4 times daily; for those weighing 6 to 14 pounds, one capsule twice daily is suggested.

(*b*) In cats, 125 milligrams twice daily; in more acute conditions three times daily.

(iii) Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed.

(iv) Use of the drug is contraindicated in animals with a history of an allergic reaction to any of the penicillins. Ampicillin is contraindicated in infections caused by penicillinase-producing organisms.

(v) Not for use in animals which are raised for food production.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.107 Ampicillin trihydrate oral dosage forms.

§ 540.107a Ampicillin trihydrate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Ampicillin trihyrate tablets are composed of ampicillin trihydrate with suitable binders, fillers, lubricants, expanders, coloring, and flavoring. Each tablet contains 50 or 100 milli-

grams of ampicillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. Its loss on drying is not more than 10 percent. The tablets disintegrate within 30 minutes. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7 of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* It shall be packaged in accordance with the requirements of § 510.45 of this chapter.

(3) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and shall, in addition, be labeled "veterinary ampicillin tablets".

(4) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, toxicity, moisture, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, loss on drying, and disintegration time.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 containers, each containing not less than 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample solution as follows: Place a representative number of tablets into a high-speed glass blender jar with sufficient distilled water to give a stock solution of convenient concentration. Blend for 3 minutes. Further dilute an aliquot of the stock solution with distilled water to give the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter using the procedure described in paragraph (e) (1) of that section.

(c) *Conditions of marketing*—(1) *Specifications.* The drug contains ampicillin as ampicillin trihydrate and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000029 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is administered orally for treatment of infections associated with abscesses, lacerations, and wounds caused by *Staphylococcus spp.* and *Streptococcus spp.* in dogs.

(ii) Dosage is recommended at 5 mg per pound of body weight, at 8-hour intervals 1 to 2 hours prior to feeding. Treatment should be continued for 36 to 48 hours after all symptoms have subsided.

(iii) It is not for use in animals which have shown hypersensitivity to penicillin or for infections caused by penicillinase-producing organisms.

(iv) It is not for use in animals which are raised for food production.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.107b Ampicillin trihydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Ampicillin trihydrate capsules are composed of ampicillin trihydrate with or without one or more diluents, binders, or lubricants, enclosed in a gelatin capsule. Each capsule contains ampicillin trihydrate equivalent to 125, 250, or 500 milligrams of ampicillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. Its loss on drying is not less than 10 percent and not more than 15 percent. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7(a) (1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and, in addition, this drug shall be labeled "ampicillin capsules, veterinary."

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, safety, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Place the contents of a representative number of capsules into a blending jar and add sufficient distilled water to give a stock solution of convenient concentration. Blend for 3 minutes. Filter through Whatman No. 2 filter paper. Further dilute an aliquot of the filtrate with distilled water to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is in capsule form and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs as follows:

(*a*) It is administered as a treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (tracheobronchitis and tonsillitis); urinary tract infections (cystitis); bacterial gastroenteritis; generalized infections (septicemia) associated with abscesses, lacerations, and wounds; and bacterial dermatitis.

(*b*) Administer 5 to 10 milligrams per pound of body weight two or three times daily. In severe or acute conditions, 10 milligrams per pound of body weight should be given three times daily. Dosage should be administered 1 to 2 hours prior to feeding.

(ii) It is used in cats as follows:

(*a*) It is administered as a treatment against strains of gram-negative and gram-positive organisms sensitive to ampicillin and associated with respiratory tract infections (bacterial pneumonia); urinary tract infections (cystitis); and generalized infections (septicemia) associated with abscesses, lacerations, and wounds.

(*b*) Administer 10 to 30 milligrams per pound of body weight two or three times daily. Dosage should be administered 1 to 2 hours prior to feeding.

(iii) The drug may be given as an emergency measure; however, in vitro sensitivity tests on samples collected prior to treatment should be made. Ampicillin is contraindicated for use in infections caused by penicillinase-producing organisms and for use in dogs and cats known to be allergic to any of the penicillins. It is also not to be used in animals raised for food production.

(iv) For use only by or on the order of a licensed veterinarian.

§ 540.107c Ampicillin trihydrate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Ampicillin trihydrate for oral suspension is a mixture of ampicillin trihydrate with one or more suitable and harmless colorings, flavorings, buffers, sweetening ingredients, and preservatives. When reconstituted as directed in the labeling, it contains ampicillin trihydrate equivalent to 25 milligrams of ampicillin per milliliter. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. Its moisture content is not more than 2.5 percent. Its pH, when reconstituted as directed in the labeling, is not less than 5.0 and is not more than 7.5. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7(a) (1) of this chapter.

(2) *Labeling.* The drug shall be labeled in accordance with the requirements prescribed by paragraph (c) of this section and § 510.55 of this chapter, and in addition, it shall be labeled "ampicillin for oral suspension, veterinary".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, safety, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the drug as directed in the labeling. Place an accurately measured representative portion of the sample into a suitable volumetric flask and dilute to volume 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a convenient concentration. Mix well. Further dilute an aliquot with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Reconstitute the drug as directed in the labeling. Place an accurately measured aliquot, usually a single dose, into an appropriate-sized volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1). Mix well. Further dilute with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug reconstituted as directed in the labeling.

(c) *Conditions of marketing*—(1) *Specifications.* The drug contains ampicillin as ampicillin trihydrate and conforms to the requirements of paragraph (a) of this section. When reconstituted as directed in the labeling, it contains 125 milligrams of ampicillin per 5 milliliters of suspension.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dogs.* (*a*) It is indicated in the treatment of respiratory tract infections (tracheobronchitis and tonsillitis) due to *E. coli, Pseudomonas spp., Proteus spp., Staphylococcus spp.,* and *Streptococcus spp.,* urinary tract infections (cystitus) due to *E. coli, Staphylococcus spp.; Streptococcus spp.,* and *Proteus spp.;* bacterial gastroenteritis due to *E. coli;* generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus spp.* and *Streptococcus spp.;* bacterial dermatitis due to *Staphylococcus spp., Streptococcus spp., Proteus spp.,* and *Pseudomonas spp.*

(*b*) It is administered orally, 5 to 10 milligrams per pound of body weight 2 or 3 times daily, 1 to 2 hours prior to feeding. In severe or acute conditions, 10 milligrams per pound of body weight 3 times daily.

(ii) *Cats.* (*a*) It is indicated in the treatment of respiratory tract infections (bacterial pneumonia) due to *Staphylococcus spp., Streptococcus spp., E. coli,* and *Proteus spp.;* urinary tract infections (cystitis) due to *E. coli, Staphylococcus spp., Streptococcus spp., Proteus spp.,* and *Corynebacterium spp.;* generalized infections (septicemia) associated with abscesses, lacerations, and wounds, due to *Staphylococcus spp., Streptococcus spp., Bacillus spp.,* and *Pasteurella spp.*

(*b*) It is administered orally, 10 to 30 milligrams per pound of body weight 2 or 3 times daily, 1 to 2 hours prior to feeding.

(iii) *Duration of treatment.* In dogs and cats, duration of treatment is usually 3 to 5 days. Continue treatment 48 hours after the animal's temperature has returned to normal and all other signs of infection have subsided. If no response is obtained within 3 to 5 days, reevaluate diagnosis and treatment. Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment.

(iv) *Restrictions.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.107d Ampicillin trihydrate soluble powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Ampicillin trihydrate soluble powder is a dry mixture of ampicillin trihydrates with one or more suitable and harmless diluents and stabilizing agents. Each gram contains an amount of ampicillin trihydrate equivalent to 88.2 milligrams of ampicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin it is represented to contain. Its moisture content is not more than 5.0 percent. Its pH in an aqueous solution containing 20 milligrams of ampicillin per milliliter is not less than 3.5 and not more than 6.0. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7(a) (1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and in addition, this drug shall be labeled "ampicillin soluble powder, veterinary".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, safety, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, moisture and pH.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample, usually 1 gram, in sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3) to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Dissolve an accurately weighed sample, usually 1 gram, in sufficient distilled water to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with distilled water to the prescribed concentration.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 20 milligrams of ampicillin per milliliter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) Indicated for oral use in swine in the treatment of porcine colibacillosis (*E. coli*) and salmonellosis (*Salmonella spp.*) infections in swine up to 75 pounds of body weight,

and bacterial pneumonia caused by *Pasteurella multocida, Staphylococcus spp. Streptococcus spp.* and *Salmonella spp.*

(ii) The drug is administered at a dosage level of 5 milligrams of ampicillin activity per pound of body weight twice daily, administered orally by gavage or in drinking water for up to 5 days.

(iii) For use in swine only. Not for use in other animals which are raised for food production. Treated swine must not be slaughtered for food during treatment and for 24 hours following the last treatment.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.107e Ampicillin trihydrate boluses.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Ampicillin trihydrate boluses are composed of ampicillin trihydrate with or without one or more suitable and harmless diluents buffers, preservatives, stabilizing agents and lubricants. Each bolus contains the equivalent of 400 milligrams of ampicillin. Its potency is satisfactory if it is not less than 90 and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. Its loss on drying is not more than 5 percent. The ampicillin trihydrate used conforms to the standards prescribed in § 440.7(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and, in addition, this drug shall be labeled "ampicillin boluses, veterinary."

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate, used in making the batch, for potency, safety, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 boluses.

(b) *Test and methods of assay*—(1) *Potency.* Use *either* of the following methods, however, the results obtained from the microbiological agar diffusion assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of boluses into a high-speed glass blending jar with sufficient 0.1*M* potassium phosphate buffer pH 8.0 (solution 3) to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 3 to the reference concentration of 0.1 microgram ampicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Place a representative number of boluses in a high-speed glass blender jar and add sufficient distilled water to give a convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot with distilled water to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is in bolus form and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.40 of this chapter.

(4) *Conditions of use.* (i) It is administered orally to non-ruminating calves for the treatment of colibacillosis caused by *E. coli,* bacterial enteritis caused by *Salmonella spp.* and bacterial pneumonia caused by *Pasteurella spp.*

(ii) It is administered at a dosage level of 5 milligrams per pound of body weight twice daily.

(iii) For use in non-ruminating calves only. Not for use in other animals which are raised for food production.

(iv) Treated calves must not be slaughtered for food during treatment and for 15 days after the last treatment.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.114 Benzathine cloxacillin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Benzathine cloxacilline is the *N, N'*-dibenzylethylenediamine salt of 5-methyl-3-(*o*-chlorophenyl)-4-isoxazolyl penicillin. It is so purified and dried that:

(i) Its potency is not less than 704 nor more than 821 micrograms of cloxacillin per milligram on an anhydrous basis.

(ii) It passes the safety test.

(iii) Its moisture content is not more than 5.0 percent.

(iv) Its pH in an aqueous suspension containing 10 milligrams per milliliter is not less than 3.0 nor more than 6.5.

(v) It passes the identity test.

(vi) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, safety, moisture, pH, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 300 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Use the microbiological agar diffussion assay method. Proceed in accordance with § 436.105 of this chapter, using the cloxacillin working standard as the standard of comparison and preparing the sample for assay as follows: Dissolve an accurately weighted portion of the sample in sufficient methanol to give a convenient stock solution. Immediately dilute an aliquot of this stock solution with solution 1 to the reference concentration of 5 micrograms of cloxacillin per milliliter estimated.

(2) *Safety.* Proceed in accordance with § 436.33 of this chapter.

(3) *Moisture.* Proceed in accordance with § 436.201 of this chapter.

(4) *pH.* Proceed in accordance with § 436.202 of this chapter, using an aqueous suspension prepared by adding 10 milligrams per milliliter.

(5) *Identity.* Transfer approximately 20 milligrams of the sample to a 50-milliliter Erlenmeyer flask. Add 5.0 milliliters of 5*N* sodium hydroxide and heat in a steam bath 20 minutes. Cool. Transfer 1 milliliter to an extraction funnel; add approximately 10 milliliters of water and 1 milliliter of dilute sulfuric acid (1:2). Shake with 50 milliliters of ether. Discard the aqueous layer, and wash the ether layer with approximately 30 milliliters of water. Discard the aqueous layer again and extract with approximately 50 milliliters of 0.1*N* sodium hydroxide. Obtain a spectrum of the 0.1*N* sodium hydroxide solution from 300 nanometers to 240 nanometers against a reagent blank. Treat about 15 milligrams of the cloxacillin working standard in the same manner. The sample is satisfactory if the spectrum obtained from the sample solution matches that of the standard solution with maximum at about 282 nanometers and minimum at about 257 nanometers.

(6) *Crystallinity.* Proceed as directed in § 436.203 of this chapter.

§ 540.114a Sterile benzathine cloxacillin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Benzathine cloxacillin is the *N,N'*-dibenzylethylenediamine salt of 5-methyl-3-(*o*-chlorophenyl)-4-isoxazolyl penicillin. It is so purified and dried that:

(i) Its potency is not less than 704 nor more than 821 micrograms of cloxacillin per milligram on an anhydrous basis.

(ii) It is sterile.

(iii) It passes the safety test.

(iv) Its moisture content is not more than 5.0 percent.

(v) Its pH in an aqueous suspension containing 10 milligrams per milliliter is not less than 3.0 nor more than 6.5.

(vi) It passes the identity test.

(vii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, safety, moisture, pH, identity, and crystallinity.

(ii) Samples required:

(a) For all tests except sterility: 10 packages, each containing approximately 300 milligrams.

(b) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Use the microbiological agar diffusion assay method: Proceed in accordance with § 436.105 of this chapter, using the cloxacillin working standard as the standard of comparison and prepare the sample for assay as follows: Dissolve an accurately weighed portion of the sample in sufficient methanol to give a convenient stock solution. Immediately dilute an aliquot of this stock solution with solution 1 to the reference concentration of 5.0 micrograms of cloxacillin per milliliter estimated.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e) (2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation shake the tubes at least once daily.

(3) *Safety.* Proceed in accordance with § 436.33 of this chapter.

(4) *Moisture.* Proceed in accordance with § 436.201 of this chapter.

(5) *pH.* Proceed in accordance with § 436.202 of this chapter, using an aqueous suspension prepared by adding 10 milligrams per milliliter.

(6) *Identity.* Transfer approximately 20 milligrams of the sample to a 50-milliliter Erlenmeyer flask. Add 5.0 milliliters of 5*N* sodium hydroxide and heat in a steam bath 20 minutes. Cool. Transfer 1 milliliter to an extraction funnel; add approximately 10 milliliters of water and 1 milliliter of dilute sulfuric acid (1:2). Shake with 50 milliliters of ether. Discard the aqueous layer and wash the ether layer with approximately 30 milliliters of water. Discard the aqueous layer again and extract with approximately 50 milliliters of 0.1*N* sodium hydroxide. Obtain a spectrum of the 0.1*N* sodium hydroxide solution from 300 nanometers to 240 nanometers against a reagent blank. Treat about 15 milligrams of the cloxacillin working standard in the same manner. The sample is satisfactory if the spectrum obtained from the sample solution matches that of the standard solution with maximum at about 282 nanometers and minimum of about 257 nanometers.

(7) *Crystallinity.* Proceed as directed in § 436.203 of this chapter.

§ 540.119 Sodium dicloxacillin monohydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sodium dicloxacillin monohydrate capsules are composed of sodium dicloxacillin monohydrate and one or more suitable diluents and lubricants. Each capsule contains sodium dicloxacillin monohydrate equivalent to 50, 100, 200, or 500 milligrams of dicloxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of dicloxacillin that it is represented to contain. The moisture content is not more than 5 percent. The sodium dicloxacillin monohydrate conforms to the requirements of § 440.19(a) (1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The sodium dicloxacillin monohydrate used in making the batch for potency, safety, moisture, pH, organic chlorine content, free chloride content, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The sodium dicloxacillin monohydrate used in making the batch: 10 containers, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 5 micrograms of dicloxacillin per milliliter (estimated) for the microbiological agar diffusion assay and to the prescribed concentration for the iodometric assay.

(ii) *Assay procedure.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter.

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is in capsule form and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs in the treatment of pyoderma (pyogenic dermatitis) known to be due to penicillinase-producing staphylococci which have been shown to be sensitive to the drug.

(ii) It is administered to dogs at the rate of 5 milligrams to 10 milligrams per pound of body weight, three times daily. In severe cases the dose may be increased to 25 milligrams per pound of body weight three times daily. Treatment should be continued for 24 to 48 hours after the animal has become afebrile or asymptomatic. The drug should be administered 1 to 2 hours before feeding to insure maximum absorption.

(iii) For use in the treatment of dogs only. Not for use in animals which are raised for food production.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.129 Potassium hetacillin oral dosage forms.

§ 540.129a Potassium hetacillin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Potassium hetacillin tablets are composed of potassium hetacillin with or without one or more suitable buffer substances, diluents, binders, lubricants, flavorings, and colorings. Each tablet contains an amount of potassium hetacillin equivalent to 50, 100, or 200 milligrams of ampicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. The moisture content is not more than 5 percent. Tablets shall disintegrate within 30 minutes. The potassium hetacillin used conforms to the requirements of § 440.29 of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of section 512(b) of the Federal Food, Drug, and Cosmetic Act and § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The potassium hetacillin used in making the batch for potency, safety, moisture, pH, potassium hetacillin content, identity, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The potassium hetacillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for ampicillin in § 436.105 of this chapter, using the ampicillin working standard as the standard of comparison and preparing the sample for assay as follows: Place a representative number of tablets in a high-speed glass blender with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in § 436.212(e) (1) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is in capsule or tablet form. The capsules conform to the

certification requirements of § 540.129b, and the tablets conform to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000015 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs and cats as a treatment against strains of organisms sensitive to potassium hetacillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(ii) Dosage is administered as follows:

(*a*) In dogs, administer twice daily at a minimum rate of 5 milligrams per pound of body weight. In severe infections the frequency of the dosage may be increased to three times daily, or alternatively, the dosage may be increased to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, the dosage may be increased to 20 milligrams per pound of body weight twice daily. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. The oral drug should be administered 1 to 2 hours prior to feeding to ensure maximum absorption.

In stubborn infections, therapy may be required for several weeks.

(*b*) In cats the recommended dosage is 50 milligrams twice daily. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. The oral drug should be administered in a fasting state to ensure maximum absorption. In stubborn infections, therapy may be required for several weeks.

(iii) For use in dogs and cats only. Not to be used in animals which are raised for food production.

(iv) For use only by or the order of a licensed veterinarian.

§ 540.129b Potassium hetacillin capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Potassium hetacillin capsules are composed of potassium hetacillin with or without one or more suitable diluents, lubricants, and drying agents. Each capsule contains an amount of potassium hetacillin equivalent to 50, 100, or 200 milligrams of ampicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. The moisture content is not more than 3 percent. The potassium hetacillin used conforms to the requirements of § 440.29.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §§ 540.129a and 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of section 512(b) of the Federal Food, Drug, and Cosmetic Act and § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The potassium hetacillin used in making the batch for potency, safety, moisture, pH, potassium hetacillin content, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The potassium hetacillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for ampicillin in § 436.105 of this chapter, using the ampicillin working standard as the standard of comparison and preparing the sample for assay as follows: Place a representative number of capsules in a high-speed glass blender with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(c) *Conditions of marketing.* The conditions of marketing of potassium hetacillin capsules are described in § 540.129a (c).

§ 540.129c Potassium hetacillin oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Potassium hetacillin oral suspension is potassium hetacillin with one or more suitable and harmless colorings, flavorings and gelling agents suspended in a suitable and harmless non-aqueous vehicle. It contains in each milliliter an amount of potassium hetacillin equivalent to 50 milligrams of ampicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin it is represented to contain. Its moisture content is not more than 1.0 percent. Its pH is not less than 7.0 and not more than 9.0. It gives a positive identity test for hetacillin. The potassium hetacillin used conforms to the requirements of § 440.29 of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The potassium hetacillin used in making the batch for potency, safety, moisture, pH, potassium hetacillin content, identity and crystallinity.

(*b*) The batch for potency, moisture, pH and identity.

(ii) Samples required:

(*a*) The potassium hetacillin used in making the batch, 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of eight immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for ampicillin in § 436.105 of this chapter, using the ampicillin working standard as the standard for comparison and preparing the sample for assay as follows: Place an accurately measured aliquot (usually 1 milliliter) into a high-speed glass blender jar, with sufficient 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3) to give a stock solution of convenient concentration. Blend 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, preparing the sample as follows: Transfer about 5.0 milliliters of the well shaken sample to a centrifuge tube. Add 10 milliliters of benzene, shake vigorously for 3 minutes and centrifuge at medium speed for 5 minutes. Carefully decant the benzene without disturbing the precipitate. Add 5 milliliters of carbon dioxide-free distilled water.

(4) *Hetacillin identity.* Proceed as directed in § 436.305 of this chapter preparing the sample solution as follows: Place 1.0 milliliter of the well shaken sample into a 50-milliliter volumetric flask. Bring to volume with a 4:1 solution of acetone and 0.1 *N* hydrochloric acid.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is in liquid form and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000015 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs and cats as a treatment against strains of organisms susceptible to potassium hetacillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft-tissue infections, and post-surgical infections.

(ii) Dosage is administered as follows:

(*a*) In dogs, administer twice daily at a minimum rate of 5 milligrams per pound of body weight. In severe infections the frequency of the dosage may be increased to three times daily, or alternatively, the dosage may be increased to 10 milligrams per pound of body weight twice daily. For stubborn urinary tract infections, the dosage may be increased to 20 milligrams per pound of body weight twice daily. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic. The drug should be administered 1 to 2 hours prior to feeding to insure maximum absorption. In stubborn infections, therapy may be required for several weeks.

(*b*) In cats the recommended dosage is 50 milligrams twice daily. Treatment should be continued for 48 to 72 hours

after the animal has become afebrile or asymptomatic. The drug should be administered 1 to 2 hours prior to feeding to insure maximum absorption. In stubborn infections, therapy may be required for several weeks.

(iii) For use in dogs and cats only. Not to be used in animals raised for food production.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.153 Aluminum penicillin tablets.

(a) *Requirements for certification*—(1) The requirements for certification for aluminum penicillin tablets are described under § 440.153 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.153(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for aluminum penicillin tablets are described under § 440.153 of this chapter.

§ 540.155 Benzathine penicillin G oral suspension, benzathine penicillin G for oral suspension (benzathine penicillin G powder).

(a) *Requirements for certification*—(1) The requirements for certification for benzathine penicillin G oral suspension and benzathine penicillin G for oral suspension (benzathine penicillin G powder) are described under § 440.155c of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.155c(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for benzathine penicillin G oral suspension and benzathine penicillin G for oral suspension (benzathine penicillin G powder) are described under § 440.155c of this chapter.

§ 540.160 Dibenzylamine penicillin and potassium penicillin powder, buffered.

(a) *Requirements for certification*—(1) The requirements for certification for dibenzylamine penicillin and potassium penicillin powder, buffered, are described under § 440.160 of this chapter.

(2) When it is packaged for dispensing and intended for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.160(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription," each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for dibenzylamine penicillin and potassium penicillin powder, buffered, are described under § 440.160 of this chapter.

§ 540.163 Ephedrine penicillin tablets.

(a) *Requirements for certification.* (1) The requirements for certification for ephedrine penicillin tablets are described under § 440.563 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.563(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for ephedrine penicillin tablets are described under § 440.563 of this chapter.

§ 540.166 Hydrabamine penicillin G oral suspension.

(a) *Requirements for certification*—(1) The requirements for certification for hydrabamine penicillin G oral suspension are described under § 440.166 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.166(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription," each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for hydrabamine penicillin G oral suspension are described under § 440.166 of this chapter.

§ 540.173 Potassium phenoxymethyl penicillin oral dosage forms.

§ 540.173a Phenoxymethyl penicillin for oral suspension; potassium phenoxymethyl penicillin for oral solution.

(a) *Requirements for certification*—(1) The requirements for certification for phenoxymethyl penicillin for oral suspension and potassium phenoxymethyl penicillin for oral solution are described under § 440.171b(a) of this chapter.

(2) When phenoxymethyl penicillin for oral suspension and potassium phenoxymethyl penicillin for oral solution are packaged for dispensing and intended solely for veterinary use, their label and labeling shall comply with all the requirements prescribed by paragraph (c) of this section and § 510.55 of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for phenoxymethyl penicillin for oral suspension are described under § 440.171b(b) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug consists of soluble granules which conform to the certification requirements of paragraph (a) of this section.

(2) *Sponsors.* To No. 000986 in § 510.600(c) of this chapter, approval for soluble granules which when dissolved in water produce a solution of 125 or 250 milligrams of potassium phenoxymethyl penicillin per 5 milliliters; to 043731, approval for 125 milligrams per 5 milliliters.

(3) *Conditions of use.* (i) The drug is administered to dogs and cats orally for the treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to potassium phenoxymethyl penicillin.

(ii) It is administered at a dosage of 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(iii) It should be administered 1 to 2 hours prior to feeding for maximum absorption.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.173b Penicillin tablets.

(a) *Requirements for certification*—(1) The requirements for certification of penicillin tablets are described under § 440.180a of this chapter.

(2) When penicillin tablets are packaged for dispensing and intended solely for veterinary use: (i) The label and labeling shall comply with all the requirements prescribed by § 440.180a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drugs by the laity in all cases except those in which the veterinary prescription statement is required by regulations under paragraph (c) of this section. In those cases, the veterinary prescription statement shall comply with the requirements prescribed by § 201.105 of this chapter.

(ii) If it contains added vitamins, the labels shall bear the name and quantity of each substance and a statement that such substances are present only for furnishing additional vitamins while animals are eating less feed.

(iii) If it is intended for use in animals raised for food production, it shall be used in accordance with § 540.174a of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for penicillin tablets are described under § 440.180a of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Each tablet contains potassium phenoxymethyl penicillin and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsors.* To No. 000986 in § 510.600(c) of this chapter, approval for tablets containing 125, 250, or 500 milligrams of the drug; to 043731, approval for tablets containing 125 or 250 milligrams of the drug.

(3) *Conditions of use.* (i) The drug is administered to dogs and cats for the treatment of respiratory, urogenital, skin and soft tissue infections and septicemia caused by pathogens susceptible to potassium phenoxymethyl penicillin.

(ii) It is administered orally at a dosage of 10 to 15 milligrams per pound of body weight every 6 to 8 hours.

(iii) It should be administered 1 to 2 hours prior to feeding for maximum absorption.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.174 Procaine penicillin oral dosage forms.

§ 540.174a Buffered penicillin powder, penicillin powder with buffered aqueous diluent.

(a) *Requirements for certification.*—(1) The requirements for certification for buffered penicillin powder and penicillin powder with buffered aqueous diluent are described under § 440.180f of this chapter.

(2) When buffered penicillin powder and penicillin powder with buffered aqueous diluent are packaged for dispensing and intended solely for veterinary use: (i) Their labels and labeling shall comply with all the requirements prescribed by § 440.180f(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(ii) If it contains added vitamins or minerals, the labels shall bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(iii) If it is intended for use in animals raised for food production, it shall be used in accordance with paragraph (c) of this section.

(b) *Tests and methods of assay.* The tests and methods of assay for buffered penicillin powder are described under § 440.180f of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Complies with the requirements for procaine penicillin found in paragraph (a) of this section or § 540.713b.

(2) *Sponsor.* [Reserved]

(3) *Special considerations.* The quantities of antibiotic in paragraph (c)(5) of this section refer to the activity of the master standard.

(4) *Related tolerances.* See § 556.510 of this chapter.

(5) *Conditions of use.* It is used in the drinking water of chickens as follows:

(i) *Amount per gallon.* 100,000 units.

(a) *Indications for use.* For treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).

(b) *Limitations.* As procaine penicillin; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

(ii) *Amount per gallon.* 50,000 to 100,000 units.

(a) *Indications for use.* For prevention of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).

(b) *Limitations.* As procaine penicillin; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin.

§ 540.174b Penicillin streptomycin powder; penicillin-dihydrostreptomycin powder.

(a) *Requirements for certification.* Penicillin-streptomycin powder and penicillin-dihydrostreptomycin powder conform to all the requirements and are subject to all procedures prescribed by § 440.180b(a) of this chapter for penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets, except that:

(1) Each gram contains not less than 50,000 units of penicillin (except if it is intended solely for veterinary use each gram contains not less than 2,200 units of penicillin) and not less than 5 milligrams of streptomycin or dihydrostreptomycin. Its moisture content is not more than 1.0 percent, except that if it is intended solely for veterinary use: It is not more than 2.0 percent if it contains not more than 110 milligrams of streptomycin or dihydrostreptomycin per gram; or it is not more than 3.5 percent if it contains more than 110 milligrams of streptomycin or dihydrostreptomycin per gram; and the person who requests certification has submitted to the Commissioner results of tests and assays that show that such amounts of moisture do not adversely affect the stability of such veterinary-use drug.

(2) In lieu of the labeling prescribed by § 440.180b(a)(1)(ii) of this chapter, each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each gram and the statement "Expiration date _____", the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays that show such drug as prepared by him is stable for such period of time.

(3) In lieu of the minimum number of tablets prescribed by § 440.180b(a)(1)(iii) of this chapter, a person who requests certification of a batch shall submit with his request a sample of the batch consisting of 1 immediate container for each 5,000 immediate containers but in no case less than 6 immediate containers. Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Penicillin content.* Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 440.80a(b)(1) of this chapter, except paragraph (b)(1)(ix) of that section. The penicillin content of the powder is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(ii) *Streptomycin content.* Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 536.502(a)(2). The streptomycin content of the powder is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(iii) *Dihydrostreptomycin content.* Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 536.502(a)(3). The dihydrostreptomycin content of the powder is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Complies with the requirements for penicillin-streptomycin powder found in paragraph (a) of this section.

(2) *Sponsor.* [Reserved]

(3) *Special considerations.* The quantities of antibiotics in paragraph (c)(5) of this section refer to the activity of the master standards.

(4) *Related tolerances.* See §§ 556.510 and 556.610 of this chapter.

(5) *Conditions of use.* It is used in the drinking water of certain animals as follows:

(i) *Chickens*—(a) *Amount per gallon.* 100,000 to 119,000 units of penicillin with 250 to 304 milligrams of streptomycin.

(1) *Indications for use.* For treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).

(2) *Limitations.* As procaine penicillin plus streptomycin sulfate; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin and streptomycin.

(b) *Amount per gallon.* 50,000 to 100,000 units of penicillin with 125 to 250 milligrams of streptomycin.

(1) *Indications for use.* For prevention of chronic respiratory disease (air-sac

infection) and blue comb (nonspecific infectious enteritis).

(2) *Limitations.* As procaine penicillin plus streptomycin sulfate; not for use in laying chickens; prepare fresh solution daily; withdraw 1 day before slaughter; as sole source of penicillin and streptomycin.

(ii) *Turkeys—(a) Amount per gallon.* 100,000 to 119,000 units of penicillin and 250-304 milligrams of streptomycin.

(*1*) *Indications for use.* For treatment of infectious sinusitis and blue comb (nonspecific infectious enteritis).

(2) *Limitations.* As procaine penicillin plus streptomycin sulfate; not for use in laying birds; prepare fresh solution daily; withdraw 3 days before slaughter; as sole source of penicillin and streptomycin.

§ 540.174c Procaine penicillin in oil capsules.

(a) *Requirements for certification*—(1) The requirements for certification for procaine penicillin in oil capsules are described under § 440.174 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.174(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production".

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin in oil capsules are described under § 440.174 of this chapter.

§ 540.180 Penicillin oral dosage forms.

§ 540.180a Penicillin and novobiocin capsules.

(a) *Requirements for certification.* The requirements for certification for penicillin and novobiocin capsules are described under § 440.180d of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for penicillin and novobiocin capsules are described under § 440.180d of this chapter.

§ 540.180b Penicillin-streptomycin tablets; penicillin-dihydrostreptomycin tablets.

The requirements for certification and the tests and methods of assay for penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets are described under § 440.180b of this chapter, except if they are intended for use in parakeets and canaries, each tablet contains not less than 2.5 milligrams of streptomycin or dihydrostreptomycin and not less than 32,500 units of penicillin; the streptomycin or dihydrostreptomycin used in tablets for veterinary use may conform to the standards prescribed by § 539.170(a)(1) of this chapter.

§ 540.181 Crystalline penicillin oral dosage forms.

§ 540.181a Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension.

(a) *Requirements for certification*—(1) The requirements for certification for crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension are described under § 440.180e of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.180e(a)(3) of the chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production".

(b) *Tests and methods of assay.* The tests and methods of assay for crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, and potassium penicillin G oral suspension are described under § 440.180e of this chapter.

§ 540.181b Potassium penicillin G in drinking water.

(a) [*Reserved*]

(b) [*Reserved*]

(c) *Conditions of marketing*—(1) *Specifications.* The drug contains 0.384 billion units of potassium penicillin G per container. Potassium penicillin G must conform to the specifications in § 540.280 (a), except for sterility and pyrogens.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in turkeys for treatment of erysipelas caused by *Erysipelothrix insidiosa.*

(ii) It is administered in the drinking water of turkeys at the rate of 1,500,000 units per gallon of water for 5 days.

(iii) Concentrated stock solution prepared for use with medication proportioners must be prepared fresh every 24 hours. Recommended use levels (gravity flow watering system) must be prepared fresh every 12 hours. For best results treatment should be started at the first sign of infection.

(iv) Discontinue treatment at least 1 day prior to slaughter of the turkeys. Not to be used in turkeys producing eggs for human consumption.

Subpart B—Implantation or Injectable Dosage Forms

§ 540.207 Sterile ampicillin trihydrate implantation and injectable dosage forms.

§ 540.207a Sterile ampicillin trihydrate suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile ampicillin trihydrate suspension is ampicillin trihydrate in a suitable and harmless oil base. It may contain one or more suitable and harmless preservatives, antioxidants, and complexing or suspending agents. It contains, in each milliliter, an amount of ampicillin trihydrate equivalent to 200 milligrams of ampicillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. It is sterile. Its moisture content is not more than 4.0 percent. The ampicillin trihydrate used conforms to the requirements of § 440.7a(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) The results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, safety, loss on drying, pH, ampicillin content, crystallinity, and identity.

(*b*) The batch for potency, sterility, and moisture.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 5 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive:

(i) *Microbiological agar diffusion assay.* Proceed in accordance with § 436.105 of this chapter, preparing the sample as follows: Using a 22-gage hypodermic needle and suitable syringe, place an accurately measured representative portion of the sample (usually 1 milliliter) into a high-speed glass blender jar. Add 1.0 milliliter of polysorbate 80 and sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3) to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter.

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Using a suitable syringe and needle, transfer a 2.5-milliliter portion of the sample to a separatory funnel containing 100 milliliters of diethyl ether. Extract twice with 150 milliliters of 0.2*N* hydrochloric acid, collecting the extracts in a 500-milliliter volumetric flask. Bring to volume with distilled water to obtain a concentration of 1 milligram per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that

section, except use medium B in lieu of medium A.

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Sterile ampicillin suspension contains 200 milligrams of ampicillin (as ampicillin trihydrate) per milliliter of nonaqueous vehicle and conforms to the requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.40 of this chapter.

(4) *Conditions of use.* (i) The drug is administered intramuscularly to calves for the treatment of bacterial enteritis caused by *E. coli* susceptible to ampicillin.

(ii) It is administered at a dose of 3 milligrams per pound of body weight, once or twice daily, for up to 3 days.

(iii) It is not for use in other animals raised for food production.

(iv) Treated animals must not be slaughtered for food use during treatment or for 9 days after the last treatment.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.207b Sterile ampicillin trihydrate for suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile ampicillin trihydrate for suspension is a dry mixture of ampicillin trihydrate and one or more suitable and harmless buffer substances, stabilizers, suspending agents, and preservatives. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its loss on drying is not less than 11.4 percent and not more than 14.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.0. The ampicillin trihydrate used conforms to the requirements of § 440.7a of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and in addition, this drug shall be labeled "sterile ampicillin for suspension, veterinary".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, sterility, pyrogens, safety, loss on drying, and pH.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container or, if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute the resultant solution with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), for the microbiological agar diffusion assay, or distilled water for the iodometric assay, to give a stock solution of convenient concentration.

(ii) *Assay procedure.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with distilled water to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except in lieu of paragraph (e)(1)(i)(*a*), prepare the sample for test as follows: From each of 10 immediate containers, aseptically transfer approximately 300 milligrams of sample into a sterile 500-milliliter Erlenmeyer flask containing approximately 400 milliliters of diluting fluid D. Add at least 200,000 Levy units[1] of penicillinase. Repeat the process using 10 additional containers. Swirl both of the stoppered flasks to completely solubilize the suspension prior to filtration and proceed as directed in paragraph (e)(1)(ii) of that section. If the formulation cannot be filtered, proceed as directed in § 436.20(e)(2), except use medium B in lieu of medium A and add at least 40,000 Levy units of penicillinase to both medium B and medium E.

(3) *Pyrogens.* Proceed as directed in § 436.32(f) of this chapter, using a solution containing 20 milligrams of ampicillin per milliliter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution obtained when the product is reconstituted as directed in the labeling.

(c) *Conditions of marketing*—(1) *Specifications.* Sterile ampicillin trihydrate for suspension conforms to the standards of identity, strength, quality, and purity prescribed by paragraph (a) of this section.

(2) *Sponsor.* See No. 000015 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs and cats as a treatment against strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(ii) Dosage is administered to dogs and cats at 3 milligrams per pound of body weight twice daily by subcutaneous or intramuscular injection. Treatment should be continued for 48 to 72 hours after the animal has become afebrile or asymptomatic.

(iii) It is used in cattle in the treatment of respiratory tract infection caused by organisms susceptible to ampicillin trihydrate, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter spp., Klebsiella spp., Staphylococcus spp., Streptococcus spp., Pasteurella multocida,* and *E. coli.*

(iv) It is administered to cattle at a dosage level of 2 to 5 mg/lb of body weight once daily by intramuscular injection.

(v) Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment, and for 48 hours (4 milkings) after the last treatment. Treated cattle must not be slaughtered for food during treatment, and for 144 hours (6 days) after the last treatment.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.250 Penicillin-streptomycin; penicillin-dihydrostreptomycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin-streptomycin and penicillin-dihydrostreptomycin are procaine penicillin, crystalline, sodium penicillin, potassium penicillin, *l*-ephenamine penicillin G, or diethylaminoethyl ester penicillin G hydriodide or a mixture of two or more such salts and streptomycin sulfate of dihydrostreptomycin sulfate, with or without suitable and harmless buffer substances and suspending or dispersing agents. Each drug is sterile, nontoxic, and nonpyrogenic. Its moisture content is not more than 3.5 percent, except if it contains procaine penicillin its moisture content is not more than 4.2 percent. When prepared for injection as directed in its labeling, its pH is not less than 5.0 and not more than 7.5. The penicillin used conforms to the requirements of §§ 440.61a(a)(1), 440.65a(a)(1), 440.74a(a)(1), or 440.80a(a)(1) of this chapter. The streptomycin sulfate used conforms to the requirements prescribed for streptomycin sul-

[1] One Levy unit of penicillinase inactivates 59.3 units of penicillin G in 1 hour at 25° C. and at a pH of 7.0 in a phosphate buffered solution of a pure alkali salt of penicillin G when the substrate is in sufficient concentration to maintain a zero order reaction.

fate by § 440.70a(a)(1) of this chapter. The dihydrostreptomycin sulfate used conforms to the requirements prescribed for dihydrostreptomycin sulfate by § 444.10a(a) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium. Penicillin-streptomycin is also the drug described in § 540.274 f(a) of this chapter if it conforms to all requirements of that section and of § 540.274f(b) of this chapter, except that it contains streptomycin in lieu of a mixture of streptomycin and dihydrostreptomycin.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U.S.P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each such container may be packaged in combination with a container of a solvent consisting of water for injection U.S.P., dextrose injection U.S.P., or sodium chloride injection U.S.P.

(3) *Labeling*—(i) *It is packaged for dispensing.* In addition to the labeling requirements prescribed by § 201.105 of this chapter (regulations issued under section 502(f) of the act), each package shall bear on its label or labeling, as hereinafter indicated, the following:

(*a*) On the outside wrapper or container and the immediate container, the statement "Expiration date _____", the blank being filled in with the date that is 48 months after the month in which the batch was certified, except that the blank may be filled in with the date that is 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays, showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section, and except that in no case shall the blank be filled in with the date that is more than 24 months after the month in which the batch was certified if it contains diethylaminoethyl ester penicillin G hydriodide.

(*b*) In lieu of the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity

(*c*) If it does not contain diethylaminoethyl penicillin G hydriodide and is intended for use in the treatment of food-producing animals, the labeling shall bear the statement "Warning—The use of this drug must be discontinued for 30 days before treated animals are slaughtered for food", and, if the drug is intended for use in animals producing milk for human consumption, the labeling shall also bear the statement required by § 510.106 of this chapter.

(*d*) If it contains diethylaminoethyl penicillin G hydriodide, the labeling shall bear the statement "Warning—Not for use in animals which are raised for food production".

(ii) *It is packaged solely for manufacturing use and/or repacking.* Each package shall bear on its outside wrapper or container and the immediate container the following:

(*a*) The number of units of each salt of penicillin in each gram.

(*b*) The number of milligrams of streptomycin or dihydrostreptomycin in each gram.

(*c*) The statement "Caution: Federal law prohibits dispensing without prescription".

(*d*) The statement "For manufacturing use". "For repacking", or "For manufacturing use or repacking".

(*e*) The information required by paragraph (a)(3)(i)(*a*) of this section.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch of penicillin and streptomycin or penicillin and dihydrostreptomycin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of units of each salt of penicillin, and the number of grams of streptomycin or dihydrostreptomycin in each package, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and streptomycin or dihydrostreptomycin used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If such batch, or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(v) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: potency, sterility, toxicity, pyrogens, moisture, pH.

(*b*) The procaine penicillin used in making the batch: potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(*c*) The crystalline sodium or potassium penicillin used in making the batch: potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(*d*) The *l*-ephanamine penicillin G used in making the batch: potency, crystallinity, heat stability, penicillin G content, and specific rotation.

(*e*) The diethylaminoethyl ester penicillin G hydriodide used in making the batch: potency, crystallinity, and penicillin G content.

(*f*) The streptomycin or dihydrostreptomycin used in making the batch: potency, histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(iii) Except as otherwise provided by paragraph (a)(4)(v) of this section, if such batch is packaged for dispensing, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representative samples of the following:

(*a*) The batch:

(*1*) For all tests except sterility: One immediate container for each 5,000 immediate containers in such batch, but in no case less than 12 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation, or 40 immediate containers if each contains less than 600 milligrams.

(*b*) The procaine penicillin used in making the batch: 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 440.74a(a)(2) of this chapter.

(*c*) The crystalline pencillin used in making the batch: 3 packages containing approximately equal portions of not less than 250 milligrams each packaged in accordance with the requirements of § 440.80a(a)(2) of this chapter.

(*d*) The *l*-ephenamine penicillin G used in making the batch: 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 440.65a(a)(2) of this chapter.

(*e*) The diethylaminoethyl ester penicillin G hydriodide used in making the batch: 3 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with § 440.61a(a)(2) of this chapter.

(*f*) The streptomycin or dihydrostreptomycin used in making the batch: 6 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 444.70a(a)(2) of this chapter.

(*g*) In case of an initial request for certification, each other ingredient used in making the batch: one package of each containing approximately 5 grams.

(iv) If such batch is packaged for repacking, such person shall submit with

his request a sample consisting of the following:

(a) For all tests except sterility; 12 approximately equal portions of at least 2 grams.

(b) For sterility testing; 20 packages, each containing approximately equal portions of at least 600 milligrams.

Each such portion shall be taken from a different part of such batch, and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(v) No result referred to in paragraph (a)(4)(ii)(b), (c), (d), (e)—and (f) of this section and no samples referred to in paragraph (a)(4)(iii)(b), (c), (d), (f), and (g) of this section are required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sodium or potassium penicillin content.* Proceed as directed in § 436.503(b) of this chapter, except prepare the sample as follows: Add the indicated amount of distilled water to the contents of a vial of the sample and shake well. Withdraw one dose of the suspension or solution with a hypodermic syringe and place in a 10-milliliter volumetric flask. Also, with the further exception that in the idometric assay, one drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2. The sodium or potassium penicillin content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(ii) *Total penicillin content.* Proceed as directed in § 440.80a(b)(1) of this chapter, except paragraphs (b)(1)(iv) and (ix) of that section. In lieu of the directions in § 440.80a(b)(1)(iv) of this chapter, place a representative aliquot of the sample in a blending jar, add 1.0 milliliter of polysorbate 80 and sufficient 1 percent phosphate buffer, pH 6.0, to make a total volume of 500 milliliters. Blend 3 to 5 minutes. For the alternative iodometric test, proceed as directed in § 440.80a(b)(5)(iv)(a) of this chapter, except add one drop of 1.2 *N* HCl to the blank immediately before the addition of the 0.01 *N* I_2.

(iii) *Procaine penicillin content.* Proceed as directed in § 436.503(c) of this chapter. The procaine penicillin content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(iv) *l-Ephenamine penicillin G content.* Proceed as directed in § 440.65a(b)(1) of this chapter, except that in the iodometric assay one drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2. The *l*-ephenamine penicillin G content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(v) *Diethylaminoethyl ester penicillin G hydriodide content.* Proceed as directed in § 440.61a(b)(1) of this chapter, except that in the iodometric assay one drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2. The diethylaminoethyl ester penicillin G hydricdide content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(vi) *Streptomycin content.* Proceed as directed in § 444.70a(b)(1)(x) and (xi) of this chapter.

(vii) *Dihydrostreptomycin content.* Proceed as directed in § 444.10a(b)(1) of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except if the product contains procaine penicillin add sufficient penicillinase to the diluting fluid to solubilize the procane penicillin. Use diluting fluid A; if the product contains lecithin, use diluting fluid D instead. Swirl the flask to completely solubilize the procaine penicillin before filtration. If the product contains sodium carboxymethylcellulose, add sufficient sterile carboxymethylcellulase to diluting fluid A or D to completely solubilize the sodium carboxymethylcellulose before filtration. If the preparation contains *l*-ephenamine penicillin, or agents that prevent solubilization, proceed as directed in § 436.20(e)(2) of this chapter, using medium B in lieu of medium A.

(3) *Toxicity.* Proceed as directed in § 440.80a(b)(4) of this chapter, using as a test dose 0.5 milliliter of a solution of the sample containing 1.0 milligram of streptomycin or dihydrostreptomycin per milliliter.

(4) *Pyrogens.* Proceed as directed in § 440.80a(b)(3) of this chapter, using as a test dose 2 milliliters per kilogram of a solution containing 5 milligrams of streptomycin or dihydrostreptomycin per milliliter.

(5) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter, except that if procaine penicillin is used proceed as directed in § 440.74a(b)(5) of this chapter.

(6) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using the solution or suspension resulting when the amount of diluent recommended in the labeling is added.

§ 540.253 Aluminum penicillin in oil.

(a) *Requirements for certification.* (1) The requirements for certification for aluminum penicillin in oil are described under § 440.253 of this chapter.

(2) When it is packaged for dispensing and is intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.253(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for aluminum penicillin in oil are described under § 440.253 of this chapter.

§ 540.255 Benzathine penicillin G implantation and injectable dosage forms.

§ 540.255a Sterile benzathine penicillin G suspension.

(a) *Requirements for certification.* The requirements for certification for benzathine penicillin G for aqueous injection for veterinary use are described under § 440.255b of this chapter, with the following exceptions:

(1) *Packaging.* It need not be packaged for dispensing in immediate containers of colorless transparent glass. If it is the aqueous suspension of the drug, conspicuously labeled for veterinary use, the container is exempt from the 10-milliliter-maximum requirement prescribed by § 440.255b(a)(2) of this chapter.

(2) *Labeling.* When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all requirements prescribed by § 440.255b(a)(3) of this chapter, except that in lieu of the requirements of § 201.100 of this chapter, it shall be labeled in accordance with the requirements prescribed by § 201.105 of this chapter, issued under section 502(f) of the act.

(b) *Tests and methods of assay.* The tests and methods of assay for benzathine penicillin G for aqueous injection are described under § 440.255b of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Meets the specifications in paragraph (a) of this section.

(2) *Sponsor.* See No. 000008 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the treatment of bacterial infections susceptible to penicillin G in horses and dogs.

(ii) Inject intramuscularly in horses at 4,000 units per pound of body weight. Inject intramuscularly or subcutaneously in dogs at 12,000 to 24,000 units per pound of body weight. The dosage should be repeated in 48 hours.

(iii) Not to be used in animals intended for food purposes.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.255b Benzathine penicillin G in oil.

(a) *Requirements for certification.* (1) The requirements for certification for benzathine penicillin G in oil are described under § 440.255a of this chapter.

(2) If it is packaged for dispensing and intended solely for veterinary use, it shall be labeled in accordance with the requirements of § 510.55(d) of this chapter, except that it shall be labeled in accordance with the requirements prescribed by § 201.105 of this chapter, issued under section 502(f) of the act.

(b) *Tests and methods of assay.* The tests and methods of assay for benzathine penicillin G in oil are described under § 440.255a of this chapter.

§ 540.255c Benzathine penicillin G and procaine penicillin for aqueous injection.

(a) *Requirements for certification.* The requirements for certification for benzathine penicillin G and procaine penicillin for aqueous injection are described under § 440.255c of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for benzathine penicillin G and procaine penicillin for aqueous injection are described under § 440.255c of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Meets the specifications in paragraph (a) of this section. Each cubic centimeter contains 150,000 units of benzathine penicillin G and 150,000 units of procaine penicillin G in aqueous suspension.

(2) *Sponsor.* See Nos. 000856, 000008, and 000015 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.510 of this chapter.

(4) *Conditions of use.* (i) It is used for the treatment of bacterial infections susceptible to penicillin G in horses, dogs, and beef cattle.

(ii) Inject intramuscularly in horses at 2 cubic centimeters per 150 pounds of body weight. Inject intramuscularly or subcutaneously in dogs at 1 cubic centimeter per 10 to 25 pounds of body weight. Inject beef cattle subcutaneously only at 2 cubic centimeters per 150 pounds body weight. The dosage should be repeated in 48 hours.

(iii) Treatment in beef cattle should be limited to two doses. Not to be used in beef cattle within 30 days of slaughter nor in horses intended for food purposes.

(iv) Restricted to use by or on the order of a licensed veterinarian.

§ 540.259 Chloroprocaine penicillin O aqueous injection.

(a) *Requirements for certification*—(1) The requirements for certification for chloroprocaine penicillin O for aqueous injection are described under § 440.259 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.259(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production".

(b) *Tests and methods of assay.* The tests and methods of assay for chloroprocaine penicillin O for aqueous injection are described under § 440.259 of this chapter.

§ 540.260 Dibenzylamine penicillin and streptomycin in oil; dibenzylamine penicillin and dihydrostreptomycin in oil.

(a) *Requirements for certification.* Dibenzylamine penicillin and streptomycin in oil and dibenzylamine penicillin and dihydrostreptomycin in oil conform to all the requirements prescribed by § 540.274e(a) for procaine penicillin and dihydrostreptomycin in oil and are subject to all procedures prescribed by § 540.274e(a) for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil except that dibenzylamine penicillin is used in lieu of procaine penicillin. The dibenzylamine penicillin used conforms to the requirements of § 440.60(a)(1) of this chapter, except paragraph (a)(1)(ii), (iii) (unless it is intended for subcutaneous injection in fowl), and (iv) of that section.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Penicillin content.* Proceed as directed in § 440.284a(b)(1) of this chapter, except the last sentence thereof. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(ii) *Streptomycin content.* Using 1.0 milliliter as the test sample, proceed as directed in § 536.501(a)(2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(iii) *Dihydrostreptomycin content.* Using 1.0 milliliter as the test sample, proceed as directed in § 536.501(a)(3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(2) *Moisture.* Using 1.0 milliliter as the test sample, proceed as directed in § 436.500(c) of this chapter.

§ 540.261 Diethylaminoethyl ester penicillin G hydriodide for aqueous injection (penicillin G diethylaminoethyl ester hydriodide for aqueous injection).

(a) *Requirements for certification*—(1) The requirements for certification for diethylaminoethyl ester penicillin G hydriodide for aqueous injection (penicillin G diethylaminoethyl ester hydriodide for aqueous injection) are described under § 440.261 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.261(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production".

(b) *Tests and methods of assay.* The tests and methods of assay for diethylaminoethyl ester penicillin G hydriodide for aqueous injection (penicillin G diethylaminoethyl ester hydriodide for aqueous injection) are described under § 440.261 of this chapter.

§ 540.265 l-Ephenamine penicillin G implantation and injectable dosage forms.

§ 540.265a l-Ephenamine penicillin G in oil.

(a) *Requirements for certification*—(1) The requirements for certification for *l*-ephenamine penicillin G in oil are described under § 440.265a(a) of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.265a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production".

(b) *Tests and methods of assay.* The tests and methods of assay for *l*-ephenamine penicillin G in oil are described under § 440.265a(b) of this chapter.

§ 540.265b l-Ephenamine penicillin G for aqueous injection.

(a) *Requirements for certification.* (1) The requirements for certification for *l*-ephenamine penicillin G for aqueous injection are described under § 440.265b(a) of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use: (i) Its label and labeling shall comply with all the requirements prescribed by § 440.265b(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(ii) If it is intended for use in animals raised for food production, it shall be used in accordance with paragraph (c) of this section.

(b) *Tests and methods of assay.* The tests and methods of assay for *l*-ephenamine penicillin G for aqueous injection are described under § 440.265b(b) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Complies with the requirements of paragraph (a) of this section.

(2) *Sponsor.* [Reserved]

(3) *Special considerations.* (i) The labeling shall bear the statement "Warning—The use of this drug must be discontinued for 5 days before treated animals are slaughtered for food."

(ii) If the drug is intended for use in animals producing milk for human consumption, the labeling shall also bear the statement "Milk that has been taken from animals during treatment and for _____ hours (_____ milkings) after the latest treatment must not be used for food", the blanks being filled with the figures 96 and 8 respectively, unless the sponsor of the drug has submitted the results of tests and assays demonstrating that residues of the drug in milk from treated animals persist for a shorter pe-

riod of time and the shorter period is authorized by the Commissioner.

(iv) If the drug is intended for use in poultry, the labeling shall bear a statement that the drug is not to be used in birds producing eggs for human consumption.

(4) *Related tolerances.* See § 556.510 of this chapter.

(5) *Conditions of use.* As an intramuscular injection in food-producing animals in an amount not to exceed 2,000 units per pound of body weight per day.

§ 540.274 Procaine penicillin G implantation and injectable dosage forms.

§ 540.274a Procaine penicillin for aqueous injection.

(a) *Requirements for certification.* (1) The requirements for certification for procaine penicillin for aqueous injection are described under § 440.274b of this chapter.

(2) When procaine penicillin for aqueous injection is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the following requirements:

(i) If it does not contain cortisone or a derivative of cortisone, its label and labeling shall comply with all of the requirements prescribed by § 440.274b(a)(3) of this chapter, except in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity in all cases except those in which the veterinary prescription statement is required by regulations under this Subchapter E. In those cases, the veterinary prescription statement shall comply with the requirements prescribed by § 201.105 of this chapter.

(ii) If it contains cortisone or a derivative of cortisone, the label and labeling of each package shall conform with the requirements prescribed by § 201.105 of this chapter and with the requirements of § 510.55 of this chapter.

(iii) If it is intended for use in animals raised for food production, it shall be used in accordance with paragraph (c) of this section.

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin for aqueous injection are described under § 440.274b of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Complies with the requirements of paragraph (a) of this section.

(2) *Sponsor.* [Reserved]

(3) *Special considerations.* (i) The labeling shall bear the statement "Warning—The use of this drug must be discontinued for 5 days before treated animals are slaughtered for food."

(ii) If the drug is intended for use in animals producing milk for human consumption, the labeling shall also bear the statement "Milk that has been taken from animals during treatment and for ------ hours (------ milkings) after the latest treatment must not be used for food", the blanks being filled with the figures 96 and 8 respectively, unless the sponsor of the drug has submitted the results of tests and assays demonstrating that residues of the drug in milk from treated animals persist for a shorter period of time and the shorter period is authorized by the Commissioner.

(iii) If the drug is intended for use in poultry, the labeling shall bear a statement that the drug is not to be used in birds producing eggs for human consumption.

(4) *Related tolerances.* See § 556.510 of this chapter.

(5) *Conditions of use.* As an intramuscular injection in food-producing animals in an amount not to exceed 2,000 units per pound of body weight per day.

§ 540.274b Procaine penicillin G aqueous suspension.

(a) *Requirements for certification.* The requirements for certification for procaine penicillin G aqueous suspension are described under § 540.274a.

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin G aqueous suspension are described under § 540.274a.

(c) *Conditions of marketing*—(1) (i) *Specifications.* Procaine penicillin G aqueous suspension conforms to the standards of identity, strength, quality, and purity prescribed by § 540.274a. Each milliliter contains 300,000 units of penicillin activity.

(ii) *Sponsor.* See No. 000936 in § 510.600(c) of this chapter.

(iii) *Conditions of use.* (a) It is used as an intramuscular injection both in the treatment of tonsillitis in dogs and in the treatment of strangles in horses when such conditions are caused by pathogens susceptible to penicillin G.

(b) It is administered to dogs at 10,000 to 15,000 units per pound of body weight per day and to horses at 3,000 to 5,000 units per pound of body weight per day.

(c) The label and labeling shall bear, in addition to the other information required by the act, a statement that the drug is not for use in food-producing animals and a statement that Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) (i) *Specifications.* Procaine penicillin G aqueous suspension conforms to the standards of identity, strength, quality, and purity prescribed by § 540.274a. Each milliliter contains 300,000 units of penicillin activity.

(ii) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(iii) *Conditions of use.* (a) It is used as an intramuscular injection in dogs and cats in the treatment of infections caused by penicillin sensitive organisms.

(b) It is administered to dogs and cats at a dosage level of 10,000 units per pound of body weight daily at 24-hour intervals. Daily treatment should be continued for at least 48 hours after temperature has returned to normal and all other signs of infection have subsided.

(c) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.274c Procaine penicillin G in oil.

(a) *Requirements for certification.* The requirements for certification for procaine penicillin G in oil are described under § 440.274a of this chapter, with the following exceptions:

(1) *Standards of identity, strength, quality and purity.* If it is conspicuously labeled for veterinary use it may contain furaltadone in accordance with § 121.249(a)(5) of this chapter and is exempt from the potency requirement in § 440.274a(a)(1) of this chapter. It is sterile only if it is packaged and labeled solely for udder instillations of cattle and it contains furaltadone. If the procaine penicillin G in oil is packaged and labeled solely for udder instillations of cattle and is not required to be sterile, the penicillin used is exempt from the requirements of § 440.74a(a)(1) (ii), (iii), and (iv) of this chapter.

(2) *Packaging.* If it is labeled solely for udder instillations of cattle it may be packaged in plastic or collapsible tubes which shall be well closed containers as defined by the U.S.P. If it is packaged and labeled solely for veterinary use, it need not meet the requirements for quantity of procaine penicillin in oil in each container, as described in § 440.274a(a)(2) of this chapter.

(3) *Labeling.* When it is packaged for dispensing and intended solely for veterinary use:

(i) If it does not contain adrenocorticotropic hormone, it shall comply with § 440.274a(a)(3) of this chapter, except in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include adequate directions and warnings for the veterinary use of the drug by the laity in all cases except those in which the veterinary prescription statement is required by regulations under this Subchapter E. In those cases, the veterinary prescription statement shall comply with the requirements prescribed by § 201.105 of this chapter. If it is intended for udder instillation in cattle it shall be exempt from the requirements of § 201.100(b)(5) of this chapter.

(ii) If it contains adrenocorticotropic hormone, it shall comply with § 201.105 of this chapter and with the requirements of § 440.274a(a)(3) of this chapter.

(iii) Each package shall bear on its label and labeling, unless it is intended for udder instillation in cattle, the statement "Warning—Not for use in animals which are raised for food production".

(4) *Requests for certification; samples.* If the batch of procaine penicillin G in oil is intended solely for udder instillations of cattle and is not required to be sterile, test results for toxicity, sterility, and pyrogens are not required.

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin in oil are described under § 440.274a of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Sterile procaine penicillin G with aluminum stearate suspension

conforms to the standards of identity, strength, quality, and purity prescribed by paragraph (a) of this section. Each milliliter contains 300,000 units of penicillin activity in sesame oil gelled with 2 percent aluminum monostearate.

(2) *Sponsor.* See No. 000003 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) It is used as an intramuscular injection in the treatment of infections caused by penicillin-susceptible organisms such as Streptococci, Staphylococci, and Corynebacteria.

(ii) It is administered to dogs and cats at 10,000 units per pound of body weight once daily and to horses at 3,000 units per pound of body weight once daily.

(iii) The label and labeling shall bear, in addition to the other information required by the act, a statement that the drug is not for use in food-producing animals and a statement that Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.274d Procaine penicillin in streptomycin sulfate solution; procaine penicillin in dihydrostreptomycin sulfate solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Procaine penicillin in streptomycin sulfate solution is procaine penicillin G suspended in an aqueous solution of streptomycin sulfate. Procaine penicillin in dihydrostreptomycin sulfate solution is procaine penicillin suspended in an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate. Such solution shall contain one or more suitable and harmless buffer substances, preservatives, and suspending or dispersing agents, and it may contain one or more suitable and harmless stabilizing agents, procaine hydrochloride in a concentration not exceeding 2 percent, a suitable antihistaminic, a suitable anticholinergic and cortisone, or a suitable derivative of cortisone. It is so purified that:

(i) Each milliliter shall contain not less than 100,000 units of procaine penicillin and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate, but each immediate container shall contain not less than 300,000 units of procaine penicillin and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate;

(ii) It is sterile;

(iii) It is nonpyrogenic;

(iv) It is nontoxic; and

(v) Its pH is not less than 5.0 and not more than 8.0.

The procaine penicillin used conforms to the requirements prescribed by § 440.74a(a)(1) of this chapter. The streptomycin sulfate used conforms to the requirements prescribed by § 444.70a(a)(1), or § 444.270b(a) of this chapter. The dihydrostreptomycin sulfate used conforms to the requirements prescribed by § 444.10a(a)(1) or § 444.270b(a)(1) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U.S.P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of transparent glass closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, unless it is packaged to contain a single dose. Each such container shall contain not less than 1.0 milliliter, and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and administration of the volume indicated, whether administered in either single or multiple dose.

(3) *Labeling*—(i) *It is packaged for dispensing and it contains an antihistaminic, and anticholinergic, or cortisone or a derivative of cortisone.* In addition to the labeling requirements prescribed by § 201.105 of this chapter (regulations issued under section 502(f) of the act), each package shall bear on the label or labeling, as hereinafter indicated, the following:

(*a*) On the outside wrapper or container, the statement "Store in refrigerator not above 15° C. (59° F.)".

(*b*) On the outside wrapper or container and the immediate container, the statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months, 24 months, or 36 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(*c*) On the label and the labeling, the statement "For use only in cats, dogs, and horses; not for use in horses to be slaughtered for human consumption".

(*d*) After the name procaine penicillin in streptomycin sulfate solution veterinary", or "procaine penicillin in dihydrostreptomycin sulfate solution veterinary", wherever such name appears, the words "with _____", in juxtaposition with such name, the blank being filled in with the established name of the antihistaminic, the anticholinergic, the cortisone, or the derivative of cortisone.

(ii) *It is packaged for dispensing and it does not contain an antihistaminic, an anticholinergic, or cortisone or a derivative of cortisone.* It shall comply with the requirements of paragraph (a)(3)(i) of this section, except:

(*a*) In lieu of the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(*b*) If it contains dihydrostreptomycin, an expiration date of 48 months or 60 months may be used if data have been submitted as described in paragraph (a)(3)(i)(*b*) of this section.

(*c*) In lieu of the statement required by paragraph (a)(3)(i)(*c*) of this section, the labeling shall bear the statement "Warning—The use of this drug must be discontinued for 30 days before treated animals are slaughtered for food", and, if the drug is intended for use in animals producing milk for human consumption, the labeling shall also bear the statement required by § 510.106 of this chapter.

(iii) *It is packaged solely for manufacturing use and/or repacking.* Each package shall bear on its outside wrapper or container and the immediate container, the following:

(*a*) The number of units of procaine penicillin and the number of milligrams or grams and streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter.

(*b*) The statement "Caution: Federal law prohibits dispensing without prescription".

(*c*) The statement "For manufacturing use", "For repacking", or "For manufacturing use or repacking".

(*d*) The information required by paragraph (a)(3)(i)(*a*) and (*b*) of this section.

(4) *Requests for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of units of procaine penicillin and the number of milligrams or grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the procaine penicillin and streptomycin sulfate or dihydrostreptomycin sulfate used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(v) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(*a*) The batch: Potency, sterility, pH and, if it does not contain a vegetable oil

as a suspending agent, toxicity and pyrogens.

(b) The procaine penicillin used in making the batch; potency (toxicity and pyrogens if it is used in making a batch containing a vegetable oil as a suspending agent), crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(c) The streptomycin sulfate or dihydrostreptomycin sulfate used in making the batch; potency (toxicity and pyrogens if it is used in making a batch containing a vegetable oil as a suspending agent), histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(iii) Except as otherwise provided by paragraph (a)(4)(v) of this section, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch:

(1) For all tests except sterility: One immediate container for each 5,000 immediate containers in such batch, but in no case less than 12 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaging during the intervals are approximately equal.

(2) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation when each container contains not less than 600,000 units or not less than 2.0 milliliters, or 40 immediate containers when each contains less than these amounts.

(b) The procaine penicillin used in making the batch; three packages, or 10 packages if it is used to make a batch containing a vegetable oil as a suspending agent, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 440.74a(a)(2) of this chapter.

(c) The streptomycin sulfate or dihydrostreptomycin sulfate used in making the batch; six packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 444.70a(a)(2) of this chapter. If the streptomycin or dihydrostreptomycin used in making the batch is a solution of the drug, the person who requests certification shall dry a sufficient quantity of the solution to meet these sample requirements.

(d) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of:

(a) For all tests except sterility; 12 approximately equal portions of at least 2 milliliters.

(b) For sterility testing: 20 packages, each containing approximately equal portions of at least 4 milliliters.

Each such portion shall be taken from different parts of such batch, and each shall be packaged in a separate container and in accordance with the requirements of paragraph (a)(2) of this section.

(v) No result referred to in paragraph (a)(4)(ii) (b) and (c) of this section, and no sample referred to in paragraph (a)(4)(iii) (b) and (c) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Procaine penicillin content.* Proceed as directed in § 440.80a(b)(1) of this chapter, except paragraph (b)(1)(iv) and (ix) of that section. In lieu of the directions in paragraph (b)(4) of this section, place a representative aliquot of the sample in a blending jar, add 1.0 milliliter of polysorbate 80 and sufficient 1 percent phosphate buffer, pH 6.0, to make a total volume of 500 milliliters. Blend 3 to 5 minutes. If the iodometric assay is used, 1 drop of the 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2. Its content of procaine penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(ii) *Streptomycin sulfate content.* Proceed as directed in § 444.70a(b)(1)(x) and (xi) of this chapter.

(iii) *Dihydrostreptomycin sulfate content.* Proceed as directed in § 444.10a(b)(1) of this chapter.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except add sufficient penicillinase to the diluting fluid to solubilize the procaine penicillin. Use diluting fluid A; if the product contains lecithin, use diluting fluid D instead. Swirl the flask to completely solubilize the procaine penicillin before filtration. If the preparation contains agents that prevent solubilization, proceed as directed in paragraph (e)(2) of that section, using medium B in lieu of medium A.

(3) *Toxicity.* Proceed as directed in § 440.80a(b)(4) of this chapter, using as a test dose 0.5 milliliter of a solution of the sample containing 1.0 milligram of streptomycin or dihydrostreptomycin per milliliter.

(4) *Pyrogens.* Proceed as directed in § 540.250(b)(4).

(5) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using the undiluted aqueous suspension.

§ 540.274e Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil.

(a) *Requirements for certification*—(1) Procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil conform to all requirements and to all procedures prescribed in § 440.274a(a) for procaine penicillin in oil for udder instillations of cattle or subcutaneous infection in fowl, except that:

(i) It contains not less than 2.0 milligrams of streptomycin or dihydrostreptomycin per milliliter. The streptomycin or dihydrostreptomycin used conforms to the standards prescribed by § 444.10a(a) or § 444.70a(a)(1) of this chapter, except the standards for sterility, pyrogens, and histamine, or by § 539.170(a)(1) of this chapter, except that if it is intended for udder instillations of cattle the dihydrostreptomycin used conforms to the standards prescribed by § 444.70a(a) of this chapter, except the standards for sterility, toxicity, pyrogens, and histamine, or by § 539.170(a)(1) of this chapter, except the standard for toxicity.

(ii) It may contain cortisone or a suitable derivative of cortisone, and/or one suitable sulfonamide, if it is intended solely for udder instillations of cattle, which ingredient, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium. If it is intended solely for udder instillations of cattle, it may be packaged in containers with one or more suitable inert gases.

(iii) In addition to the labeling requirements prescribed for procaine penicillin in oil by § 540.274c(a)(3), each package shall bear on the outside wrapper or container and the immediate container the statement "For udder instillations of cattle only" or the statement "For subcutaneous injection in fowl only"; and if it is a multiple-dose container, the statement "Shake well." Each package shall also bear on its label and labeling, if it contains one or more of the other active ingredients specified in paragraph (a)(1)(ii) of this section, after the name "procaine penicillin and streptomycin in oil" or "procaine penicillin and dihydrostreptomycin in oil", wherever it appears, the words "with _____ (the blank being filled in with the established name of each such other ingredient)", in juxtaposition with such name.

(iv) In addition to complynig with the requirements of § 440.274a(a)(4) of this chapter, a person who requests certification of a batch of procaine penicillin and streptomycin in oil or procaine penicillin and dihydrostreptomycin in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, (if it is intended for subcutaneous injection in fowl), moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin; the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch or in each prescribed dose. He shall also submit in connection with his request a sample consisting of not less than six immediate containers of the batch and (unless it was previously submitted) a sample consisting of six packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the re-

quirements of § 444.70a(a)(2) of this chapter.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Penicillin content.* Proceed as directed in § 536.501(a) or § 440.274a (b)(1)(i)(*a*) of this chapter. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that is represented to contain.

(ii) *Streptomycin content.* Proceed as directed in § 536.501(a)(4) of this chapter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(iii) *Dihydrostreptomycin content.* Proceed as directed in § 536.501(a)(5) of this chapter. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(2) *Moisture.* Using 1 milliliter as the test sample proceed as directed in § 436.500(c) of this chapter.

(Secs. 409, 507, 512, 59 Stat. 463, as amended, 72 Stat. 1785–1788, 82 Stat. 343–351; 21 U.S.C. 348, 357, 360b)

§ 540.274f Penicillin and dihydrostreptomycin-streptomycin sulfates; procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin and dihydrostreptomycin-streptomycin sulfates and procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution conform to the standards prescribed by § 544.211b(a)(1) of this chapter for dihydrostreptomycin-streptomycin sulfates, except that:

(i) It contains dry procaine penicillin, benzathine penicillin G, crystalline penicillin O, chloroprocaine penicillin O, crystalline sodium penicillin or potassium penicillin, or a mixture of any combination of such salts, or it contains procaine penicillin suspended in an aqueous solution of dihydrostreptomycin-streptomycin sulfates. The procaine penicillin used conforms to the requirements prescribed by § 440.74a(a)(1) of this chapter. The crystalline penicillin used conforms to the requirements prescribed for crystalline penicillin by § 440.80a(a)(1) of this chapter. The benzathine penicillin G used conforms to the requirement prescribed by § 440.55a(a)(1) of this chapter. The crystalline penicillin O used conforms to the requirements prescribe by § 440.80a(a)(2) of this chapter. The chloroprocaine penicillin O used conforms to the requirements prescribed by § 440.59(a)(1) of this chapter.

(ii) It may contain suitable and harmless buffer substances, preservatives, suspending, dispersing, and stabilizing agents. Each such substance, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(iii) The moisture content of the dry mixture is not more than 3.5 percent, except if it contains procaine penicillin or chloroprocaine penicillin O, its moisture content is not more than 4.2 percent, and if it contains benzathine penicillin G its moisture content is not more than 6 percent.

(iv) The pH of a solution or a suspension prepared as directed in its labeling is not less than 5.0 and not more than 7.5.

(2) *Packaging.* It shall be packaged in accordance with the requirements prescribed by § 544.211b(a)(2) of this chapter, except that each immediate container or each milliliter shall contain not less than 300,000 units of penicillin, 0.125 gram dihydrostreptomycin, and 0.125 gram streptomycin.

(3) *Labeling.* If it is a dry mixture it shall be labeled in accordance with the requirements prescribed by § 540.250(a)(3). If it is a suspension of the drug, it shall be labeled in accordance with the requirements prescribed by § 540.274d(a)(3). If it contains benzathine penicillin G or chloroprocaine penicillin O, its label and labeling shall bear the statement "Warning—Not for use in animals which are raised for food production".

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 544.211b(a)(4)(i) of this chapter, a person who requests certification of a batch shall submit a statement showing the dates on which the latest assays of the penicillin used in making the batch were completed (unless they were previously submitted), the batch marks, and the content of each salt of penicillin in each container.

(ii) Except as otherwise provided by paragraph (a)(4)(v) of this section, such person shall submit in connection with his request, results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(*a*) The batch; content of each salt of penicillin, content of dihydrostreptomycin and streptomycin, sterility, toxicity, pyrogens, moisture (if it is the dry mixture), and pH.

(*b*) The procaine penicillin used in making the batch; potency, crystallinity penicillin K content (unless it is penicillin G) and the penicillin G content if it is procaine penicillin G.

(*c*) The crystalline sodium or potassium penicillin used in making the batch; potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(*d*) The benzathine penicillin G used in making the batch; potency, crystallinity, and penicillin G content.

(*e*) The crystalline penicillin O used in making the batch; potency, crystallinity, heat stability, penicillin O content, and penicillin G content.

(*f*) The chloroprocaine penicillin O used in making the batch; potency, crystallinity, chloroprocaine penicillin O content, and chloroprocaine penicillin G content.

(*g*) The dihydrostreptomycin and streptomycin used in making the batch; potency, histamine content, and crystallinity if it is crystalline dihydrostreptomycin.

(iii) Except as otherwise provided by paragraph (a)(4)(v) of this section, if such batch is packaged for dispensing such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch:

(*1*) For all tests except sterility: One immediate container for each 5,000 immediate containers in such batch, but in no case less than 13 (14 if it contains benzathine penicillin G) immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(2) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation when each container contains not less than 600,000 units or not less than 2.0 milliliters, or 40 immediate containers when each contains less than these amounts.

(*b*) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram, each packaged in accordance with the requirements of § 440.80a of this chapter.

(*c*) The crystalline penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 250 milligrams, each packaged in accordance with the requirements of § 440.80a of this chapter.

(*d*) The benzathine penicillin G used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 440.55a(a)(2) of this chapter.

(*e*) The crystalline penicillin O and the chloroprocaine penicillin O used in making the batch; 3 packages of each, containing approximately equal portions of not less than 300 milligrams each, packaged in accordance with the requirements of § 440.80a(a)(2) of this chapter and § 440.59a(a)(2) of this chapter.

(*f*) The dihydrostreptomycin and streptomycin used in making the batch; 6 packages of each salt containing approximately equal portions of not less than 0.5 gram, each packaged in accordance with the requirements of § 444.70a(a)(2) of this chapter.

(*g*) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5.0 grams.

(iv) If such batch is packaged for repacking such person shall submit with his request a sample consisting of the following:

(*a*) For all tests except sterility; 13 (14, if it contains benzathine penicillin G) approximately equal portions of at least 2.0 grams.

(*b*) For sterility testing: 20 packages, each containing approximately equal portions of at least 1.0 gram.

Each such portion shall be taken from a different part of such batch and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(v) No result referred to in paragraph (a)(4)(ii) (*b*), (*c*), (*d*), (*e*), (*f*) and (*g*) of this section, and no sample referred to in paragraph (a)(4)(iii) (*b*), (*c*), (*d*), (*e*) and (*f*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Use as the sample for assay a representative aliquot of the suspension equivalent to one dose; or if it is a dry mixture of the drug, a representative aliquot of the drug equivalent to one does after it has been reconstituted as directed in the labeling.

(i) *Penicillin content.* If it contains:

(*a*) *Crystalline penicillin and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 540.250(b)(1)(ii) if it is the dry powder or in § 540.274d(b)(1)(i) if it is the solution; or

(*b*) *Procaine penicillin and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 540.250(b)(1)(ii) if it is the dry powder or in § 540.274d(b)(1)(i) if it is the solution; or

(*c*) *Benzathine penicillin G and dihydrostreptomycin - streptomycin sulfates.* Proceed as directed in § 440.55a(b)(1) of this chapter, except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2; or

(*d*) *Crystalline penicillin - procaine penicillin and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 436.503(a), (b), and (c) of this chapter, except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to each blank immediately before the addition of the 0.01 *N* I_2; or

(*e*) *Crystalline penicillin - benzathine penicillin G and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 436.506(a), (b), (c), and (d) of this chapter, except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to each blank immediately before the addition of the 0.01 *N* I_2; or

(*f*) *Crystalline penicillin - procaine penicillin-benzathine penicillin G and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 436.507 (a) (1), (2), (3), and (4) of this chapter, except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to each blank immediately before the addition of the 0.01 *N* I_2; or

(*g*) *Crystalline penicillin O-chloroprocaine penicillin O and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 436.503 (a), (b), (c), and (d) of this chapter, with the following exceptions:

(*1*) In the iodometric assay, 1 drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2.

(*2*) The penicillin O working standard is used as the standard of comparison in the iodometric assay.

(*3*) In the colorimetric determination of chloroprocaine penicillin O, the standard curve is prepared by using a standard solution containing 31.04 milligrams of chloroprocaine hydrochloride in 1 liter of distilled water; or

(*h*) *Procaine penicillin - benzathine penicillin G and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 536.507(a)((1) and (2) of this chapter.

The total potency and the number of units of each salt of penicillin are satisfactory if the immediate containers contain not less than 85 percent of the number of units that they are represented to contain.

(ii) *Combined potency of dihydrostreptomycin and streptomycin; content of streptomycin.* Proceed as directed in § 544.211b(b) (1) and (2) of this chapter. Its combined potency of streptomycin and dihydrostreptomycin is satisfactory if it is not less than 90 percent of the number of milligrams that it is represented to contain. Its content of streptomycin is satisfactory if it contains not less than 45 percent and not more than 55 percent of the combined potency of streptomycin and dihydrostreptomycin.

(2) *Sterility*—(i) *Penicillin and dihydrostreptomycin - streptomycin sulfate solution.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(ii) *Procaine penicillin in dihydrostreptomycin-streptomycin sulfate solution.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium B in lieu of medium A.

(3) *Toxicity.* Proceed as directed in § 540.250(b)(3), except if it contains benzathine penicillin G, proceed as directed in § 440.55a(b)(3) of this chapter, using a test suspension containing a total penicillin activity of 4,000 units per milliliter.

(4) *Pyrogens.* Proceed as directed in § 540.250(b)(4), except if it contains benzathine penicillin G proceed as directed in § 440.55a(b)(3) of this chapter, using a test suspension containing a total penicillin activity of 4,000 units per milliliter.

(5) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter, except if it contains procaine penicillin, chloroprocaine penicillin O, or benzathine penicillin G proceed as directed in § 440.74a(b)(5) of this chapter.

(6) *pH.* Proceed as directed in § 440.274b(b)(6) of this chapter.

§ 540.280 Sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt) crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, crystalline penicillin O sodium, crystalline penicillin O sodium salt, crystalline penicillin O potassium, crystalline penicillin O potassium salt).

(a) *Requirements for certification*—(1) The requirements for certification for sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt), crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, crystalline penicillin O sodium, crystalline penicillin O sodium salt, crystalline penicillin O potassium, crystalline penicillin O potassium salt) are described under § 440.80a of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use: (i) Its label and labeling shall comply with all the requirements prescribed by § 440.80a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(ii) If it is intended for use in animals raised for food production, it shall be used in accordance with paragraph (c) of this section.

(b) *Tests and methods of assay.* The tests and methods of assay for sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt), crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, crystalline penicillin O sodium, crystalline penicillin O sodium salt, crystalline penicillin O potassium, crystalline penicillin O potassium salt) are described under § 440.80a of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Complies with the requirements of paragraph (a) of this section.

(2) *Sponsor.* [Reserved]

(3) *Special considerations.* (i) The labeling shall bear the statement "Warning—The use of this drug must be discontinued for 5 days before treated animals are slaughtered for food".

(ii) If the drug is intended for use in animals producing milk for human consumption, the labeling shall also bear the statement "Milk that has been taken from animals during treatment and for _____ hours (_____ milkings) after the latest treatment must not be used for food", the blanks being filled with the figures 96 and 8 respectively, unless the sponsor of the drug has submitted the results of tests and assays demonstrating that residues of the drug in milk from treated animals persist for a shorter period of time and the shorter period is authorized by the Commissioner.

(iii) If the drug is intended for use in poultry, the labeling shall bear a statement that the drug is not to be used in birds producing eggs for human consumption.

(4) *Related tolerances.* See § 556.510 of this chapter.

(5) *Conditions of use.* As an intramuscular or intravenous injection in food-producing animals in an amount not to exceed 2,000 units per pound of body weight per day.

§ 540.281 Crystalline penicillin implantation and injectable dosage forms.

§ 540.281a Crystalline penicillin and epinephrine in oil.

(a) *Requirements for certification*—(1) The requirements for certification for crystalline penicillin and epinephrine in oil are described under § 440.280d of this chapter.

(2) When crystalline penicillin and epinephrine in oil is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 440.280d(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for crystalline penicillin and epinephrine in oil are described under § 440.280d of this chapter.

§ 540.281b Buffered crystalline penicillin.

(a) *Requirements for certification.* The requirements for certification for buffered crystalline penicillin are described under § 440.81 of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for buffered crystalline penicillin are described under § 440.81 of this chapter.

Subpart C—Ophthalmic and Topical Dosage Forms

§ 540.380 Penicillin ophthalmic and topical dosage forms.

§ 540.380a Penicillin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin ointment, is calcium penicillin, crystalline penicillin, procaine penicillin, or *l*-ephenamine penicillin G in a suitable and harmless ointment base, with or without a suitable anesthetic. If it is intended solely for topical veterinary use and not for udder instillation in dairy animals and is conspicuously so labeled, it may contain nitrofurazone. If it is intended for ophthalmic use, it contains crystalline penicillin G and it is sterile. Its moisture content is not more than 1.0 percent. Its potency is not less than 250 units per gram. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 440.80a(a)(1) of this chapter except the limitation on penicillin K content and except § 440.80a(a)(1)(i), (ii), (iii), and (iv) of this chapter, but its potency is not less than 300 units per milligram. The crystalline penicillin G used in making penicillin ophthalmic ointment conforms to the requirements of § 440.80a(a)(1) of this chapter except the limitation on penicillin K content and except § 440.80a(a)(1)(iv) of this chapter. The procaine penicillin used conforms to the requirements of § 440.74a(a)(1) of this chapter, except paragraphs (a)(1)(ii). The *l*-ephenamine penicillin G used conforms to the requirements of § 440.65a(a)(1) except paragraph (a)(1)(ii), (iii), and (iv) of that section. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* Penicillin ointment, shall be packaged in collapsibel tubes, which shall be well-closed containers as defined by the U.S.P. and shall not be larger than the ⅛-ounce size if such ointment is represented for ophthalmic use and in no case larger than the 2-ounce size. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* (i) In addition to the labeling requirements prescribed by § 201.105 of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(*a*) An expiration date that conforms to the requirements prescribed by § 432.5(a)(3) of this chapter.

(*b*) On the outside wrapper or container, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)", unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section after having been stored at room temperature; but in no case shall such statement be required if it is labeled with an expiration date that is 9 months after the month during which the batch was certified.

(ii) In lieu of the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(4) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin used in making the batch for potency, moisture, pH, for crystallinity if it is a crystalline salt of penicillin, for heat stability if it is crystalline penicillin or *l*-ephenamine penicillin G, for the penicillin G content if it is penicillin G, for the specific rotation if it is *l*-ephenamine penicillin G, and for toxicity if the ointment is intended for ophthalmic use.

(*b*) The batch for potency and moisture and for sterility if the ointment is intended for ophthalmic use.

(ii) Samples required:

(*a*) The penicillin used in making the batch: Five packages, or in the case of crystalline penicillin, 10 packages, each containing approximately 60 milligrams if it is not procaine penicillin, and approximately 300 milligrams if it is procaine penicillin, packaged in accordance with the requirements of § 440.74a(a)(2) or § 440.80a(a)(2) of this chapter.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of five immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 440.80a(b)(1) of this chapter, except paragraph (ix) of that section, and in lieu of the directions in § 440.80a(b)(1)(iv) of this chapter, prepare the sample by one of the following techniques:

(i) *Extraction.* Place a representative portion of the sample (usually approximately 1 gram, accurately weighed) or the entire contents of a single-dose container in a separatory funnel containing 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 25 milliliters of 1-percent phosphate buffer, pH 6.0, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of buffer. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of buffer at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives and make the proper estimated dilutions with buffer.

(ii) *Blending.* Place an accurately weighed representative portion of the sample (usually approximately 1 gram), or the entire contents of a single-dose container, in a blending jar containing 1.0 milliliter of polysorbate 80 and sufficient 1-percent phosphate buffer, pH 6.0, to give a final volume of 200 milliliters. If the sample consists of substantially more than 1 gram, use sufficient buffer to give a final volume of 500 milliliters. Using a high-speed blender, blend the mixture for 2 minutes and then make the proper estimated dilutions with buffer. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 436.500(c) of this chapter, using a weighed sample of approximately 1 gram dissolved in 10 milliliters of a mixture of equal parts of dry chloroform and carbon tetrachloride, but in lieu of calculating the milliliters of Karl Fischer reagent equivalent to 10 milliliters of chloroform, determine the milliliters of reagent equivalent to 10 milliliters of the mixture of chloroform and carbon tetrachloride.

(3) *Sterility.* If the ointment is intended for ophthalmic use, proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e) (3) of that section.

(Secs. 409, 507, 512, 59 Stat. 463, as amended, 72 Stat. 1785–1788, as amended, 82 Stat. 343–351; 21 U.S.C. 348, 357, 360b)

§ 540.380b Procaine penicillin-neomycin-polymyxin in oil; procaine penicillin-neomycin-polymyxin ointment.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Procaine penicillin-neomycin-polymyxin in oil is a suspension of procaine penicillin neomycin and polymyxin in refined peonut oil or sesame oil, with or without the addition of one or more suitable and harmless dispersing and suspending agents. Procaine penicillin-neomycin-polymyxin ointment is procaine penicillin, neomycin, and polymyxin in a suitable and harmless ointment base. Each of the drugs may contain a suitable anesthetic, a suitable and harmless preservative, a suitable and harmless salt of cobalt, one or more suitable sulfonamides, and cortisone or a suitable derivative of cortisone. The moisture content of each drug is not more than 1.0 percent. Each drug contains not less than 25,000 units of procaine penicillin, not less than 17.5 milligrams of neomycin, and not less than 5,000 units of polymyxin per milliliter or per gram. The procaine penicillin used conforms to the requirements of § 440.74a (a) (1) of this chapter, except paragraph (a) (1) (ii), (iii), and (iv) of that section. The neomycin used conforms to the standards prescribed by § 444.42a(a) (1) (i), (v), and (vi) of this chapter. The polymyxin used conforms to the requirements of § 444.170a(a) (1) of this chapter, except the standard for toxicity. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging; labeling; request for certification, samples.* Each drug conforms to all requirements and procedures prescribed for penicillin ointment veterinary, by § 540.380a(a) (2) (b) (except that procaine penicillin-neomycin-polymyxin in oil, veterinary, may be packaged in plastic tubes), (a) (3) and (4), except that:

(i) In addition to the labeling prescribed for penicillin ointment, veterinary, by § 540.380a(a) (3), if they contain one or more of the active ingredients specified in paragraph (a) of this section, each package shall bear on the outside wrapper or container and the immediate container, after the name "procaine penicillin - neomycin - polymyxin in oil, veterinary" or "procaine penicillin - neomycin - polymyxin ointment, veterinary", wherever it appears, the words "with _____," the blank being filled in with the established name of each such other ingredient, in juxtaposition with such name.

(ii) In addition to complying with the requirements of § 540.380a(a) (4), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and the dates of the latest tests and assays of the neomycin (for potency, moisture, and pH) and polymyxin (for potency) used in making the batch; the number of units of penicillin; the number of milligrams of neomycin, and the number of units of polymyxin per milliliter or per gram. He shall also submit in connection with his requests a sample consisting of five packages each of the neomycin and polymyxin used in making the batch, each package containing approximately equal portions of not less than 0.5 gram.

(b) *Tests and methods of assay—*(1) *Potency—*(i) *Penicillin content.* Proceed as directed in § 540.380a(b) (1). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter or per gram that it is represented to contain.

(ii) *Neomycin content.* Proceed as directed in § 448.510d(b) (1) (ii) of this chapter, except that sufficient penicillinase is added to the sample under test to inactivate the penicillin. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter or per gram that it is represented to contain.

(iii) *Polymyxin content.* Proceed as directed in § 436.509(a) (4) of this chapter, except calculate from the quantity of neomycin found (using the method prescribed in paragraph(b) (1) (ii) of this section) the quantity of neomycin that would be present when the sample is diluted to contain 10 units of polymyxin (labeled potency) per milliliter, and prepare the polymyxin standard curve by adding the calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use the standard curve to calculate the polymyxin content of the sample. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per milliliter or gram that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 540.380a(b) (2).

(Secs. 403, 507, 512, 59 Stat. 463, as amended, 72 Stat. 1785–1788, 82 Stat. 343–351; 21 U.S.C. 348, 357, 360b)

Subparts D–G [Reserved]

Subpart H—Intramammary Dosage Forms

§ 540.814 Benzathine cloxacillin for intramammary infusion.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Benzathine cloxacillin suspension is benzathine cloxacillin in a suitable and harmless oil base. It may contain one or more suitable and harmless preservatives, antioxidants, complexing and suspending agents. Each dose contains benzathine cloxacillin equivalent to 500 milligrams of cloxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cloxacillin that it is represented to contain. Its moisture content is not more than 1.0 percent. The benzathine cloxacillin used conforms to the requirements of § 540.114.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Request for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) The results of tests and assays on:

(*a*) The benzathine cloxacillin used in making the batch for potency, safety, moisture, pH, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The benzathine cloxacillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay—*(1) *Potency.* Proceed as directed for cloxacillin in § 436.105 of this chapter using the sodium cloxacillin working standard as the standard of comparison and preparing the sample for assay as follows: Expel the contents of the syringe into a high speed glass blender jar containing sufficient methanol to give a final volume of 500 milliliters. Blend for 3–5 minutes. Immediately dilute an aliquot of this stock solution with solution 1 to the reference concentration of 5.0 micrograms of cloxacillin per milliliter.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(c) *Conditions of marketing—*(1) *Specifications.* The drug contains benzathine cloxacillin equivalent to 500 milligrams cloxacillin in each dose, and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* (i) See code No. 000015 in § 510.600(c) of this chapter for conditions of use as in paragraph (c) (3) (i) of this section.

(ii) See code No. 000029 in § 510.600 (c) of this chapter, approval for use as in paragraph (c) (3) (ii) of this section.

(3) *Conditions of use.* (i) (*a*) The drug is used for treatment of mastitis caused by Staphylococcus aureus and Streptococcus agalactiae including penicillin resistant strains in dairy cows during the dry period.

(*b*) It is administered aseptically into each infected quarter immediately after last milking or early in dry period.

(*c*) For use in dry cows only.

(*d*) Not to be used within 30 days of calving.

(*e*) Animals infused with this product must not be slaughtered for food use for 30 days after the latest infusion.

(*f*) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) (*a*) The drug is used for treatment and prophylaxis of bovine mastitis in nonlactating cows due to Streptococcus agalactiae and Staphylococcus aureus.

(b) It is administered in each infected quarter immediately after last milking.

(c) For use in dry cows only.

(d) Not to be used within 4 weeks (28 days) of calving.

(e) Animals infused with this product must not be slaughtered for food use for 4 weeks (28 days) after the latest infusion.

(f) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.814a Sterile benzathine cloxacillin for intramammary infusion.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile benzathine cloxacillin suspension veterinary is sterile benzathine cloxacillin in a suitable and harmless oil base. It may contain one or more suitable and harmless preservatives, antioxidants, complexing and suspending agents. Each dose contains benzathine cloxacillin equivalent to 500 milligrams of cloxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cloxacillin that it is represented to contain. It is sterile. Its moisture content is not more than 1.0 percent. The benzathine cloxacillin used conforms to the requirements of § 540.114a.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.-55 of this chapter.

(3) *Request for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) The results of tests and assays on:

(a) The benzathine cloxacillin used in making the batch for potency, safety, moisture, pH, identity, sterility and crystallinity;

(b) The batch for potency, sterility, and moisture.

(ii) Samples required:

(a) The benzathine cloxacillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 5 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for cloxacillin in § 436.105 of this chapter using the sodium cloxacillin working standard as the standard of comparison and preparing the sample for assay as follows: Expel the contents of the syringe into a high speed glass blender jar containing sufficient methanol to give a final volume of 500 milliliters. Blend for 3–5 minutes. Immediately dilute an aliquot of the stock solution with solution 1 to the reference concentration of 5.0 micrograms of cloxacillin per milliliter.

(2) *Sterility.* Proceed in accordance with § 436.20 of this chapter using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A and medium F in lieu of medium E. During the period of incubation, shake the tubes at least once daily.

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is sterile and contains benzathine cloxacillin equivalent to 500 milligrams cloxacillin in each 6 milliliters of peanut oil vehicle, and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000003 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used for treatment of mastitis caused by Staphylococcus aureus and Streptococcus agalactiae in dairy cows at the time of drying-off of the cow.

(ii) It is administered aseptically at the rate of 6 milliliters per infected quarter immediately after last milking at the time of drying-off of the cow.

(iii) For use in dry cows only.

(iv) Not to be used within 30 days of calving.

(v) Milk taken from treated cows prior to 72 hours (6 milkings) after calving must not be used for human food.

(vi) Animals infused with this product the time of infusion until 72 hours after must not be slaughtered for food from calving.

(vii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.829 Potassium hetacillin for intramammary infusion.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Potassium hetacillin for intramammary infusion contains potassium hetacillin in a menstruum of refined peanut oil with a suitable and harmless dispersing agent. It contains in each 10 milliliter syringe an amount of potassium hetacillin equivalent to 62.5 milligrams of ampicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. It gives a positive identity test for hetacillin. Its moisture content is not more than 1.0 percent. Its pH is not less than 7.0 and not more than 8.0. The potassium hetacillin used conforms to the requirements of § 440.29 of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.-55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter each such request shall contain:

(i) Results of tests and assays on:

(a) The potassium hetacillin used in making the batch for potency, safety, moisture, pH, potassium hetacillin content, identity, and crystallinity.

(b) The batch for potency, moisture, pH, and identity.

(ii) Samples required:

(a) The potassium hetacillin used in making the batch, 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 8 immediate containers.

(b) *Tests and method of assay.*—(1) *Potency.* Proceed as directed for ampicillin in § 436.105 of this chapter using the ampicillin working standard as the standard of comparison and preparing the sample for assays as follows: Expel the syringe contents into a high speed glass blending jar containing 1 milliliter of polysorbate 80 and sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3) to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.-202 of this chapter, preparing the sample for assay as follows: Transfer the contents of the well-shaken 10-milliliter syringe into a large centrifuge tube, add 20.0 milliliters of benzene, shake vigorously for 3 minutes and centrifuge at medium speed for 5 minutes. Carefully decant the benzene without disturbing the precipitate. Reconstitute the residue with 10.0 milliliters of carbon dioxide-free water.

(4) *Hetacillin identity.* Proceed as directed in § 436.305 of this chapter preparing the sample solution as follows: Place 1.0 milliliter of the well-shaken sample into a 50 milliliter volumetric flask. Brink to volume with a 4:1 solution of acetone and 0.1*N* hydrochloric acid.

(c) *Conditions of marketing*—(1) *Specifications.* The drug is in an oil suspension and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000015 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used for the treatment of acute, chronic, or subclinical bovine mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae, Streptococcus dysgalactiae, Staphylococcus aureus,* and *Escherichia coli.*

(ii) Infuse 10 milliliters (potassium hetacillin equivalent to 62.5 milligrams ampicillin activity) into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given. If definite improvement is not noted within 48 hours after treatment, the causal organism should be further investigated.

(iii) Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.874 Procaine penicillin G intramammary dosage forms.

§ 540.874a Procaine penicillin G in oil.

(a) *Requirements for certification.* The requirements for certification for procaine penicillin G in oil are described under § 540.274c.

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin G in oil are described under § 540.274c.

(c) *Conditions of marketing*—(1) *Specifications.* Each 10 milliliters of the drug contains 100,000 units of procaine penicillin G. The drug complies with the requirements of § 540.274c(a).

(2) *Sponsor.* See No. 010515 in § 510.-600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the treatment of bovine mastitis in lactating cattle (or cows) only.

(ii) Ten milliliters of the drug is administered by intramammary infusion in each infected quarter. Treatment may be repeated at 12-hour intervals up to a total of 3 doses, as indicated by the clinical response.

(iii) Milk that has been taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food.

(iv) Animals should not be slaughtered for food during treatment or within 3 days after the last treatment.

§ 540.874b Procaine penicillin G-sodium novobiocin in oil.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Procaine penicillin G-sodium novobiocin in oil is a suspension of procaine penicillin G and sodium novobiocin in refined peanut oil, with or without one or more suitable and harmless dispersants, suspending agents and preservatives and with or without the addition of a gelling agent. It contains in each milliliter 10,000 units of procaine penicillin G and 10 mg of novobiocin. Its procaine penicillin G content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of units of penicillin G it is represented to contain. Its novobiocin content is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of novobiocin it is represented to contain. The drug is intended for use by udder instillation and each single dose as recommended in its labeling contains not more than 100,000 units of penicillin G. Its moisture content is not more than 1 percent. The procaine penicillin G used conforms to the requirement of § 440.-74a(a)(1) of this chapter, except paragraph (a)(1)(ii), (iii), and (iv) of that section. The sodium novobiocin used conforms to the requirements of § 455.51 of this chapter, except paragraph (a)(1)(ii).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) The results of tests and assays on:

(*a*) The procaine penicillin G used in making the batch for potency, moisture, pH, crystallinity, and procaine penicillin G content.

(*b*) The sodium novobiocin used in making the batch for potency, loss on drying, pH, residue on ignition, specific rotation, identity, and crystallinity.

(*c*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The procaine penicillin used in making the batch: 10 packages, each containing not less than 300 milligrams.

(*b*) The sodium novobiocin used in making the batch, 6 packages, each containing approximately 600 ml.

(*c*) The batch: A minimum of 8 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Penicillin content.* Proceed as directed in § 436.105 using the novobiocin-resistant strain of *Staphylococcus aureus* (ATCC 12692),[1] preparing the sample for assay as follows: Place the equivalent of one dose of the sample into a high-speed glass blender jar with 1 milliliter of polysorbate 80 and sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1) to give a stock solution of convenient concentration. Blend 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 1 unit of penicillin per milliliter (estimated).

(ii) *Novobiocin content.* Proceed as directed in § 436.105, preparing the sample for assay as follows: Place the equivalent of one dose of the sample into a high-speed glass blender jar with 1 ml of polysorbate 80 and sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3) to give a stock solution of convenient concentration. Blend 3 to 5 minutes. To an aliquot of the stock solution, add 0.5 ml of penicillinase solution. Further dilute the aliquot of stock solution with 10 percent potassium phosphate buffer, pH 6.0 (solution 6) to the reference concentration of 0.5 microgram of novobiocin per milliliter (estimated). Allow to stand for one-half hour at 37° C. before filling the cylinders on the plates.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

§ 540.874c Procaine penicillin G-neomycin in oil.

(a) *Requirements for certification.* Procaine penicillin G-neomycin in oil conforms to all requirements and is subject to all procedures prescribed by § 440.274 for procaine penicillin G in oil, except that:

(1) It contains neomycin sulfate. The neomycin used conforms to the standards prescribed by § 444.42a(a)(1)(i), (v) and (vi) of this chapter.

(2) It may contain cortisone or a suitable derivative of cortisone and/or one suitable sulfonamide.

(3) In addition to the labeling requirements prescribed by § 440.274a(a)(3) of this chapter, each package shall bear on the outside wrapper or container and the immediate container the statement "For udder instillation of cattle only." If it contains cortisone or a derivative of cortisone and/or a sulfonamide, each package shall bear on its label and labeling, after the name "procaine penicillin G-neomycin in oil," wherever it appears, the words "with ------," the blank being filled in with the established names of such other ingredients, in juxtaposition with such name.

(4) In addition to complying with the requirements of § 440.274a(a)(4) of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, moisture, and pH; and the number of units of procaine penicillin G and the number of milligrams of neomycin in each gram or milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than 5 immediate containers of the batch and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making the batch.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Total penicillin content; crystalline penicillin content; procaine penicillin content.* Proceed as directed in § 536.501(a)(1), (2), and (3) of this chapter.

(ii) *Neomycin content.* Prepare the sample as directed in § 540.380a(b)(1), except use 0.10 *M* phosphate buffer, pH 8.0, and add sufficient penicillinase to inactivate the penicillin present. Proceed as directed in § 436.517(b)(1) of this chapter. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 540.380a(b)(2).

(Secs. 409, 507, 512, 59 Stat. 463, as amended, 72 Stat. 1785–1788, as amended, 82 Stat. 343–351; 21 U.S.C. 348, 357, 360b)

§ 540.874d Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil.

(a) *Requirements for certification.* The requirements for certification for procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil are described under § 540.274e.

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil are described under § 540.274e.

§ 540.874e Procaine penicillin and dihydrostreptomycin in oil.

(a) *Requirements for certification.* The requirements for certification for procaine penicillin and dihydrostreptomycin in oil are described under § 540.274e.

(b) *Tests and methods of assay.* The tests and methods of assay for procaine penicillin and dihydrostreptomycin in oil are described under § 540.274e.

(c) *Conditions of marketing*—(1) *Specifications.* Each 10 milliliter disposable syringe contains 1,000,000 units of

[1] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

procaine penicillin G and 1 gram of dihydrostreptomycin base, as dihydrostreptomycin sulfate in a peanut oil base with aluminum monostearate and hydrogenated peanut oil as gelling and hardening agents. The product meets the specifications of § 540.274e of this chapter.

(2) *Sponsor.* See No. 011538 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) For intramammary use to reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(ii) The drug is administered at the last milking prior to drying off. The drug is infused, 1 syringe into each quarter.

(iii) Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 540.874f Procaine penicillin G-novobiocin for intramammary infusion.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Procaine penicillin G-novobiocin for intramammary infusion is a suspension of procaine penicillin G and sodium novobiocin in refined vegetable oil with a suitable and harmless suspending agent and preservative. It contains in each 10-milliliter dose 100,000 units of procaine penicillin G and 150 milligrams of sodium novobiocin. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of units of penicillin or milligrams of novobiocin that it is represented to contain. Its moisture content is not more than 1.0 percent. The procaine penicillin G used conforms to the requirements of § 440.74a of this chapter, except sterility and pyrogens, and the novobiocin used conforms to the requirements of § 455.51 of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The procaine penicillin G used in making the batch for potency percent G content, safety, moisture, pH, and crystallinity.

(*b*) The sodium novobiocin used in making the batch for potency, safety, loss on drying, pH, specific rotation, identity, and crystallinity.

(*c*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The procaine penicillin G used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The sodium novobiocin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter using test organism 0 in lieu of A to assay for penicillin content, preparing the samples for assay as follows:

(*i*) *Penicillin content.* Expel the syringe contents into a high speed glass blender jar containing 1 milliliter of polysorbate 80 and sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1) to give a final volume of 500 milliliters. Blend for 3 to 5 minutes. Further dilute an aliquot of this stock solution with solution 1 to the reference concentration of 1 unit of penicillin per milliliter (estimated).

(ii) *Novobiocin content.* Expel the syringe contends into a high speed glass blender jar containing 1 milliliter of polysorbate 80 and sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3) to give a final volume of 500 milliliters. Blend for 3 to 5 minutes. To an aliquot of this stock solution, add sufficient penicillinase to inactivate the penicillin; further dilute with 10 percent potassium phosphate buffer, pH 6.0 (solution 6) to the reference concentration of 0.5 microgram of novobiocin per milliliter (estimated). Allow to stand for ½ hour at 37° C before filling the cylinders on the plates.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The drug contains a suspension of procaine penicillin G, 100,000 units, and novobiocin sodium, equivalent to 150 milligrams of novobiocin, in 10 milliliters of peanut oil vehicle, and conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) Use for the treatment of mastitis in lactating cows caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae.*

(ii) Infuse 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(iii) For udder instillation in lactating cattle only.

(iv) Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals.

(v) Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food.

(vi) Treated animals must not be slaughtered for food for 15 days following the latest treatment.

(vii) If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

§ 540.881 Crystalline penicillin-streptomycin-polymyxin-oxytetracycline-carbomycin powder; crystalline penicillin-dihydrostreptomycin-polymyxin-oxytetracycline-carbomycin powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Crystalline penicillin-streptomycin-polymyxin-oxytetracycline-carbomycin powder and crystalline penicillin - dihydrostreptomycin - polymyxin - oxytetracycline - carbomycin powder are a mixture of crystalline penicillin, streptomycin or dihydrostreptomycin, polymyxin, crystalline oxytetracycline or crystalline oxytetracycline hydrochloride or a combination of these drugs, and crystalline carbomycin, with one or more suitable and harmless diluents. Each immediate container of powder contains not more than 100,000 units of penicillin, not less than 200 milligrams of streptomycin or dihydrostreptomycin, not less than 150,000 units of polymyxin, not less than 425 milligrams of oxytetracycline or oxytetracycline hydrochloride or a combination of these drugs, and not less than 100 milligrams of carbomycin. Its moisture content is not more than 6.0 percent. The crystalline penicillin used conforms to the standards prescribed therefor by § 440.80a(a) of this chapter, except paragraphs (a)(1) (ii), (iii), (iv), and (v) of that section. The streptomycin used conforms to the standards prescribed therefor by § 444.70a(a)(1), except paragraph (a)(1) (ii), (iii), (iv), and (v) of that section. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 444.101a(a) of this chapter, except the standards for sterility, toxicity, pyrogens, and histamine. The polymyxin B used conforms to the standards prescribed therefor by § 444.170a(a) of this chapter, except the standard for toxicity. The oxytetracycline used is produced by the growth of Streptomyces Rimosus. The crystalline oxytetracycline base has a potency of not less than 900 micrograms per milliliter on the anhydrous basis, has a moisture content of not more than 7.5 percent, and a pH of from 5.5 to 7.5. The crystalline oxytetracycline hydrochloride has a potency of not less than 835 micrograms per milligram, a moisture content of not more than 1.5 percent, and a pH of from 2.3 to 2.9. The crystalline carbomycin used is produced by the growth of Streptomyces halstedii, has a potency of not less than 750 µg. per milligram, and has a moisture content of not more than 5.0 percent and a pH of from 5.0 to 8.0. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U.S.P. The composition of the immediate containers shall be such as will not cause any

change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of units of penicillin; the number of milligrams of streptomycin or dihydrostreptomycin; the number of units of polymyxin; the number of milligrams of oxytetracycline, oxytetracycline hydrochloride, or the number of milligrams of each such drug where a combination of these two drugs is used; and the number of milligrams of carbomycin, in each gram of the batch.

(*c*) The statement "For udder instillation of cattle only."

(*d*) The statement "Expiration date ----------", the blanks being filled in with the date that is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if it contains a single dose and it is packaged in an individual wrapper or container.

(*e*) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates of the latest tests and assays of the penicillin, streptomycin or dihydrostreptomycin, polymyxin, oxytetracycline, oxytetracycline hydrochloride, and carbomycin used in making the batch.

(ii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Potency and moisture.

(*b*) The penicillin used in making the batch: Potency, moisture, pH, crystallinity, and heat stability.

(*c*) The streptomycin or dihydrostreptomycin used in making the batch: Potency, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(*d*) The polymyxin used in making the batch: Potency.

(*e*) The oxytetracycline and oxytetracycline hydrochloride used in making the batch: Potency, moisture, pH, and crystallinity.

(*f*) The carbomycin used in making the batch: Potency, moisture, pH, and crystallinity.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: 1 package for each 5,000 packages in the batch, but in no case less than 6 packages.

(*b*) The penicillin used in making the batch: 10 packaging each containing equal portions of not less than 60 milligrams.

(*c*) The streptomycin or dihydrostreptomycin used in making the batch: 6 packages each containing approximately equal portions of not less than 0.5 gram.

(*d*) The polymyxin used in making the batch: 5 packages each containing approximately equal portions of not less than 0.5 gram.

(*e*) The oxytetracycline used in making the batch: 5 packages of each salt used, each containing approximately equal portions of not less than 0.5 gram.

(*f*) The carbomycin used in making the batch: 5 packages each containing approximately equal portions of not less than 0.5 gram.

(*g*) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a) (4) (ii) (*b*), (*c*), (*d*), (*e*), and (*f*) of this section, and no samples referred to in paragraph (a) (4) (iii) (*b*), (*c*), (*d*), (*e*), and (*f*) of this section, is required if such result or samples have been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Penicillin content.* Wash the contents of one immediate container of the sample into a 100-milliliter volumetric flask with approximately 70 milliliters of absolute methanol. Shake the mixture for 1 minute, dilute to 100 milliliters with absolute methanol, and mix thoroughly. Centrifuge a portion of this mixture to obtain a clear methanol solution. Dilute an aliquot of the clear solution with sufficient 1.0-percent phosphate buffer, pH 6.0, to obtain a concentration of 1.0 unit per milliliter (estimated) and proceed as directed in § 440.80a(b) (1) of this chapter. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(ii) *Oxytetracycline content.* To an aliquot of the clear methanol solution prepared as directed in paragraph (a) (1) (i) of this section, add sufficient penicillinase to completely inactivate the penicillin and then dilute with sufficient 0.1 *M* monopotassium phosphate buffer, pH 4.5, to obtain a concentration of 0.25 microgram per milliliter (estimated) and proceed as directed in § 446.81a(b) (1) of this chapter, except use the oxytetracycline working standard (obtained from the U.S.P. Reference Standards Committee, 46 Park Avenue, New York 16, N.Y.) as the standard of comparison. Its content of oxytetracycline is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(iii) *Carbomycin content.* To an aliquot of the clear methanol solution prepared as directed in paragraph (a) (1) (i) of this section, add sufficient penicillinase to completely inactivate the penicillin and then dilute with sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to obtain a concentration of 1.0 microgram per milliliter (estimated) and proceed as directed in paragraph (a) (4) (i) of this section. Its content of carbomycin is satisfactory if it contains not less than 35 percent of the number of milligrams that it is represented to contain.

(iv) *Streptomycin content.* Using 10 milliliters of a freshly prepared 2-percent solution of anhydrous trichloroacetic acid in acetone, wash the contents of an immediate container of the sample into an extraction funnel prepared by fusing a ground-glass joint to the top of a medium porosity sintered-glass funnel (30 millimeters diameter). Shake the mixture for 1 minute and draw off the liquid under vacuum. Repeat the extraction with four 10-milliliter portions of a 2-percent solution of trichloroacetic acid in acetone and discard the filtrates. Wash the residue in the funnel with five 10-milliliter portions of 0.1 *M* potassium phosphate buffer (pH 8.0), withdrawing the washings with vacuum. Collect and combine the washings and dilute them to 50 milliliters with 0.1 *M* potassium phosphate buffer, pH 8.0. Proceed as directed in § 447.70a(b) (1) (i) through (ix) of this chapter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(v) *Dihydrostreptomycin content.* Using the dihydrostreptomycin working standard as the standard of comparison, proceed as directed in paragraph (b) (1) (iv) of this section. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(vi) *Polymyxin content.* Dilute an aliquot of the buffer washings prepared as directed in paragraph (b) (1) (iv) of this paragraph with sufficient 10-percent potassium phosphate buffer, pH 6.0, to obtain a concentration of 10 units per milliliter (estimated). Proceed as directed in § 444.170a(b) (2) (i) of this chapter. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(3) *Oxytetracycline used in making the powder*—(i) *Potency.* Dilute the

sample to be tested with sufficient 0.1 *N* HCl to give an appropriate stock solution. Further dilute with sufficient 0.1 *M* monopotassium phosphate buffer, pH 4.5, to obtain a concentration of 0.24 microgram per milliliter, and proceed as directed in § 446.10a(b)(1)(viii) of this chapter, using the oxytetracycline working standard as the standard of comparison, except:

(*a*) Prepare the standard stock solution by dissolving an appropriate amount of the working standard in sufficient 0.1 *N* HCl to give a concentration of 1,000 micrograms per milliliter. This solution may be kept in the refrigerator for 1 week. Do not freeze.

(*b*) To prepare solutions for the standard curve, make further dilution of the stock solution with 0.1 *M* monopotassium phosphate buffer, pH 4.5, to obtain concentrations of 0.148, 0.188, 0.240, 0.308, and 0.400 microgram per milliliter.

(ii) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

(iii) *Toxicity.* Proceed as directed in § 440.80a(b)(4), using as a test dose 0.5 milliliter of an aqueous solution containing 2.0 milligrams per milliliter, prepared by dissolving 40 milligrams (as the anhydrous compound) in 2.0 milliliters of 0.1 *N* HCl (if it is the base) and diluting with the required amount of water.

(iv) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(v) *Crystallinity.* Proceed as directed in § 440.80a(b)(5)(iii) of this chapter.

(4) *Carbomycin used in making the powder*—(i) *Potency*—(*a*) *Plate assay*—(*1*) *Cylinders (cups).* Use cylinders described under § 440.80a(b)(1)(i) of this chapter.

(*2*) *Culture media.* Prepare the culture media for the base and seed layers and for carrying the test organism as directed in § 440.80a(b)(*1*)(ii)(*a*) of this chapter, except for the base and seed layers adjust the media to pH 8.0 after sterilization. Make the nutrient broth for preparing an inoculum of the test organism as directed in § 440.80a(b)(1)(ii)(*c*) of this chapter.

(*3*) *Working standard.* Keep the working standard at refrigeration in tightly stoppered vials, which in turn are kept in larger stoppered vials containing a suitable desiccant. Dry approximately 50 milligrams of the standard as described in § 440.80a(b)(5)(i) of this chapter. Dissolve the weight of dry working standard in sufficient methyl alcohol to give a concentration of 10,000 micrograms per milliliter. Further dilute with sterile distilled water to give a stock solution of 100 micrograms per milliliter. This stock solution may be kept under refrigeration for 1 week. Make daily dilutions to a concentration of 1 microgram per milliliter using 0.1 *M* potassium phosphate buffer, pH 8.0.

(*4*) *Preparation of sample.* Prepare the sample to be tested by dissolving in a small amount of methyl alcohol and then further dilute in 0.1 *M* phosphate buffer, pH 8.0, to make an appropriate stock solution.

(*5*) *Preparation of suspension.* Proceed as directed in § 455.106(b)(1)(v) of this chapter, except add 0.2 milliliter of the adjusted bulk suspension to 100 milliliters of agar that has been melted and cooled to 48° C.

(*6*) *Preparation of plates.* Proceed as directed in § 455.106(b)(1)(vi) of this chapter.

(*7*) *Assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 microgram per milliliter standard and three cylinders with the sample diluted to 1.0 microgram per milliliter (estimated) in 0.1 *M* potassium phosphate buffer, pH 8.0, alternating standard and sample. At the same time, prepare a standard curve, using concentrations of the standard of 0.64, 0.80, 1.0, 1.25, and 1.56 micrograms per milliliter. Use three plates for the determination of each concentration on the curve except the 1.0 microgram per milliliter concentration, a total of 12 plates. The 1.0 microgram per milliliter concentration is the reference point of the curve. On each of three plates fill three cylinders with the 1.0 microgram per milliliter standard and the other three cylinders with the concentration of the standard under test. Thus there will be 36 of the 1.0 microgram determinations and nine determinations for each of the other points on the curve. Incubate the plates for 16 to 18 hours at 32° C. to 35° C. and measure the diameters of the circles of inhibition. Average the readings of the 1.0 microgram per milliliter concentrations and the readings of the concentration tested for each set of three plates and average also all 36 readings of the 1.0 microgram per milliliter concentration. The average of the 36 readings of the 1.0 microgram per milliliter concentration is the correction point for the curve. Correct the average value obtained for each concentration to the figure it would be if the average 1.0 microgram per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correction of the 0.8 microgram concentration the average of the 36 readings of the 1.0 microgram concentration is 20.0 millimeters and the average of the 1.0 microgram concentration of this set of three plates is 19.8 millimeters, the correction is +0.2 millimeter.

If the average reading of the 0.8 microgram concentration of these same three plates is 19.0 millimeters, the corrected value is 19.2 millimeters. Plot these corrected values, including the average of the 1.0 microgram per milliliter concentration, on two-cycle semilogarithmic paper using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 1.0 microgram per milliliter unit zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 1.0 microgram per milliliter unit value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(ii) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

(iii) *Toxicity.* Proceed as directed in § 440.80a(b)(4) of this chapter, using as a test dose 0.5 milliliter of a solution containing 2 milligrams per milliliter.

(iv) *pH.* Using an aqueous solution containing 10 milligrams per milliliter, proceed as directed in § 440.80a(b)(5)(ii) of this chapter.

(v) *Crystallinity.* Proceed as directed in § 440.80a(b)(5)(iii) of this chapter.

PART 544—OLIGOSACCARIDE CERTIFIABLE ANTIBIOTIC DRUGS FOR ANIMAL USE

Subpart A—Oral Dosage Forms

Sec.
544.110 Dihydrostreptomycin boluses.
544.170 Streptomycin oral dosage forms.
544.170a Streptomycin-polymyxin - bacitracin tablets.
544.170b Streptomycin hydrochloride/streptomycin sulfate oral solution.
544.173 Streptomycin/dihydrostreptomycin oral dosage forms.
544.173a Streptomycin/dihydrostreptomycin tablets.
544.173b Streptomycin/dihydrostreptomycin syrup; streptomycin/dihydrostreptomycin in gel (streptomycin/dihydrostreptomycin oral suspension); potency.
544.173c Streptomycin / dihydrostreptomycin sodium sulfathiazole solution.
544.173d Streptomycin/dihydrostreptomycin sulfate oral powder; streptomycin sulfate/dihydrostreptomycin sulfate oral granules; dihydrochloride oral powder/oral granules.
544.173e Streptomycin / dihydrostreptomycin-kaolin-pectin-aluminum hydroxide gel powder.

Subpart B—Implantation or Injectable Dosage Forms

544.211 Dihydrostreptomycin / streptomycin implantation or injectable dosage forms.
544.211a Dihydrostreptomycin / streptomycin sulfates aqueous solution.
544.211b Dihydrostreptomycin / streptomycin sulfates.
544.274 Streptomycin sulfate/dihydrostreptomycin sulfate/crystalline dihydrostreptomycin sulfate injectable.

Subpart C—Ophthalmic and Topical Dosage Forms

544.370 Streptomycin ophthalmic and topical dosage forms.
544.370a Streptomycin for topical use.
544.370b Streptomycin-erythromycin ointment.
544.373 Streptomycin / dihydrostreptomycin ophthalmic and topical dosage forms.
544.373a Streptomycin / dihydrostreptomycin ointment.

Sec.
544.373b Streptomycin / dihydrostreptomycin-polymyxin-neomycin ointment.

Subpart D—Otic Dosage Forms

544.473 Streptomycin / dihydrostreptomycin otic with antifungal agent.

Subparts E–H [Reserved]

Subpart I—Certain Other Dosage Forms

544.973b Streptomycin / dihydrostreptomycin solution for inhalation therapy.

AUTHORITY: Secs. 507, 512, 59 Stat. 463 as amended, 82 Stat. 343–351 (21 U.S.C. 357, 360b).

Subpart A—Oral Dosage Forms

§ 544.110 Dihydrostreptomycin boluses.

(a) *Requirements for certification.* The requirements for certification for dihydrostreptomycin boluses are described under § 544.173a(a).

(b) *Tests and methods of assay.* The tests and methods of assay for dihydrostreptomycin boluses are described in § 544.173a(b).

(c) *Conditions of marketing*—(1) *Specifications.* (i) The drug is in bolus form and conforms to the requirements of § 544.173a(a).

(ii) Each bolus contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(2) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.200 of this chapter.

(4) *Conditions of use.* (i) It is administered orally to calves as an aid in the treatment and control of bacterial scours (colibacillosis) of calves caused by *E. coli* organisms sensitive to dihydrostreptomycin.

(ii) It is administered at a dosage level of 5 milligrams of dihydrostreptomycin for each pound of body weight every 12 hours until the animal returns to normal. Treatment should continue 24 to 48 hours after symptoms have subsided.

(iii) Treated animals should not be used for food within 10 days after the latest treatment. Treatment with the drug must not exceed 5 days.

§ 544.170 Streptomycin oral dosage forms.

§ 544.170a Streptomycin - polymyxin-bacitracin tablets.

(a) *Requirements for certification*—(1) The requirements for certification for streptomycin-polymyxin-bacitracin tablets are described under § 444.170a of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 444.170a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for streptomycin-polymyxin-bacitracin tablets are described under § 444.170a of this chapter.

§ 544.170b Streptomycin hydrochloride/streptomycin sulfate oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin hydrochloride solution oral and streptomycin sulfate solution oral are aqueous solutions of streptomycin hydrochloride or streptomycin sulfate, with one or more suitable and harmless preservatives and with or without one or more essential vitamin and mineral substances for nutritive purposes. The drug may also contain one or more suitable and harmless buffer substances and stabilizing agents. Its potency is not less than 250 milligrams per milliliter. Its pH is not less than 4 and not more than 7. It is nontoxic. Each preservative, buffer substance, and stabilizing agent used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin in each milliliter of the immediate container.

(iii) The statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time, such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(iv) The name and quantity of each preservative used.

(v) The statement "For oral veterinary use only".

(vi) If it contains added vitamins or minerals, the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(vii) If it is intended for use in animals raised for food production, it shall be used in accordance with paragraph (c) of this section.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, and the number of milligrams of streptomycin per milliliter. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, and pH.

(ii) Such person shall also submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers.

(b) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 444.70a(b)(1) of this chapter. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin per milliliter that it is represented to contain.

(2) *Toxicity.* Proceed as directed in § 444.70a(b)(3) of this chapter.

(3) *pH.* Proceed as directed in § 444.70a(b)(6)(ii) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Complies with the requirements for streptomycin sulfate found in paragraph (a) of this section or §§ 544.173a(a) or 544.173d(a).

(2) *Sponsor.* [Reserved]

(3) *Special considerations.* The quantities of antibiotic in paragraph (c)(5) of this section refer to the activity of the master standard.

(4) *Related tolerances.* See § 556.610 of this chapter.

(5) *Conditions of use.* It is used as streptomycin sulfate in drinking water as follows:

(i) *Calves*—(a) *Amount per gallon.* 0.5 to 1.5 grams.

(b) *Indications for use.* Treatment of bacterial diarrhea (scours) of calves.

(c) *Limitations.* Administer not more than 5 days; prepare fresh solution daily; withdraw 2 days before slaughter; as sole source of streptomycin.

(ii) *Chickens*—(a) *Amount per gallon.* 0.5 to 1.5 grams.

(b) *Indications for use.* Treatment of chronic respiratory disease (air-sac infection); maintenance of weight gains during periods of stress; treatment of blue comb (nonspecific infectious enteritis).

(c) *Limitations.* Administer not more than 5 days; not for use in laying chickens; prepare fresh solution daily; withdraw 4 days before slaughter; as sole source of streptomycin.

(iii) *Swine*—(a) *Amount per gallon.* 0.5 to 1.5 grams.

(b) *Indications for use.* Treatment of bacterial enteritis (scours) in swine.

(c) *Limitations.* Administer not more than 4 days; prepare fresh solution daily; as sole source of streptomycin.

§ 544.173 Streptomycin/dihydrostreptomycin oral dosage forms.

§ 544.173a Streptomycin/dihydrostreptomycin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin tablets and dihydrostreptomycin tablets are streptomycin or dihydrostreptomycin tablets with or without glucuronolactone, kaolin, or other suitable and harmless absorbent ingredients, pectin, and dried aluminum hydroxide gel, with or without bismuth glycolylarsanilate and one or more suitable sulfonamides, and with or without the addition of one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. It may contain chlorhexidine dihydrochloride or vitamin A and/or bismuth subcarbonate. The potency of each tablet is not less than 37.5 milligrams. If it contains chlorhexidine dihydrochloride, each tablet contains 375 milligrams of chlorhexidine dihydrochloride and 37.5 milligrams of dihydrostreptomycin. Its moisture content is not more than 10 percent. Tablets not exceeding 15 millimeters in diameter, or not intended only for preparing solutions, shall disintegrate within 1 hour. The streptomycin or dihydrostreptomycin used conforms either to the standards prescribed by § 444.70a (a) (1) of this chapter or § 444.10a(a) of this chapter, except the standards for sterility, pyrogens, and histamine content, or to the standards prescribed by § 539.170(a) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate container shall be a well closed container or a tight container as defined by the U. S. P. and it may contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* In addition to the labeling requirements prescribed by § 201.105 of this chapter (regulations issued under section 502(f) of the act), each package shall bear on the outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(i) The statement "Expiration date _____", the blank being filled in with the date that is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of test and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed in paragraph (a) (1) of this section.

(ii) If it contains, in addition to streptomycin or dihydrostreptomycin one or more of the other active ingredients specified in paragraph (a) (1) of this section, after the name "streptomycin tablets" or "dihydrostreptomycin tablets", wherever it appears, the words "with _____", the blank being filled in with the established name of each such other ingredient and the words being in juxtaposition with such name.

(iii) In lieu of the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity. If it contains bismuth subcarbonate, its label and labeling shall include reference to its use only in cats and dogs.

(iv) If it is intended for use in animals raised for food production, it shall be used in accordance with paragraph (c) of this section, § 544.110(c) or § 544.170b(c)

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch of streptomycin or dihydrostreptomycin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the potency of each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Average potency per tablet, average moisture, and if required by paragraph (a) (1) of this section, disintegration time.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch: potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch:

(*1*) For potency and moisture: One tablet for each 5,000 tablets in the batch, but in no case less than 30 tablets, collected by taking single tablets throughout the entire time of tableting so that the quantities tableted during the intervals are approximately equal.

(2) For disintegration time: 6 tablets.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 444.70a(a) (2) of this chapter.

(c) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a) (4) (ii) (*b*) of this section, and no sample referred to in paragraph (a) (4) (iii) (*b*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Streptomycin content.* Using 12 tablets, proceed as directed in § 444.70a(b) (1) of this chapter, except paragraph (b) (1) (x) and (xi) of that section, and in lieu of the directions in paragraph (b) (1) (v) of that section, prepare the sample as follows: Place the tablets in a glass blending jar containing 500 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0. Using a high-speed blender, blend for 3 to 5 minutes and then make the proper estimated dilutions in the buffer solution; except if it is a bolus, add 1 milliliter polysorbate 80 and 499 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0, to a glass blending jar, turn on blender, and add three boluses. Blend for 5 minutes and then allow to stand at room temperature for at least 1 hour. Blend again for 5 minutes. Pour contents of blending jar into a beaker, stir with a magnetic stirrer and while stirring remove an aliquot for making the proper estimated dilutions. The average potency of streptomycin tablets is satisfactory if they contain not less than 85 percent of the number of milligrams that they are represented to contain.

(ii) *Dihydrostreptomycin content.* Proceed as directed in paragraph (b) (1) (i) of this section, using the dihydrostreptomycin working standard as a standard of comparison. The average potency of dihydrostreptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i). of this chapter.

(3) *Disintegration time.* Proceed as directed in § 440.180a(b) (3) of this chapter.

(c) *Conditions of marketing*—(1) *Chemical name.* Chlorhexidine dihydrochloride: 1,1'-hexamethylenebis [5-*p*-chlorophenyl) biguanide] dihydrochloride.

(2) *Specifications.* (i) The drug in tablet form conforms to the requirements of § 544.173a(a) of this chapter and in oral suspension to § 544.173b(a) of this chapter.

(ii) Dihydrostreptomycin sulfate is the sulfate salt of the antibiotic substance obtained by hydrogenation of the antibiotic substance produced by the growth of *Streptomyces griseus* or the

same antibiotic substance produced by any other means.

(3) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(4) *Special considerations.* The quantities of antibiotic in paragraph (c)(6) of this section refer to the activity of the master standard.

(5) *Related tolerances.* See §§ 556.200 and 556.120 of this chapter.

(6) *Conditions of use.* It is used as dihydrostreptomycin sulfate in tablets or suspension for oral administration to calves as follows:

(i) *Amount.* 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.

(ii) *Indications for use.* For treatment of bacterial scours in calves.

(iii) *Limitations.* Administer one dose per day for 5 days; withdraw 3 days before slaughter.

§ 544.173b Streptomycin/dihydrostreptomycin syrup; streptomycin/dihydrostreptomycin in gel (streptomycin/dihydrostreptomycin oral suspension); potency.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Streptomycin syrup and dihydrostreptomycin syrup are streptomycin or dihydrostreptomycin dissolved in a suitable and harmless diluent that contains one or more suitable and harmless preservatives. Streptomycin in gel and dihydrostreptomycin in gel are streptomycin and dihydrostreptomycin dissolved or suspended in a suitable and harmless gel base that contains a suitable and harmless adsorbent and one or more suitable and harmless preservatives. Each such drug may contain one or more suitable and harmless suspending or dispersing agents, flavorings, pectin, chlorhexidine dihydrochloride, bismuth glycolylarsanilate, bismuth magma, or bismuth subcarbonate, suitable mineral salts, procaine hydrochloride, a suitable antispasmodic agent, and one or more suitable sulfonamides. Its potency is not less than 10 milligrams per milliliter; however, if it contains chlorhexidine dihydrochloride, each milliliter contains 12.5 milligrams of chlorhexidine dihydrochloride and 1.25 milligrams of dihydrostreptomycin. The streptomycin used conforms to the standards prescribed therefor by § 444.70a(a)(1) of this chapter, except paragraphs (a)(1)(ii), (iv), (v), and (vi) of that section. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 444.10a(a) of this chapter respectively, except the standards for sterility, pyrogens, moisture, and histamine content. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium

(2) *Packaging.* In all cases the immediate container shall be glass, so closed as to be a tight container as defined by the U.S.P. and of such composition that will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* In addition to the labeling requirements prescribed by § 201.105 of this chapter (regulations issued under section 502(f) of the act), each package shall bear on the outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(i) The statement "Expiration date _____", the blank being filled in with the date that is 18 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 24 months or 36 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(ii) If it contains, in addition to streptomycin or dihydrostreptomycin, one or more of the other active ingredients specified in paragraph (a)(1) of this section, after the name "streptomycin sirup", "streptomycin in gel", "dihydrostreptomycin sirup", or "dihydrostreptomycin in gel", wherever such name appears, the words "with _____ (the blank being filled in with the established name of each such other ingredient)", in juxtaposition with such name.

(iii) In lieu of the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(iv) If it is intended for use in animals raised for food production, it shall be used in accordance with § 544.173a(c).

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making the batch was completed, the potency per milliliter of the batch, the quantity of each ingredient used in making the batch, the date on which the latest assay comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch; average potency per milliliter.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 444.70a(a)(2) of this chapter.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(*b*) of this section, and no sample referred to in paragraph (a)(4)(iii)(*b*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay—*(1) *Streptomycin content.* Proceed as directed in § 444.70a(b)(1) of this chapter, except paragraph (b)(1)(xi) of that section, and except that if it is in an oil base proceed as directed in § 536.501(a)(2) of this chapter. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin that it is represented to contain.

(2) *Dihydrostreptomycin content.* Using dihydrostreptomycin working standard as the standard of comparison, proceed as directed in § 444.70a(b)(1) of this chapter, except paragraph (b)(1)(xi) of that section, and except that if it is in an oil base proceed as directed in § 536.501(a)(3) of this chapter. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of dihydrostreptomycin that it is represented to contain.

(c) *Conditions of marketing.* The conditions of marketing are described under § 544.173a(c).

§ 544.173c Streptomycin/dihydrostreptomycin sodium sulfathiazole solution.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Streptomycin-sodium sulfathiazole solution and dihydrostreptomycin-sodium sulfathiazole solution are streptomycin or dihydrostreptomycin and sodium sulfathiazole dissolved in a suitable and harmless vehicle. Each milliliter contains not less than 35 milli-

grams of streptomycin or dihydrostreptomycin and not less than 25 milligrams of sodium sulfathiazole. It is sterile. It is nontoxic. It is nonpyrogenic. It contains no histamine nor histamine-like substance. Its pH is not less than 5.0 and not more than 8.0. The streptomycin used conforms to the standards prescribed therefor by § 444.70a(a)(1) of this chapter, except paragraph (a)(1)(vi) of that section. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 444.10a(a) of this chapter, except the standard for moisture. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium

(2) *Packaging; labeling.* It shall be packaged and labeled in accordance with the requirements of § 444.270b(a)(2) and (3) of this chapter, except that in addition to the requirements of paragraph (c) each package shall bear on the outside wrapper or container and the immediate container:

(i) The composition of the vehicle.

(ii) The number of milligrams of sodium sulfathiazole in each milliliter of the batch.

(iii) The statement "For veterinary use only".

(iv) The statement "Warning—Not for use in animals which are raised for food production".

(3) *Requests for certification, samples.* The person who requests certification of a batch shall submit in connection with his request the same information and number of samples for the batch as prescribed by § 444.270b(a)(4) of this chapter.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 444.70a(b)(1)(x) of this chapter, except if it contains dihydrostreptomycin use the dihydrostreptomycin working standard as a standard of comparison. Its content of streptomycin or dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) *Sterility, pyrogens, histamine, streptomycin content if it is dihydrostreptomycin.* Proceed as directed in §§ 444.70a(b)(2), (4), and (5), and 444.270b(b)(2) of this chapter.

(3) *Toxicity.* Proceed as directed in § 440.80a(b)(4) of this chapter, using as a test dose 0.5 milliliter of a solution containing 1.5 milligrams of streptomycin or dihydrostreptomycin per milliliter.

(4) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using the undiluted drug.

§ 544.173d Streptomycin / dihydrostreptomycin sulfate oral powder; streptomycin sulfate/dihydrostreptomycin sulfate oral granules; dihydrochloride oral powder/oral granules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate powder oral, streptomycin sulfate granules oral, dihydrostreptomycin sulfate powder oral, dihydrostreptomycin sulfate granules oral, dihydrostreptomycin hydrochloride powder oral, and dihydrostreptomycin hydrochloride granules oral are streptomycin sulfate, dihydrostreptomycin sulfate, or dihydrostreptomycin hydrochloride, with or without one or more suitable and harmless diluents and stabilizing agents, with or without one or more suitable sulfonamides, and with or without one or more essential vitamin and mineral substances for nutritive purposes. Its potency is not less than 3.75 grams per pound. Its moisture content is not more than 7 percent. The streptomycin or dihydrostreptomycin used conforms to the standards prescribed by § 539.17(a)(1). Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of milligrams of streptomycin or dihydrostreptomycin per gram and the number of grams in the immediate container.

(*c*) If it contains one or more sulfonamides, the name and quantity of each such ingredient.

(*d*) The statement "Expiration date ----------", the blank being filled in with the date that is 12 months (if its potency is less than 150 grams per pound) or 36 months (if its potency is 150 grams or more per pound) after the month during which the batch was certified, except that if the person who requests certification has submitted to the Commissioner results of tests and assays that show that such drug as prepared by him is stable for 24 months, 36 months, 48 months, or 60 months, such date may be used for such drug.

(*e*) The statement "For oral veterinary use only".

(*f*) If it contains added vitamins or minerals, the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(*g*) If it is intended for use in animals raised for food production, it shall be used in accordance with § 544.170b(c) of this chapter.

(*h*) The statement "For manufacturing use", "For repacking", or "For manufacturing use or repacking", when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(ii) On the label and labeling, if it contains one or more sulfonamides, after the name "streptomycin sulfate powder oral", "streptomycin sulfate granules oral", "dihydrostreptomycin sulfate powder oral", "dihydrostreptomycin sulfate granules oral", "dihydrostreptomycin hydrochloride powder oral", or "dihydrostreptomycin hydrochloride granules oral", wherever such name appears, the words "with sulfonamide(s)", in juxtaposition with such name.

(iii) On the circular or other labeling within or attached to the packaged, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch; potency and moisture.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, moisture, pH, and streptomycin content if it is dihydrostreptomycin.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers, unless each such container is packaged to contain more than 15 grams, in which case the sample shall consist of 15 grams for each 5,000 immediate containers in the batch, but in no case less than five 15-gram portions. Such samples shall be collected by taking single immediate containers or 15-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(b) The streptomycin or dihydrostreptomycin used in making the batch; 6 packages containing approximately equal portions of not less than 1.0 gram each, packaged in accordance with the requirements of § 539.170(a)(2) of this chapter.

(c) In case of an initial request for certification, the other ingredients used in making the batch; one package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(b) of this section, and no sample referred to in paragraph (a)(4)(iii)(b) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 444.70a(b)(1) of this chapter, except if it contains dihydrostreptomycin use the dihydrostreptomycin working standard as the standard of comparison. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin or dihydrostreptomycin per gram that it is represented to contain.

(2) *Moisture.* Using a 1-gram sample, proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 544.173c Streptomycin / dihydrostreptomycin - kaolin - pectin-aluminum hydroxide gel powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin-kaolin-pectin-aluminum hydroxide gel powder and dihydrostreptomycin-kaolin-pectin aluminum hydroxide gel powder are streptomycin or dihydrostreptomycin, kaolin, pectin, and dried aluminum hydroxide gel, with or without the addition of one or more suitable and harmless diluents, colorings, and flavorings. Its content of streptomycin or dihydrostreptomycin is not less than 37.5 milligrams per gram of powder. Its moisture content is not more than 10 percent. The streptomycin used conforms to the standards prescribed therefor by § 444.70a(a)(1) of this chapter, except paragraph (a)(1)(ii), (iv), and (v) of that section. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 444.10a(a) of this chapter, except the standards for sterility, pyrogens, and histamine content. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium

(2) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(a) The batch mark.

(b) The number of milligrams of streptomycin or dihydrostreptomycin per gram in the immediate containers.

(c) The quantity of kaolin, pectin, and aluminum hydroxide per gram in the immediate container.

(d) The statement "Expiration date _____", the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months, 36 months, or 48 months after the month in which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(e) The statement "For veterinary use only".

(f) The statement "Warning—Not for use in animals which are raised for food production".

(ii) On the circular or other labeling within or attached to the package, directions and precautions adequate for the use of such powder, including:

(a) Clinical indications.

(b) Dosage and administration.

(c) Contraindications.

(d) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than the number of such containers.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the potency per gram of powder, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(a) The batch; average potency per gram of powder and average moisture.

(b) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch; one immediate container for each 5,000 containers in the batch, but in no case less than 20 such containers, unless each such container is packaged to contain more than 1.0 gram, in which case the sample shall consist of 1.0 gram for each 5,000 immediate containers in the batch, but in no case less than 20 grams. Such samples shall be collected by taking single immediate containers or 1.0-gram portions at such intervals throughout the entire time the containers are being filled that the quantities packaged during the intervals are approximately equal.

(b) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 444.70a(a)(2) of this chapter.

(c) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5.0 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(b) of this section, and no sample referred to in paragraph (a)(4)(iii)(b) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Streptomycin content.* Using 3.0 grams of the sample, proceed as directed in § 444.70a(b)(1) of this chapter, except paragraph (b)(1)(xi) of that section. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin it is represented to contain.

(ii) *Dihydrostreptomycin content.* Proceed as directed in paragraph (b)(1)(i) of this section, using the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of dihydrostreptomycin it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

Subpart B—Implantation or Injectable Dosage Forms

§ 544.211 Dihydrostreptomycin / streptomycin implantation or injectable dosage forms.

§ 544.211a Dihydrostreptomycin /streptomycin sulfates aqueous solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Dihydrostreptomycin-streptomycin sulfates solution is an aqueous solution of dihydrostreptomycin-streptomycin sulfates. Such solution conforms to all standards prescribed by § 544.211b(a)(1) for dihydrostreptomycin-streptomycin sulfates, except the limitation on moisture content, and except that:

(i) It may contain suitable and harmless buffer substances, preservatives, and stabilizing agents. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(ii) Its pH is not less than 5.0 and not more than 7.5.

(2) *Packaging.* It shall be packaged in accordance with the requirements of § 444.270b(a) (2) of this chapter.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 444.70a(a) (3) (ii) or (iii) of this chapter.

(4) *Request for certification; samples.* In addition to complying with the requirements of § 544.211b(a) (4), a person who requests certification of a batch shall submit in connection with his initial request one package containing approximately 5.0 grams of each other ingredient used in making the batch.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 444.10a(b) (1) of this chapter. Its total potency is satisfactory if it contains not less than 90 percent of the combined number of milligrams of dihydrostreptomycin and streptomycin than it is represented to contain.

(2) *Content of streptomycin sulfate.* Proceed as directed in § 444.10a(b) (2) of this chapter, making appropriate dilutions so that the aliquot used for the colorimetric measurement contains 5.0 milligrams of streptomycin (estimated), and modify the calculations in accordance with the dilutions made. Its content of streptomycin is satisfactory if it contains not less than 40 percent and not more than 60 percent of the total potency as determined under paragraph (b) (1) of this section.

(3) *Sterility, toxicity, pyrogens, histamine.* Proceed as directed in § 444.70a(b) (2), (3), (4), and (5) of this chapter.

(4) *pH.* Using the undiluted solution, proceed as directed in § 440.80a(b) (5) (ii) of this chapter.

§ 544.211b Dihydrostreptomycin /streptomycin sulfates.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Dihydrostreptomycin-streptomycin sulfates is a mixture of equal parts of dihydrostreptomycin sulfate and streptomycin sulfate. It is so purified and dried that:

(i) It is sterile.

(ii) It is nontoxic.

(iii) It is nonpyrogenic.

(iv) It contains no histamine or histamine like substance.

(v) Its moisture content is not more than 5 percent.

(vi) Its pH in an aqueous solution containing 0.1 gram of dihydrostreptomycin and 0.1 gram of streptomycin per milliliter is not less than 4.5 and not more than 7.0.

The dihydrostreptomycin sulfate used conforms to the standards prescribed by § 444.10a(a) of this chapter, except the standards for streptomycin content. The streptomycin sulfate used conforms to the standards prescribed by § 444.70a(a) (1) of this chapter.

(2) *Packaging.* It shall be packaged in accordance with the requirements prescribed by § 510.45, except that in case it is packaged for dispensing each immediate container shall contain not less than 0.5 gram of dihydrostreptomycin and 0.5 gram of streptomycin or multiples of each such salt up to and including 5.0 grams of dihydrostreptomycin and 5.0 grams of streptomycin.

(3) *Labeling.* It shall be labeled in accordance with § 444.70(a) (3) (ii) or (iii) of this chapter, except that each package shall bear on the outside wrapper or container the number of grams of dihydrostreptomycin, the number of grams of streptomycin, and the total number of grams of both salts in the immediate container.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the dihydrostreptomycin and streptomycin used in making the batch were completed, the content of dihydrostreptomycin and streptomycin in each container, and the date on which the latest assay of the drug comprising such batch was completed. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements described therefor by this section.

(ii) Except as otherwise provided by paragraph (a) (4) (v) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(*a*) The batch; content of dihydrostreptomycin and streptomycin, sterility, toxicity, pyrogens, histamine content, moisture, and pH.

(*b*) The dihydrostreptomycin and streptomycin used in making the batch; potency, and if crystalline dihydrostreptomycin is used, crystallinity.

(iii) Except as otherwise provided by paragraph (a) (4) (v) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch:

(*1*) For all tests except sterility: One immediate container for each 5,000 immediate containers in the batch, but in no case less than six immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(2) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(*b*) The dihydrostreptomycin used in making the batch; 3 packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 444.70a(a) (2) of this chapter.

(*c*) The streptomycin used in making the batch; three packages containing approximately 0.5 gram packaged in accordance with the requirements of § 444.70a(a) (2) of this chapter.

(iv) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(*a*) For all tests except sterility: 6 packages.

(*b*) For sterility testing: 20 packages.

Each such package shall contain not less than 0.5 gram of dihydrostreptomycin and 0.5 gram of streptomycin taken from different parts of such batch, and each shall be packaged in accordance with the requirements for veterinary use of § 444.70a(a) (2) of this chapter.

(v) No result referred to in paragraph (a) (4) (ii) of this section, and no sample referred to in paragraph (a) (4) (iii) (*b*) and (*c*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 444.10a(b) (1) of this chapter. Its total potency is satisfactory if it contains not less than 90 percent of the combined number of milligrams of dihydrostreptomycin and streptomycin that it is represented to contain.

(2) *Content of streptomycin sulfate.* Proceed as directed in § 444.10a(b) (2) of this chapter, making appropriate dilution so that the aliquot used for the colorimetric measurement contains 5.0 milligrams of streptomycin (estimated) and modify the calculations in accordance with the dilutions made. Its content of streptomycin is satisfactory if it contains not less than 45 percent and not more than 55 percent of the total potency as determined under paragraph (b) (1) of this section.

(3) *Sterility, toxicity, pyrogens, histamine, moisture, pH.* Using the total potency of the sample for preparing dilutions and weighings, proceed as directed in § 444.70a(b) (2), (3), (4), (5), and (6) of this chapter.

§ 544.274 Streptomycin sulfate / dihydrostreptomycin sulfate / crystalline dihydrostreptomycin sulfate injectable.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate injection is an aqueous solution of streptomycin sulfate. Dihydrostreptomycin sulfate injection is an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate. Such solution conforms to all standards prescribed by § 444.70a(a) of this chapter for streptomycin sulfate or § 444.10a(a)

of this chapter for dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate, except:

(i) The limitation on moisture content does not apply.

(ii) The histamine test may be omitted if it has been performed on streptomycin sulfate, dihydrostreptomycin sulfate, or crystalline dihydrostreptomycin sulfate used in preparing the solution.

(iii) It contains one or more suitable and harmless preservatives.

(iv) Its pH is not less than 5.0 and not more than 8.0.

(v) It may contain one or more suitable and harmless buffer substances and stabilizing agents.

(2) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U.S.P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling*—(i) It shall be labeled in accordance with the requirements prescribed by § 201.105 of this chapter and each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity in lieu of the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" (as provided in § 201.105(b)(1) of this chapter) unless such statement is required by regulations issued under section 512(i) of the act.

(ii) Its labeling shall bear any additional information required for the drug by specific regulations.

(iii) On the outside wrapper or container and the immediate container, the statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified except that the blank may be filled in with the date that is 18 months, 24 months, 36 months, 48 months, or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(iv) On the outside wrapper or container the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)" unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section after having been stored at room temperature.

(v) The statement "Warning—The use of this drug must be discontinued for 30 days before treated animals are slaughtered for food". If the drug is intended for use in animals producing milk for human consumption, the labeling shall also bear the statement "Milk that has been taken from animals during treatment and for _____ hours (_____ milkings) after the latest treatment must not be used for food", the blanks being filled with the figures 96 and 8 respectively, unless the sponsor of the drug has submitted the results of tests and assays demonstrating that residues of the drug in milk from treated animals persist for a shorter period of time and the shorter period is authorized by the Commissioner.

(4) *Request for certification, check tests and assays; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams or grams dissolved in each of such packages, the date on which the latest assay of the drug comprising such batch was completed, and if it is crystalline dihydrostreptomycin sulfate injection, the batch mark and (unless it was previously submitted) the date on which the latest assay of the crystalline dihydrostreptomycin sulfate used in making such batch was completed.

(ii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch; potency, sterility, toxicity, pyrogens, histamine content (except that the result of this test performed on the streptomycin sulfate, dihydrostreptomycin sulfate, or crystalline dihydrostreptomycin sulfate used in making the batch may be submitted instead), pH, and streptomycin content, if it is dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate.

(*b*) The streptomycin sulfate or dihydrostreptomycin sulfate used in making the batch; potency on dry basis and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch, if packaged for dispensing:

(*1*) For all tests except sterility: One immediate container for each 5,000 immediate containers in such batch; but in no case less than five immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(2) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(*b*) The batch, if packaged for use in the manufacture of another drug:

(*1*) For all tests except sterility: Five packages.

(2) For sterility testing: 20 packages.

Each such package shall contain approximately 2 milliliters, taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (a)(2) of this section.

(*c*) The streptomycin or dihydrostreptomycin used in making the batch; one immediate container, unless it is crystalline dihydrostreptomycin, in which case the sample shall consist of three immediate containers. Each immediate container shall contain approximately 0.5 gram or the dried drug. If the streptomycin or dihydrostreptomycin used in making the batch is a solution of the drug, the person who requests certification shall dry a sufficient quantity of such solution for potency testing on the dry basis.

(*d*) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(*b*) of this section, and no sample referred to in paragraph (a)(4)(iii)(*c*) of this section is required if such result or sample has been previously submitted.

(v) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of the batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by paragraph (a)(4)(iii)(*b*) of this section. From the information required by paragraph (a)(4)(ii)(*a*) of this section may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(b) *Tests and methods of assay*—(1) If it is streptomycin sulfate injection, proceed as directed in § 444.70a(b) of this chapter.

(2) If it is dihydrostreptomycin sulfate injection or crystalline dihydrostreptomycin sulfate injection, proceed as directed in § 444.10a(b) of this chapter, except that the histamine test may be omitted if it is performed on the dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate used in preparing the injection, and except that in lieu of the directions in § 444.10a(b)(2) of this chapter determine the streptomycin content as follows:

(i) *Preparation of standard.* Prepare a standard aqueous solution of the Food and Drug Administration streptomycin working standard containing 0.25 milligram of streptomycin base per milliliter.

Transfer 1.0, 1.5, and 2.0 milliliter aliquots to test tubes (approximately 16 millimeters×150 millimeters. Add 1.0, 0.5, and 0 milliliter of distilled water to give a 2.0-milliliter volume.

(ii) *Preparation of sample.* Dilute 1.0 milliliter of the dihydrostreptomycin sulfate solution to be tested (containing 250 to 500 milligrams of dihydrostreptomycin) to 25.0 milliliters in a volumetric flask. Transfer 2.0 milliliters to a test tube.

(iii) *Blank.* Use 2.0 milliliters of distilled water.

(iv) *Procedure.* To each tube containing 2.0 milliliters, add, in turn, 8.0 milliliters of 0.1*N* NaOH (freshly prepared from 1*N* NaOH), mix thoroughly, and immediately determine the optical density at 325 mμ in a suitable spectrophotometer. Set the spectrophotometer at 100-percent light transmission for the blank similarly treated. Return the solution to the test tube, heat in a boiling water bath for 10 minutes, cool in an ice bath for 3 minutes, and allow to come to room temperature. Determine the optical density at 325 mμ. The difference in reading before and after heating is the optical density of the aliquot. Prepare a standard curve. The concentration of streptomycin in the sample solution obtained directly from the standard curve times 1,250, divided by the number of milligrams of dihydrostreptomycin in the original dihydrostreptomycin solution, equals the percent of streptomycin.

Subpart C—Ophthalmic and Topical Dosage Forms

§ 544.370 Streptomycin ophthalmic and topical dosage forms.

§ 544.370a Streptomycin for topical use.

(a) *Requirements for certification*—(1) The requirements for certification for streptomycin for topical use; streptomycin with _____ (the blank being filled in with the name of the vehicle if a package combination) for topical use are described under § 444.570b of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 444.570b(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for streptomycin for topical use are described under § 444.570b of this chapter.

§ 544.370b Streptomycin-erythromycin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin-erythromycin ointment is streptomycin and erythromycin in a suitable and harmless ointment base, with or without one or more suitable sulfonamides and with or without suitable and harmless dispersing and suspending agents. Its moisture content is not more than 1.0 percent. It contains per gram not less than 3 milligrams of streptomycin and not less than 5 milligrams of erythromycin. The streptomycin used conforms to the requirements of § 444.70a(a)(1) of this chapter, except paragraph (a)(1)(ii), (iii), (iv), and (v) of that section. The erythromycin used is produced by the growth of *Streptomyces erythreus*, has a potency of not less than 850 micrograms per milligram (on the anhydrous basis), has a moisture content of not more than 10 percent, its pH in a saturated aqueous solution is not less than 8 and not more than 10.5, and it gives a characteristic color test with acetone and hydrochloric acid. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* Streptomycin-erythromycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of milligrams of streptomycin and the number of milligrams of erythromycin in each gram or milliliter of the batch.

(*c*) If it contains one or more sulfonamides, the name and quantity of each such ingredient in each gram or milliliter of the batch.

(*d*) The statement "For veterinary use only".

(*e*) The statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified except that the blank may be filled in with the date which is 18 months, 24 months, or 36 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assay showing that after having been stored for such period of time, such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if it contains a single dose and it is packaged in an individual wrapper or container.

(ii) On the label and labeling, if it contains one or more sulfonamides, after the name "streptomycin-erythromycin ointment", wherever it appears, the words "with sulfonamide(s)", in juxtaposition with such name.

(iii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) *Requests for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the dates on which the latest assays of the streptomycin and erythromycin used in making such batch were completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Potency and moisture.

(*b*) The streptomycin and erythromycin used in making the batch: Potency, pH, moisture, and color-identity test, if it is erythromycin.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(*b*) The streptomycin used in making the batch: 6 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 444.70a(a)(2) of this chapter.

(*c*) The erythromycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(*d*) In case of an initial request for certification, the ingredients used in making the ointment base of the batch: 1 package of each, containing approximately 200 grams, except for the suspending or dispersing agents and sulfonamides used, in which case the sample shall consist of approximately 5 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(*b*) of this section, and no samples referred to in paragraph (a)(4)(iii)(*b*) and (*c*) of this section, is required if such result or samples have been previously submitted.

(b) *Tests and methods of assay*—(1) *Ointment*—(i) *Potency*—(*a*) *Streptomycin content.* Proceed as directed in § 444.70a(b) (1) (i) through (ix) of this chapter, except prepare the sample as follows: Place a representative quantity of the ointment (usually an entire container) in a blending jar containing approximately 225 milliliters of chloroform. Using a high-speed blender, blend the mixture for 3 minutes. Transfer the blended material to a large Buchner funnel (at least 10 centimeters in diameter) fitted with a highly retentive filter paper and attached to a vacuum line. Apply vacuum long enough to insure removal of chloroform from the filter cake. Place the filter cake and the paper in a blending jar containing 250 milliliters of 0.1 *M* phosphate buffer, pH 8.0, and blend for 10 minutes. Filter the blended material through a fast, porous, filter paper. Dilute the filtrate to obtain a solution for assay containing 1.0 microgram per milliliter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(*b*) *Erythromycin content*—(*1*) *cylinders* (*cups*). Use cylinders described under § 440.80a(b) (1) (i) of this chapter.

(2) *Culture media.* Prepare the culture media for the base and seed layers and for carrying the test organism as directed in § 440.80a(b) (1) (ii) (*a*) of this chapter, except for the base and seed layers adjust the media to pH 8.0 after sterilization. Make the nutrient broth for preparing an inoculum of the test organism as directed in § 440.80a(b(1) (ii) (*c*) of this chapter.

(*3*) *Working standard.* Keep the working standard (obtained from the U.S.P. Reference Standards Committee, 46 Park Avenue, New York 16, N.Y.) at refrigeration in tightly stoppered vials, which in turn are kept in larger stoppered vials containing a suitable desiccant. Dry 30 milligrams to 50 milligrams of the standard as described in § 440.80a (b) (5) (i) of this chapter. Dissolve the weight of dry working standard in sufficient methyl alcohol to give a concentration of 10,000 micrograms per milliliter. Further dilute with 0.1 *M* potassium phosphate buffer, pH 7.8 to 8.0, to give a stock solution of 1,000 micrograms per milliliter. This stock solution may be kept under refrigeration for 1 week.

(*4*) *Standard curve.* Using the working-standard stock solution, prepare a standard curve as directed in § 444.70a (b) (1) (iv) of this chapter.

(*5*) *Preparation of spore suspension.* The test organism is *Sarcina lutea* ATCC 9341.[1] Maintain the test organism on slants of nutrient agar described in paragraph (b) (1) (i) (*b*) (2) of this section and transfer to a fresh agar slant once a week. Prepare a suspension of the test organism as follows: Streak an agar slant heavily with the test organism. Wash the growth off in about 3 milliliters of nutrient broth described in paragraph (b) (1) (i) (*b*) (2) of this section. Use the suspension so obtained to inoculate the surface of a Roux bottle containing 300 milliliters of the nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash the growth from the agar surface with 20 milliliters of nutrient broth described in paragraph (b) (1) (i) (*b*) (2) of this section. If an aliquot of this bulk suspension, when diluted with nutrient broth 1:10, gives a 10-percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6,500 Angstrom units, it is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution, so that an aliquot of the adjusted suspension diluted 1:10 gives 10-percent light transmission. (The adjusted bulk suspension only, and not the 1:10 dilution of it, is used in preparing the seed layer.) The bulk suspension may be used in the test for 2 weeks. Add 0.3 milliliter of the adjusted bulk suspension to 100 milliliters of agar described in paragraph (b) (1) (i) (*b*) (2) of this section, which has been melted and cooled to 48° C.

(*6*) *Preparation of plates.* Add 21 milliliters of the agar prepared in paragraph (b) (1) (i) (*b*) (2) of this section to each Petri dish (20 mm. x 100 mm.). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Add 4.0 milliliters of the inoculum prepared under paragraph (b) (1) (i) (*b*) (*5*) of this section to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(*7*) *Assay.* Place a representative quantity of the ointment (usually an entire container) in a blending jar and add sufficient methyl alcohol to give a volume of approximately 100 milliliters. Using a high-speed blender, blend the mixture for 2 to 3 minutes. Add 400 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0, and blend for 2 to 3 minutes. Dilute the mixture to 1.0 microgram per milliliter (estimated) using 0.1 *M* potassium phosphate buffer, pH 8.0, and proceed as directed in § 444.70a(b) (1) (viii) and (ix) of this chapter, except that the incubation temperature is 32° C. to 35° C. The sample may also be prepared by placing a representative quantity of the ointment in a 1,000 milliliter volumetric flask. Add 50 milliliters of ethyl ether and shake until dissolved. Add approximately 200 milliliters of methyl alcohol and bring to the 1,000 milliliter mark using distilled water. Dilute the mixture to 1.0 microgram per milliliter (estimated), using 0.1 *M* potassium phosphate buffer, pH 8.0, and proceed as directed in § 444.70a(b) (1) (viii) and (ix) of this chapter, except that the incubation temperature is 32° C. to 35° C. Its content of erythromycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(ii) *Moisture.* Proceed as directed in § 436.500(c) of this chapter.

(2) *Erythromycin used in making the ointment*—(i) *Moisture.* Proceed as directed in § 440.74a(b) (5) of this chapter. Use the value obtained to calculate the weighed samples used in this paragraph.

(ii) *Potency.* Proceed as directed in paragraph (b) (1) (i) (*b*) of this section, except in the preparation of the solution of the sample dissolve 40 milligrams (as the anhydrous compound) in a small amount of methyl alcohol and then further dilute in 0.10 *M* potassium phosphate buffer, pH 8.0, to make a solution containing 1.0 microgram per milliliter (estimated).

(iii) *Toxicity.* Proceed as directed in § 436.33 of this chapter.

(iv) *pH.* Using a saturated aqueous solution (100 milligrams per milliliter), proceed as directed in § 440.80a(b) (5) (ii) of this chapter.

(v) *Color-identity test.* Dissolve about 3 milligrams of the sample in 2 milliliters of acetone and add an equal volume of concentrated hydrochloric acid. A rapid color development takes place beginning with orange, changing to red, and finally resulting in a deep purple. Shake with 2 milliliters of chloroform. A portion of the purple color extracts into the chloroform layer.

§ 544.373 Streptomycin/dihydrostreptomycin ophthalmic and topical dosage forms.

§ 544.373a Streptomycin/dihydrostreptomycin ointment.

(a) *Requirements for certification*—(1) The requirements for certification for streptomycin ointment and dihydrostreptomycin ointment are described under § 444.570a(a) of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use, its label and labeling shall comply with the requirements prescribed by § 444.570a(a) (3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for streptomycin ointment and dihydrostreptomycin ointment are described under § 444.570a (b) of this chapter.

§ 544.373b Streptomycin / dihydrostreptomycin - polymyxin - neomycin ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin-polymyxin-neomycin ointment and dihydrostreptomycin-polymyxin-neomycin ointment are streptomycin or dihydrostreptomycin, polymyxin, and neomycin in a suitable and harmless ointment base, with or without one or more suitable sulfonamides, and with or without suitable and harmless dispersing and suspending agents. Their moisture content is not more than 1 percent. Their potency is such that when used as directed in their

[1] Available from: American Type Culture Collection, 12301 Parklawn Dr., Rockville, MD 20852.

labeling each dose shall contain not less than 250 milligrams of streptomycin or dihydrostreptomycin, 100,000 units of polymyxin B, and 150 milligrams of neomycin. The streptomycin used conforms to the requirements of § 444.70a (a) (1) of this chapter, except paragraph (a) (1) (ii), (iii), (iv), and (x). The dihydrostreptomycin used conforms to the requirements of § 444.10a(a) of this chapter, except the standards for sterility, toxicity, pyrogens, and histamine. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 444.170a(a) (1) of this chapter, except the standard for toxicity. The neomycin used conforms to the standards prescribed by § 444.42a(a) (1) (i), (v) and (vi) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* Each batch of ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of milligrams of streptomycin or dihydrostreptomycin, the number of milligrams of neomycin, and the number of units of polymyxin B in each gram of the batch.

(*c*) If the batch contains one or more sulfonamides, the name and quantity of each such ingredient per gram of the batch.

(*d*) The statement "For veterinary use only".

(*e*) The statement "Expiration date _____", the blank being filled in with the date that is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if it contains a single dose and it is packaged in an individual wrapper or container.

(ii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) *Requests for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the dates on which the latest assays of the streptomycin or dihydrostreptomycin, polymyxin B, in neomycin used in making such batch were completed; the quantity of each such ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of;

(*a*) The batch: Potency and moisture.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch: Potency, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(*c*) The polymyxin B used in making the batch: Potency.

(*d*) The neomycin used in making the batch: Potency, moisture, and pH.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 7 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(*b*) The streptomycin or dihydrostreptomycin used in making the batch: 6 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 444.70a(a) (2) of this chapter.

(*c*) The polymyxin B used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(*d*) The neomycin used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(*e*) In case of an initial request for certification, the ingredients used in making the batch: 1 package of each ointment-base ingredient, containing approximately 200 grams; 1 package of each suspending or dispersing agent used, containing approximately 5 grams; 1 package of each sulfonamide used, containing approximately 5 grams.

(iv) The results referred to in paragraph (a) (4) (ii) (*b*), (*c*), and (*d*) of this section and the samples referred to in paragraph (a) (4) (iii) (*b*), (*c*), and (*d*) of this section are not required if such results or samples have been previously submitted.

(b) *Tests and methods of assay*— (1) *Potency*—(i) *Streptomycin content.* Proceed as directed in § 444.70a(b) (1) (i) through (ix) of this chapter, inclusive, except prepare the sample in one of the following ways:

(*a*) *Extraction.* Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add a 20-milliliter portion of 0.1 *M* potassium phosphate buffer, pH 8.0, and shake well. Remove the buffer layer and repeat the extraction with 20-milliliter portions of buffer at least three times and any additional times that may be necessary to insure complete extraction of the antibiotic. Combine the extractives and make the appropriate estimated dilutions in 0.1 *M* potassium phosphate buffer, pH 8.0.

(*b*) *Blending.* Place a convenient sized representative quantity of the sample in a blending jar containing 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to give a volume of 200 milliliters. Using a high-speed blender, blend for 2 minutes and then make the appropriate estimated dilutions with buffer. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(ii) *Dihydrostreptomycin content.* Proceed as directed in paragraph (b) (1) of this section, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(iii) *Polymyxin content.* Proceed as directed in § 444.170a(b) (2) (i) of this chapter with the following exceptions:

(*a*) In lieu of the directions for the preparation of the sample described in paragraph (b) (2) (i) (*g*) of § 444.170a of this chapter, prepare the sample as follows: Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 25 milliliters of 10-percent potassium phosphate buffer, pH 6.0, containing 2 grams of K_2HPO_4 and 8 grams of KH_2PO_4 in each 100 milliliters, and shake. Remove the buffer layer and repeat the extraction with 25-milliliter portions of buffer at least three times and any additional times that may be necessary to insure complete extraction of the antibiotic. Combine the extractives and make the proper estimated dilutions in 10-percent potassium phosphate buffer pH 6.0, to give a concentration of 10 units per milliliter (estimated). If the sample contains a water-soluble base, accurately weigh a representative sample and place in a blending jar containing 1 milliliter of polysorbate 80 and sufficient 10 percent potassium phosphate buffer, pH 6.0, to give a final volume of 200 milliliters.

Use a high-speed blender and blend the mixture for 2 minutes. Make the proper estimated dilutions, using 10 percent potassium phosphate buffer, pH 6.0.

(*b*) The standard curve is prepared in the following concentrations: 6.4, 8.0, 10.0, 12.5, and 15.6 units per milliliter in 10 percent potassium phosphate buffer, pH 6.0. The 10 units per milliliter concentration is used as the reference point. Calculate from the quantity of neomycin found (using the method described in paraglaph (b)(1)(iv) of this section), the quantity of neomycin that would be present when the sample is diluted to contain 10 units of polymyxin (labeled potency) per milliliter. Prepare the polymyxin standard curve by adding the calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use the standard curve to calculate the polymyxin content. Its content of polymyxin is satifsactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(iv) *Neomycin content.* Proceed as directed in § 436.517(b)(1) of this chapter, with the following exceptions:

(*a*) In lieu of the directions for the preparation of the sample described in § 436.517(b)(1)(vii) of this chapter, prepare the sample as directed in paragraph (b)(1)(i)(*a*) of this section or by a blending technique as follows: Place a convenient sized representative quantity of the sample in a blending jar containing 1.0 milliliter of a 0.3-percent aqueous solution of dioctyl sodium sulfosuccinate and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to give a volume of 200 milliliters. Using a high-speed blender, blend for 5 minutes and then make the appropriate estimated dilutions with buffer.

(*b*) Use as the test organism the Food and Drug Administration dihydrostreptomycin- (and streptomycin-) resistant strain of *Staphylococcus aureus* (American Type Culture Collection 6538-PR)[1] which is grown and maintained on media containing 1,000 micrograms of dihydrostreptomycin per milliliter of agar. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 540.380a(b)(2) of this chapter.

Subpart D—Otic Dosage Forms

§ 544.473 Streptomycin/dihydrostreptomycin otic with antifungal agent.

(a) *Requirements for certification*—(1) The requirements for certification for streptomycin otic with antifungal agent; streptomycin otic with _____; dihydrostreptomycin otic with antifungal agent; dihydrostreptomycin otic with _____ (the blank being filled in with the established name of the antifungal agent), are described under § 444.470a(a) of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 444.470a(a)(3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for streptomycin otic with antifungal agent and dihydrostreptomycin otic with antifungal agent are described under § 444.470a(b) of this chapter.

Subparts E–H [Reserved]

Subpart I—Certain Other Dosage Forms

§ 544.973b Streptomycin / dihydrostreptomycin solution for inhalation therapy.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Streptomycin solution for inhalation therapy and dihydrostreptomycin solution for inhalation therapy is a suitable and harmless aqueous-organic solution of streptomycin or dihydrostreptomycin, with or without suitable and harmless preservatives, colorings, volatile oils, flavorings, buffer substances, and stabilizing agents. Its potency is not less than 50 milligrams per milliliter. Its pH is not less than 5.0 and not more than 8.0. The streptomycin or dihydrostreptomycin used conforms to the standards prescribed by § 444.10a(a)(1) of this chapter or § 444.70a(a)(1) of this chapter, except the standards for sterility, pyrogens, and histamine, or to the standards prescribed by § 539.170(a)(1). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefore in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(*c*) The statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified.

(*d*) The name and quantity of each preservative used.

(*e*) The statement "For veterinary use only".

(*f*) The statement "Warning—Not for use in animals which are raised for food production".

(4) *Requests for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch and the number of milligrams of streptomycin or dihydrostreptomycin per milliliter in the batch. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency and pH.

(ii) Such person shall also submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers.

(*b*) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 444.70a(b)(1) of this chapter, except that if it contains dihydrostreptomycin use the dihydrostreptomycin working standard as the standard of comparison. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams per milliliter that it is represented to contain.

(2) *pH.* Proceed as directed in § 440.80a(b)(5)(ii) of this chapter, using the undiluted drug.

PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

Subpart A—Oral Dosage Forms

Sec.

546.110 Chlortetracycline oral dosage forms.
546.110a Crude chlortetracycline.
546.110b Chlortetracycline seed.
546.110c Chlortetracycline powder (chlortetracycline hydrochloride powder).
546.110d Chlortetracycline hydrochloride tablets.
546.110e Chlortetracycline - sulfamethazine tablets.
546.110f Chlortetracycline hydrochloride-neomycin tablets.
546.110g Chlortetracycline hydrochloride in oil oral.
546.113 Chlortetracycline bisulfate oral dosage forms.
546.113a Chlortetracycline bisulfate soluble powder.
546.113b Chlortetracycline bisulfate-sulfamethazine bisulfate soluble powder.
546.180 Tetracycline oral dosage forms.
546.180a Tetracycline hydrochloride capsules.
546.180b Tetracycline tablets.
546.180c Tetracycline boluses.
546.180d Tetracycline soluble powder.
546.180e Tetracycline oral liquid.
546.180f Tetracycline oral suspension.

[1] Available from: American Type Culture Collection, 12301 Parklawn Dr., Rockville, MD 20852.

Subpart B—[Reserved]

Subpart C—Ophthalmic and Topical Dosage Forms

Sec.
546.312 Chlortetracycline/tetracycline ophthalmic and topical dosage forms.
546.312a Chlortetracycline - neomycin-streptomycin / dihydrostreptomycin ointment; tetracycline hydrochloride-neomycin - streptomycin/dihydrostreptomycin ointment.
546.312b Chlortetracycline/ chlortetracycline hydrochloride/tetracycline hydrochloride ophthalmic.
546.381 Tetracycline hydrochloride ophthalmic and topical dosage forms.
546.381a Tetracycline hydrochloride-neomycin topical spray ointment.
546.381b Tetracycline hydrochloride-neomycin in oil suspension.

Subpart D—Otic Dosage Forms

546.481 Tetracycline hydrochloride otic.

Subparts E–F—[Reserved]

Subpart G—Rectal Dosage Forms

546.713 Chlortetracycline/chlortetracycline hydrochloride/tetracycline hydrochloride suppositories.

AUTHORITY: Secs. 507, 512, 59 Stat. 463 as amended; 82 Stat. 343–351 (21 U.S.C. 357, 360b).

Subpart A—Oral Dosage Forms

§ 546.110 Chlortetracycline oral dosage forms.

§ 546.110a Crude chlortetracycline.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Crude chlortetracycline oral is crude chlortetracycline with suitable and harmless diluents, with or without buffer substances and suspending and dispersing agents (and with or without one or more essential vitamins and mineral substances for nutritive purposes). It contains not less than 2 grams of chlortetracycline activity per pound, except it shall contain 100 grams of chlortetracycline activity per pound if it is intended for use in the treatment of psittacosis in psittacine birds (parrots, macaws, and cockatoos). Its moisture content is not more than 6 percent.

(2) *Packaging.* In all cases the immediate container shall be a well-closed container as defined by the U.S.P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not more than 100 pounds.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of grams of chlortetracycline in each pound of the batch.

(*c*) The statement "For oral veterinary use only" and if it is intended for use in the treatment of psittacosis in psittacine birds, a statement to the effect that wet mashes prepared with the drug should be discarded after 24 hours.

(*d*) The statement "Expiration date _____", the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(ii) On the circular or other labeling within or attached to the package:

(*a*) Adequate directions and warnings for the veterinary use of such drug by the laity.

(*b*) If it is intended for use in animals raised for food production, labeling in accordance with the requirements of regulations in Parts 121 and 558 of this chapter.

(4) *Request for certification; samples.* (i) In addition to complying with § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of grams of chlortetracycline in each pound of the batch, and the quantity of each other ingredient used in making the batch, and the date on which the latest assay of the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for average potency and average moisture.

(ii) Such person shall submit in connection with his request a sample of the batch consisting of 1 ounce for each 3,000 pounds in the batch, but in no case less than five 1-ounce portions, collected by taking single 1-ounce portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay—*(1) *Potency.* Accurately weigh approximately 3.0 grams of the sample and place in a blending jar containing 200 milliliters of an acid-acetone solution prepared with 1 part 4 *N* HCl, 6 parts distilled water, and 13 parts acetone. Blend for 3 minutes. Using an aliquot of the liquid, make the proper estimated dilutions in *M*/10 monopotassium phosphate buffer pH 4.5, shake well, and proceed as directed in § 446.10a(b)(1)(viii) of this chapter. Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of grams that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 546.110b Chlortetracycline seed.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Chlortetracycline seed is dehulled millet seed containing chlortetracycline. It contains 0.5 milligram of chlortetracyline per gram. Its moisture content is not more than 10 percent. The chlortetracycline used conforms to the requirements prescribed therefor by § 446.10(a)(1) of this chapter, except paragraph (a)(1)(ii), (iv), and (v) of that section, or to the requirements prescribed by § 446.510b(a)(1). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate container shall be a well closed container as defined by the U.S.P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of milligrams of chlortetracycline in each gram of the batch.

(*c*) The statement "For oral veterinary use only".

(*d*) The statement "Expiration date _____", the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(ii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracyline used in making such batch was completed, the number of milligrams in each immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following,

made by him on an accurately representative sample of:

(*a*) The batch: Potency and moisture.

(*b*) The chlortetracycline used in making the batch: Potency, toxicity, moisture, pH, and crystallinity.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: One container for each 5,000 containers in the batch, but in no case less than five immediate containers. Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time the containers are being filled that the quantities filled during the intervals are approximately equal.

(*b*) The chlortetracycline used in making the batch: 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 446.10(a) (2) of this chapter.

(c) In case of an initial request for certification, each other ingredient used in making the batch: One package of each, containing approximately 5 grams.

(iv) The results referred to in paragraph (a) (4) (ii) (*b*) of this section and the sample referred to in paragraph (a) (4) (iii) (*b*) of this section are not required if such results or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Accurately weigh approximately 10 grams of the sample and place in a blending jar containing 500 milliliters of 0.01 *N* HCl. Blend for 3 minutes. Using an aliquot of the liquid, make the proper estimated dilutions in 10 *M* monopotassium phosphate buffer, pH 4.5, shake well, and proceed as directed in § 446.10a(b) (1) (viii) of this chapter. Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

§ 546.110c Chlortetracycline powder (chlortetracycline hydrochloride powder).

(a) *Requirements for certification.* The requirements for certification for chlortetracylcine powder (chlortetracycline hydrochloride powder); tetracycline hydrochloride powder; tetracycline powder, are described under § 446.510b of this chapter, with the following exceptions:

(1) Standards of identity, strength, quality, and purity: It may contain one or more suitable and harmless vitamin substances.

(2) It is packaged for dispensing and intended solely for veterinary use: Its label and labeling shall comply with all the requirements prescribed by § 446.510b (a) (3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drugs by the laity.

(3) If it is intended for use in animals raised for food production, it shall also be labeled in accordance with the requirements of paragraph (c) of this section.

(b) *Tests and methods of assay*—The tests and methods of assay for chlortetracycline powder (chlortetracycline hydrochloride powder), tetracycline hydrochloride powder, and tetracycline powder, are described under § 446.510b of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Meets the requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(3) *Special considerations.* The quantities of antibiotic in paragraph (c) (5) of this section refer to the activity of the master standard.

(4) *Related tolerances.* See § 556.150 of this chapter.

(5) *Conditions of use.* (i) It is used in drinking water as follows:

(*a*) *Chickens.* Used as chlortetracycline hydrochloride or chlortetracycline bisulfate as follows:

(*1*) *Amount per gallon.* 100 milligrams.

(*i*) *Indications for use.* Prevention of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).

(*ii*) *Limitations.* Not to be used for more than 14 consecutive days; as sole source of chlortetracycline.

(*2*) *Amount per gallon.* 200 milligrams.

(*i*) *Indications for use.* Treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.

(*ii*) *Limitations.* Not to be used for more than 14 consecutive days; as sole source of chlortetracycline.

(*b*) *Growing chickens.* Used as chlortetracycline hydrochloride or chlortetracycline bisulfate as follows:

(*1*) *Amount per gallon.* 1,000 milligrams.

(*2*) *Indications for use.* Aid in the control of mortality due to fowl cholera.

(*3*) *Limitations.* Not for laying chickens; not to be used for more than 14 consecutive days; withdraw 24 hours prior to slaughter; as sole source of chlortetracycline.

(c) *Chickens and turkeys.* Used as chlortetracycline hydrochloride or chlortetracycline bisulfate as follows:

(*1*) *Amount per gallon.* 400 milligrams.

(*2*) *Indications for use.* Control of synovitis.

(*3*) *Limitations.* Not for laying chickens; not to be used for more than 14 consecutive days; as sole source of chlortetracycline.

(*d*) *Turkeys.* Used as chlortetracycline hydrochloride or chlortetracycline bisulfate as follows:

(*1*) *Amount per gallon.* 100 milligrams.

(*i*) *Indications for use.* Prevention of blue comb (nonspecific infectious enteritis, mud fever), infectious sinusitis, hexamitiasis.

(*ii*) *Limitations.* Not to be used for more than 14 consecutive days; as sole source of chlortetracycline.

(*2*) *Amount per gallon.* 200 milligrams.

(*i*) *Indications for use.* Treatment of blue comb (nonspecific infectious enteritis, mud fever), infectious sinusitis, hexamitiasis; prevention of synovitis.

(*ii*) *Limitations.* Not to be used for more than 14 consecutive days; as sole source of chlortetracycline.

(e) *Swine.* Used as chlortetracycline hydrochloride as follows:

(*1*) *Amount per gallon.* 100 to 200 milligrams.

(*i*) *Indications for use.* As an aid in prevention of bacterial enteritis.

(*ii*) *Limitations.* Administer for not more than 46 days; do not slaughter animals for food within 24 hours of treatment; prepare a fresh solution daily; as sole source of chlortetracycline.

(*2*) *Amount per gallon.* 200 to 400 milligrams.

(*i*) *Indications for use.* As an aid in prevention of bacterial pneumonia; for treatment of bacterial enteritis.

(*ii*) *Limitations.* Administer for not more than 46 days; do not slaughter animals for food within 24 hours of treatment; prepare a fresh solution daily; as sole source of chlortetracycline.

(*3*) *Amount per gallon.* 400 to 600 milligrams.

(*i*) *Indications for use.* For treatment of bacterial pneumonia.

(*ii*) *Limitations.* Administer for not more than 24 days; do not slaughter animals for food within 24 hours of treatment; prepare a fresh solution daily; as sole source of chlortetracycline.

(ii) It is used as chlortetracycline hydrochloride as a drench for calves as follows:

(*a*) *Amount.* Two milligrams per pound of body weight.

(*b*) *Indications for use.* For treatment of bacterial pneumonia, bacterial diarrhea, and shipping fever.

(*c*) *Limitations.* Administer 2 milligrams per pound of body weight per day for not more than 5 days; do not slaughter animals for food within 3 days of treatment; prepare a fresh solution daily; as sole source of chlortetracycline.

§ 546.110d Chlortetracycline hydrochloride tablets.

(a) *Requirements for certification*—(1) The requirements for certification for chlortetracycline hydrochloride tablets; tetracycline hydrochloride tablets; tetracycline tablets, are described under § 446.110a of this chapter.

(2) Exemption of chlortetracycline hydrochloride tablets from certification: Chlortetracycline hydrochloride tablets that conform to the requirements of § 446.110a(a) (1) of this chapter (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes; and the chlortetracyline hydrochloride used in making the tablets may conform to § 546.110a(a) (1) shall be exempt from the certification requirements of section 512(n) of the act, if they comply with all the following conditions:

(i) If the drug contains added vitamins or minerals, its label bears the name and quantity of each such substances and a statement that such substances are present only for furnishing additional vitamins and minerals while the birds are eating less feed.

(ii) The labels bear an expiration date that is not more than 24 months after the month during which the batch was last assayed and released by the manufacturer.

(iii) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(iv) The circular or other labeling within or attached to the package bears information that only the antibiotic is intended for use in the prevention or treatment of the following conditions of parakeets and canaries, due to organisms sensitive to chlortetracycline, and further, bears directions and warnings adequate for such uses:

(*a*) Respiratory disease, bacterial (pneumonia, bronchitis, rhinitis).

(*b*) Infectious arthritis due to a filterable agent.

(*c*) Bacterial enteritis.

(*d*) Stimulate food intake, growth, and to maintain body weight.

(*e*) When intended for use in the conditions set forth in paragraph (a) (2) (iv) (*a*), (*b*), and (*c*) of this section, the potency must be such, that when used as directed in the labeling, each ounce of drinking water contains not less than 25 milligrams of chlortetracycline.

(*f*) When intended for use in the conditions set forth in paragraph (a) (2) (iv) (*d*) of this section, the potency must be such, that when used as directed in the labeling, each ounce of drinking water contains not less than 5.0 milligrams of chlortetracycline.

(b) *Tests and methods of assay.* The tests and methods of assay for chlortetracycline tablets (chlortetracycline hydrochloride tablets), tetracycline hydrochloride tablets, and tetracycline tablets, are described under § 446.110a except for the moisture test required under paragraph (b) (2), if it is tetracycline hydrochloride tablets and stability data have been submitted to prove that the drug is stable when it contains not more than 60 percent moisture, use the method described in § 436.201 of this chapter and proceed as directed in § 436.201(e) (3) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Meets the requirements of paragraphs (a) and (b) of this section.

(2) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(3) *Special considerations.* The quantities of antibiotic in paragraph (c) (5) of this section refer to the activity of the master standard.

(4) *Related tolerances.* See § 556.150 of this chapter.

(5) *Conditions of use.* It is used as chlortetracycline hydrochloride in tablets for oral ingestion by calves as follows:

(i) *Amount.* 250 milligrams per tablet.

(*a*) *Indications for use.* Treatment of bacterial scours in calves.

(*b*) *Limitations.* As sole source of chlortetracycline; 250 milligrams per 100 pounds of animal weight per day for 3 days; do not administer within 24 hours of slaughter.

(ii) *Amount.* 250 milligrams per tablet.

(*a*) *Indications for use.* Prevention of bacterial scours in newborn calves.

(*b*) *Limitations.* As sole source of chlortetracycline; 250 milligrams per animal per day for not more than 3 days; do not administer within 24 hours of slaughter.

(iii) *Amount.* 25 milligrams per tablet.

(*a*) *Indications for use.* Aid in reduction of incidence of bacterial scours in calves.

(*b*) *Limitations.* 75 milligrams per animal per day.

§ 546.110e Chlortetracycline-sulfamethazine tablets.

(a) *Requirements for certification.* The requirements for chlortetracycline-sulfamethazine tablets are described under § 546.110d(a).

(b) *Tests and methods of assay.* The tests and methods of assay for chlortetracycline-sulfamethazine tablets are described under § 546.110d(b).

(c) *Conditions of marketing*—(1) *Chemical name.* Sulfamethazine: *N'*-(4,6-Dimethyl-2-pyrimidinyl) sulfanilamide.

(2) *Specifications.* Meets the requirements of § 546.110d as it regards chlotetracycline hydrochloride tablets and of § 546.113a.

(3) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(4) *Special considerations.* The qualities of antibiotic in paragraph (c) (6) of this section refer to the activity of the master standard.

(5) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(6) *Conditions of use.* It is used in tablets for oral ingestion by calves as follows:

(i) *Amount.* 125 milligrams of chlortetracycline with 2.5 grams of sulfamethazine per tablet.

(ii) *Indications for use.* Treatment of bacterial scours in calves.

(iii) *Limitations.* 125 milligrams of chlortetracycline with 2.5 grams of sulfamethazine per 100 pounds of animal weight per day for 3 days; do not administer within 5 days of slaughter for food; as chlortetracycline hydrochloride; as sole source of chlortetracycline and sulfamethazine.

§ 546.110f Chlortetracycline hydrochloride-neomycin tablets.

(a) *Requirements for certification.* Chlortetracycline hydrochloride-neomycin tablets and tetracycline hydrochloride-neomycin tablets are tablets that conform to all requirements and are subject to all procedures prescribed by § 446.110b(a) of this chapter for chlortetracycline hydrochloride capsules and tetracycline hydrochloride capsules, except that:

(1) Each tablet shall contain not less than 125 milligrams of neomycin. The neomycin used conforms to the standards prescribed by § 444.42a(a) (1) (i), (iv), (v), and (vi) of this chapter. Tablets not exceeding 15 millimeters in diameter, or not intended only for preparing solutions, shall disintegrate within 1 hour.

(2) If it is intended for use in animals which are raised for food production, it shall also be labeled in accordance with the requirements of paragraph (c) of this section.

(3) In addition to complying with the requirements of § 446.110b(a) (4) of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the number of milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride and neomycin in each tablet of the batch, the batch mark, and, if required by paragraph (a) (1) of this section, disintegration time, and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request (unless it was previously submitted) a sample consisting of 5 packages contining approximately equal portions of not less than 0.5 gram each of the neomycin used in making the batch, and a sample of 6 tablets for disintegration-time studies.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Chlortetracycline hydrochloride content.* Prepare the sample as follows: Using a mortar and pestle, grind 5 tablets to a fine powder. Using 200 milliliters of absolute methyl alcohol, quantitatively transfer the powder to a blending jar and blend at high speed for 2 minutes. Centrifuge a portion of the liquid at high speed for sufficient time (usually 15 minutes) to obtain a substantially clear solution. Dilute an aliquot of the clear solution in sufficient 0.10 *M* monobasic potassium phosphate buffer, pH 4.5, to give a concentration of 0.06 microgram per milliliter (estimated). Proceed as directed in § 446.10a(b) (1) (viii) of this chapter. Its content of chlortetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per tablet that it is represented to contain.

(ii) *Tetracycline hydrochloride content.* Prepare the sample as directed in paragraph (b) (1) (i) of this section, except dilute the sample to an estimated concentration of 0.24 microgram per milliliter and proceed as directed in § 446.81a(b) (1) (iii) of this chapter. Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per tablet that it is represented to contain.

(iii) *Neomycin content.* Proceed as directed in § 436.517(a) (1) (ii) of this chapter if *Staphylococcus epidermidis* is used as the test organism. If *Staphylococcus aureus* is used as the test organism proceed as follows: Immedi-

ately after the second blending, heat a convenient size aliquot of the blend in a steam bath for 30 minutes, cool, and dilute to 10 micrograms per milliliter (estimated). Its content of neomycin is satisfactory if it contains 85 percent of the number of milligrams of activity per tablet that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 444.180a(b)(3) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Meets the requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(3) *Special considerations.* The quantities of antibiotics in paragraph (c)(5) of this section refer to the activity of the master standard.

(4) *Related tolerances.* See §§ 556.150 and 556.430 of this chapter.

(5) *Conditions of use.* It is used in tablets for oral ingestion by calves as follows:

(i) *Amount.* 125 milligrams of chlortetracycline with 125 milligrams of neomycin per tablet.

(ii) *Indications for use.* Treatment of bacterial scours in calves.

(iii) *Limitations.* 125 milligrams of neomycin and of chlortetracycline per 100 pounds of animal weight per day for 3 days; do not administer within 24 hours of slaughter; as chlortetracycline hydrochloride and neomycin sulfate; as sole source of chlortetracycline and neomycin.

§ 546.110g Chlortetracycline hydrochloride in oil oral.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chlortetracycline hydrochloride in oil oral is crystalline chlortetracycline hydrochloride in a suitable and harmless vegetable oil base. It contains not less than 50 milligrams of chlortetracycline hydrochloride per milliliter. Its moisture content is not more than 1.0 percent. The chlortetracycline hydrochloride used conforms to the requirements of § 446.10(a)(1) of this chapter, except paragraph (a)(1)(ii), (iv), and (v) of that section. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* The immediate containers shall be well closed or tight containers as defined by the U.S.P. They shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good marketing, storage, and distribution practice shall be disregarded. Unless it is packaged for repacking, each such container shall be filled with a volume of chlortetracycline hydrochloride in oil in excess of that designated, which excess shall be sufficent to permit the withdrawal and the administration of the volume indicated, whether administered in single or multiple doses.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated:

(i) On the outside wrapper or container and the immediate container of the package:

(*a*) The batch mark.

(*b*) The number of milligrams of chlortetracycline hydrochloride per milliliter.

(*c*) The statement "Expiration date ----------", the blank being filled in wit hthe date that is 24 month, 36 months, or 48 months after the month during which the batch was certified.

(*d*) The statement "For oral use in suckling pigs only."

(ii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline hydrochloride used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug was completed, and a statement that each component of the oil base used conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Potency and moisture.

(*b*) The chlortetracycline hydrochloride used in making the batch: Potency, toxicity, moisture, pH, and crystallinity.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following.

(*a*) The batch: 1 package for each 5,000 packages in the batch, but in no case less than 5 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(*b*) The chlortetracycline used in making the batch: 10 packages, containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 466.10(a)(2) of this chapter.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each component of the oil base, each containing approximately 200 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(*b*) of this section, and no sample referred to in paragraph (a)(4)(iii)(*b*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 446.510a(b)(1) of this chapter. The potency is satisfactory if it contains not less than 85 percent of the number of milligrams of chlortetracycline hydrochloride that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 540.380a(b)(2) of this chapter.

§ 546.113 Chlortetracycline bisulfate oral dosage forms.

§ 546.113a Chlortetracycline bisulfate soluble powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chlortetracycline bisulfate soluble powder is chlortetracycline bisulfate with or without sulfamethazine bisulfate and with or without one or more suitable and harmless colorings, buffer substances, and diluents. It contains the equivalent of 25.6 grams or 102.4 grams of chlortetracycline hydrochloride per pound of powder. If it contains 102.4 grams equivalent of chlortetracycline hydrochloride, it may also contain sulfamethazine bisulfate equivalent to 102.4 grams of sulfamethazine. The moisture content is not more than 2 percent. The chlortetracycline bisulfate used conforms to the requirements of § 539.210d of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases, the immediate container shall be a tight container as defined by the U.S.P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of grams of chlortetracycline hydrochloride equivalent per pound and, if it contains sulfamethazine bisulfate, the number of grams of sulfamethazine equivalent per pounds in the immediate container.

(*c*) The number of pounds of powder in each immediate container.

(*d*) [Reserved]

(*e*) The statement "Expiration date ----------", the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 24, 30, 36, 42, or 48 months after the month during which the batch was certified if the person who

request certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) (1) of this section.

(ii) On the circular or other labeling within or attached to the package:

(*a*) Adequate directions and warnings for the veterinary use of such drug by the laity.

(*b*) If it is intended for use in animals raised for food production, labeling in accordance with the requirements of §546.110c.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline bisulfate used in making such batch was completed, the number of grams of chlortetracycline hydrochloride equivalent per pound, the number of pounds of powder, the number of packages of each size in the batch, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Potency and moisture.

(*b*) The chlortetracycline bisulfate used in making the batch: Potency, toxicity, moisture, butyl alcohol content, sulfate content, absorptivity, and crystallinity.

(iii) Except as otherwise provided by paragraph (a) (4) (iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: One 1-ounce portion for each 5,000 immediate containers in the batch, but in no case less than five 1-ounce portions. Such sample shall be collected by taking single 1-ounce portions at such intervals throughout the entire time the containers are being filled that the quantities filled during the intervals are approximately equal.

(*b*) The chlortetracycline bisulfate used in making the batch: 10 packages, each containing approximately equal portions or not less than 0.5 gram, packaged in accordance with the requirements of § 539.210b(a) of this chapter.

(*c*) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(iv) The result referred to in paragraph (a) (4) (ii) (*b*) of this section, and the sample referred to in paragraph (a) (4) (iii) (*b*) of this section are not required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Using an accurately weighed sample of approximately 500 milligrams, proceed as directed in § 446.10a(b) (1) of this chapter, except § 446.10a(b) (1) (ix) of this chapter. Its potency is satisfactory if it contains not less than 85 percent and not more than 125 percent of the labeled potency.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

§ 546.113b Chlortetracycline bisulfate-sulfamethazine bisulfate soluble powder.

(a) *Requirements for certification.* The requirements for certification for chlortetracycline bisulfate-sulfamethazine bisulfate soluble powder are described under § 546.113a(a).

(b) *Tests and methods of assay.* The tests and methods of assay for chlortetracycline bisulfate-sulfamethazine bisulfate soluble powder are described under § 546.113a(b).

(c) *Conditions of marketing*—(1) *Chemical name.* Sulfamethazine: *N'*-(4,6 - Dimethyl-2-pyrimidinyl) sulfanilamide.

(2) *Specifications.* Meets the requirements of § 546.113a(a).

(3) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(4) *Special considerations.* The quantities of antibiotic in paragraph (c) (6) of this section refer to the activity of the master standard.

(5) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(6) *Conditions of use.* It is used in drinking water of swine as follows:

(i) *Amount.* 250 milligrams of chlortetracycline with 250 milligrams of sulfamethazine per gallon.

(ii) *Indications for use.* Prevention and treatment of bacterial enteritis; aid in the reduction of the incidence of cervical abscesses; aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(iii) *Limitations.* Not to be used for more than 28 consecutive days; withdraw 7 days before slaughter; as sole source of chlortetracycline and sulfonamide.

§ 546.180 Tetracycline oral dosage forms.

§ 546.180a Tetracycline hydrochloride capsules.

(a) *Requirements for certification.* The requirements for certification for tetracycline hydrochloride capsules; tetracycline capsules; tetracycline phosphate complex capsules are described under § 446.110b of this chapter, with the following exceptions:

(1) Standards of identity, strength, quality, and purity: It may contain one or more suitable sulfonamides and harmless vitamin substances. The contents of each capsule shall not be limited to 50 milligrams.

(2) When it is packaged for dispensing and intended solely for veterinary use: Its label and labeling shall bear the statement "Warning—Not for use in animals which are raised for food production" and shall comply with all of the requirements prescribed by § 446.110b(a) (3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without a prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity in all cases except those in which the veterinary prescription statement is required by paragraph (c) of this section. In those cases, the veterinary prescription statement shall comply with the requirements prescribed by § 201.105 of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline hydrochloride capsules, tetracycline capsules, and tetracycline phosphate complex capsules are described under § 446.110b of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Tetracycline capsules conform to the standards of identity, strength, quality, and purity prescribed by paragraph (a) of this section.

(2) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors as listed in paragraph (c) (5) of this section.

(3) *Special considerations.* The quantity of tetracycline in paragraph (c) (5) of this section refers to the activity of tetracycline hydrochloride.

(4) [Reserved]

(5) *Conditions of use.* It is used as tetracycline hydrochloride for dogs as follows:

(i) *Amount.* 250 milligrams per capsule.

(*a*) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(*b*) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See Nos. 000003 and 000009 in § 510.600(c) of this chapter.

(ii) *Amount.* 125, 250, or 500 milligrams per capsule.

(*a*) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(*b*) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See No. 000196 in § 510.600 (c) of this chapter.

(iii) *Amount.* 50, 100, 250, or 500 milligrams per capsule.

(a) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(b) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See No. 000115 in § 510.600(c) of this chapter.

(iv) *Amount.* 50, 100, 125, 250, or 500 milligrams per capsule.

(a) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(b) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See No. 000172 in § 510.600(c) of this chapter.

§ 546.180b Tetracycline tablets.

(a) *Requirements for certification.* The requirements for certification for tetracycline tablets are described under § 546.110d(a).

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline tablets are described under § 546.110d(b).

(c) *Conditions of marketing*—(1) *Specifications.* Tetracycline tablets conform to the standards of identity, strength, quality, and purity prescribed by § 546.110d.

(2) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors as listed in paragraph (c)(5) of this section.

(3) *Special considerations.* The quantity of tetracycline in paragraph (c)(5) of this section refers to the activity of tetracycline hydrochloride.

(4) [Reserved]

(5) *Conditions of use.* It is used as tetracycline hydrochloride in dogs as follows:

(i) *Amount.* 100, 250, or 500 milligrams per tablet.

(ii) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(iii) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Sponsor.* See No. 000196 in § 510.600(c) of this chapter.

§ 546.180c Tetracycline boluses.

(a) *Requirements for certification.* The requirements for certification for tetracycline boluses are described under § 546.110d(a).

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline boluses are described under § 546.110d(b).

(c) *Conditions of marketing*—(1) *Specifications.* Tetracycline boluses conform to the standards of identity, strength, quality, and purity prescribed by § 546.110d of this chapter.

(2) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors as listed in paragraph (c)(5) of this section.

(3) *Special considerations.* The quantity of tetracycline in paragraph (c)(5) of this section refers to the activity of tetracycline hydrochloride.

(4) *Related tolerances.* See § 556.720 of this chapter.

(5) *Conditions of use.* (i) It is used as tetracycline hydrochloride in calves as follows:

(a) *Amount.* 500 milligrams per bolus.

(1) *Indications for use.* For treatment of pneumonia, shipping fever, and pneumonenteritis.

(2) *Limitations.* Administer orally 10 milligrams per pound of body weight per day divided into 2 daily doses for not more than 5 days; do not slaughter animals for food within 12 days of treatment; as sole source of tetracycline; for use by or on the order of a licensed veterinarian.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(b) Amount. 500 milligrams per bolus.

(1) *Indications for use.* For treatment of bacterial pneumonia caused by organisms susceptible to tetracycline, and bacterial enteritis caused by *E. coli* and salmonella organisms susceptible to tetracycline.

(2) *Limitations.* Administer orally 10 milligrams per pound of body weight per day divided into 2 daily doses for not more than 5 days; do not slaughter animals for food within 12 days of treatment; as sole source of tetracycline; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(ii) It is used as tetracycline hydrochloride for sheep as follows:

(a) *Amount.* 500 milligrams per bolus.

(b) *Indications for use.* For treatment of pneumonia, shipping fever, pneumoenteritis complex, and bacterial enteritis (scours).

(c) *Limitations.* Administer orally 10 milligrams per pound of body weight per day divided into 2 daily doses for not more than 4 days; do not slaughter animals for food within 5 days of treatment; as sole source of tetracycline.

(d) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

§ 546.180d Tetracycline soluble powder.

(a) *Requirements for certification.* The requirements for certification for tetracycline soluble powder are described under § 546.110c(a).

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline soluble powder are described under § 546.110c(b).

(c) *Conditions of marketing*—(1) *Specifications.* Tetracycline soluble powder conforms to the standards of identity, strength, quality, and purity prescribed by § 546.110c.

(2) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors as listed in paragraph (c)(5) of this section.

(3) *Special considerations.* The quantity of tetracycline in paragraph (c)(5) of this section refers to the activity of tetracycline hydrochloride.

(4) *Related tolerances.* See § 556.720 of this chapter.

(5) *Conditions of use.* (i) It is used as tetracycline hydrochloride in drinking water for calves as follows:

(a) *Amount.* 100 to 200 milligrams per gallon.

(1) *Indications for use.* As an aid in prevention of bacterial diarrhea, bacterial pneumonia, and shipping fever (hemorrhagic septicemia).

(2) *Limitations.* Administer for not more than 5 days; do not slaughter animals for food purposes within 5 days of treatment; prepare a fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(b) *Amount.* 200 to 400 milligrams per gallon.

(1) *Indications for use.* For treatment of bacterial diarrhea, bacterial pneumonia, and shipping fever (hemorrhagic septicemia).

(2) *Limitations.* Administer for not more than 5 days; do not slaughter animals for food purposes within 5 days of treatment; prepare fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(ii) It is used as tetracycline hydrochloride in water or milk for newborn pigs as follows:

(a) *Amount.* 52 milligrams per day.

(b) *Indications for use.* For treatment of bacterial enteritis and bacterial pneumonia.

(c) *Limitations.* Administer for not more than 3 days; do not slaughter animals for food purposes within 4 days of treatment; prepare a fresh solution daily; as sole source of tetracycline.

(d) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(iii) It is used as tetracycline hydrochloride in drinking water for swine as follows:

(a) *Amount.* 100 to 200 milligrams per gallon.

(1) *Indications for use.* As an aid in prevention of bacterial enteritis.

(2) *Limitations.* Do not slaughter animals for food purposes within 4 days of treatment; prepare a fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(b) *Amount.* 200 to 400 milligrams per gallon.

(1) *Indications for use.* As an aid in prevention of bacterial pneumonia; for treatment of bacterial enteritis.

(2) *Limitations.* Do not slaughter animals for food purposes within 4 days of treatment; prepare a fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(c) *Amount.* 400 milligrams per gallon.

(1) *Indications for use.* For treatment of bacterial pneumonia.

(2) *Limitations.* Do not slaughter animals for food purpose within 4 days of treatment; prepare a fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(iv) It is used as tetracycline hydrochloride in drinking water for turkeys and chickens as follows:

(a) *Amount.* 100 to 200 milligrams per gallon.

(1) *Indications for use.* As an aid in prevention of chronic respiratory disease (air-sac infection), hexamitiasis, blue comb (nonspecific enteritis), infectious sinusitis, and synovitis.

(2) *Limitations.* Administer for not more than 21 days; do not slaughter birds for food within 4 days of treatment; not for use in chickens and turkeys producing eggs for human consumption; prepare fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

(b) *Amount.* 200 to 400 milligrams per gallon.

(1) *Indications for use.* For treatment of chronic respiratory disease (air-sac infection), hexamitiasis, blue comb (nonspecific enteritis), infectious sinusitis, and synovitis.

(2) *Limitations.* Administer for not more than 21 days; do not slaughter birds for food within 4 days of treatment; not for use in chickens and turkeys producing eggs for human consumption; prepare a fresh solution daily; as sole source of tetracycline.

(3) *Sponsor.* See Nos. 000009 and 000069 in § 510.600(c) of this chapter.

§ 546.180e Tetracycline oral liquid.

(a) *Requirements for certification*—(1) The requirements for certification for chlortetracycline calcium sirup (chlortetracycline calcium oral drops); tetracycline sirup (tetracycline oral drops); tetracycline magnesium sirup (tetracycline magnesium oral drops) are described under § 446.111 of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 446.111(a)(3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement, "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for chlortetracycline calcium sirup (chlortetracycline calcium oral drops), tetracycline sirup (tetracycline oral drops), tetracycline magnesium sirup (tetracycline magnesium oral drops), are described under § 446.111 of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Tetracycline oral liquid conforms to the standards of identity, strength, quality, and purity prescribed by paragraph (a) of this section.

(2) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors as listed in paragraph (c)(5) of this section.

(3) *Special considerations.* The quantity of tetracycline in paragraph (c)(5) of this section refers to the activity of tetracycline hydrochloride.

(4) [Reserved]

(5) *Conditions of use.* It is used as tetracycline as follows:

(i) *Dogs*—(a) *Amount.* 25 or 100 milligrams per milliliter.

(b) *Indications for use.* For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(c) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until symptoms have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000196 in § 510.600(c) of this chapter.

(ii) *Dogs and cats*—(a) *Amount.* 100 milligrams per milliliter.

(b) *Indications for use.* For treatment of infections caused by organisms susceptible to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli.*

(c) *Limitations.* Administer orally 25 milligrams per pound of body weight per day given in divided doses every 6 hours; treatment should be continued until the temperature has been normal for 48 hours; not for use in food-producing animals; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

§ 546.180f Tetracycline oral suspension.

(a) *Requirements for certification*—(1) The requirements for certification for tetracycline hydrochloride oral suspension (tetracycline hydrochloride homogenized mixture); tetracycline phosphate complex oral suspension (tetracycline phosphate complex oral drops); tetracycline hydrochloride oral solution; tetracycline calcium oral suspension; tetracycline oral suspension are described under § 446.181c of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 446.181c(a)(3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription," each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement, "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline hydrochloride oral suspension (tetracycline hydrochloride homogenized mixture); tetracycline phosphate complex oral suspension (tetracycline phosphate complex oral drops); tetracycline hydrochloride oral solution; tetracycline calcium oral suspension; tetracycline oral suspension are described under § 446.181c of this chapter.

Subpart B—[Reserved]

Subpart C—Ophthalmic and Topical Dosage Forms

§ 546.312 Chlortetracycline/tetracycline ophthalmic and topical dosage forms.

§ 546.312a Chlortetracycline-neomycin-streptomycin / dihydrostreptomycin ointment; tetracycline hydrochloride-neomycin-streptomycin / dihydrostreptomycin ointment.

(a) *Requirements for certification*—(1) Chlortetracycline-neomycin-streptomycin ointment, chlortetracycline-neomycin-dihydrostreptomycin ointment, tetracycline hydrochloride-neomycin-streptomycin ointment, and tetracycline hydrochloride-neomycin-dihydrostreptomycin ointment conform to all requirements and are subject to all procedures prescribed by § 446.510a(a) of this chapter for chlortetracycline hydrochloride ointment and tetracycline hydrochloride ointment, except that:

(i) They contain not less than 28 milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride per gram.

(ii) They contain not less than 14 milligrams of neomycin per gram. The neomycin used conforms to the standards prescribed by § 444.42(a)(1)(i) (v), and (vi) of this chapter.

(iii) They contain not less than 14 milligrams of streptomycin or dihydrostreptomycin per gram. The streptomycin used conforms to the standards prescribed by § 444.70a(a)(1) of this chapter, except paragraph (a)(1) (ii), (iii), (iv), and (v) of that section. The dihydrostreptomycin used conforms to the

standards prescribed by § 444.10a(a) of this chapter, except the standards for sterility, toxicity, pyrogens, and histamine.

(2) Its expiration date shall be 36 months after the month during which the batch was certified

(3) In addition to complying with the requirements of § 446.510a(a)(4) of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch marks and (unless they were previously submitted) the results and dates of the latest tests and assays of the neomycin and streptomycin or dihydrostreptomycin used in making the batch for potency, moisture, pH, streptomycin content of the dihydrostreptomycin and crystallinity if it is crystalline dihydrostreptomycin. He shall also submit in connection with his request a sample consisting of not less than 8 packages of such ointment and (unless they were previously submitted) accurately representative samples of the following, in the quantities indicated:

(i) The neomycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 6 packages, each containing approximately equal portions of not less than 0.5 gram.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Chlortetracycline content.* Proceed as directed in § 446.10a(b)(1)(viii) of this chapter, except prepare the sample by one of the following methods: Place an accurately weighed sample of approximately 1 gram in an extraction funnel prepared by fusing a ground-glass joint to the top of a medium-porosity sintered-glass filter funnel (30-millimeter diameter). Wash with five 10-milliliter portions of warm iso-octane and draw off the ointment base under vacuum. Discard the iso-octane washings. Wash the residue in the funnel four times with 10-milliliter portions of 0.3 percent piperidine in acetone solution. Withdraw each washing under vacuum. Combine the four washings in a 100-milliliter volumetric flask and make to mark with 0.1 *M* potassium phosphate buffer, pH 4.5. The solution for assay may also be prepared by placing a representative portion of the sample (usually 1.0 gram, accurately weighed) in a glass blending jar containing 199 milliliters of 0.01 *N* HCl and 1 milliliter of polysorbate 80. Using a high-speed blender, blend the mixture for 2 to 3 minutes and make proper estimated dilutions using 0.1 *M* potassium phosphate buffer, pH 4.5. Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(ii) *Tetracycline hydrochloride content.* Prepare the sample as directed in paragraph (b)(1)(i) of this section and proceed as directed in § 446.81a(b) of this chapter. Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(iii) *Neomycin content.* The residue remaining in the funnel after the extraction described in paragraph (b)(1)(i) of this section contains the neomycin and streptomycin or dihydrostreptomycin. Wash this residue five times, using 10-milliliter aliquots of 0.1 *M* potassium phosphate buffer, pH 8.0, drawing each washing off under vacuum. Combine the washings in a 100-milliliter volumetric flask and make to mark with 0.1 *M* potassium phosphate buffer, pH 8.0. Using an aliquot of this aqueous solution, proceed as directed in § 436.105 of this chapter. If *Staphylococcus epidermidis* is used as the test organism, proceed as directed in § 448.510d(b)(1)(ii) of this chapter. The content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(iv) *Streptomycin content.* Using an aliquot of the aqueous solution prepared as directed in paragraph (b)(1)(iii) of this section, proceed as directed in § 444.70a(b)(1)(i) through (ix) of this chapter. The content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(v) *Dihydrostreptomycin content.* Using an aliquot of the aqueous solution prepared as directed in paragraph (b)(1)(iii) of this section, and the dihydrostreptomycin working standard as the standard of comparison, proceed as directed in § 444.70a(b)(1)(i) through (ix) of this chapter. The content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 540.380a(b)(2) of this chapter.

§ 546.312b Chlortetracycline/chlortetracycline hydrochloride/tetracycline hydrochloride ophthalmic.

(a) *Requirements for certification*—(1) The requirements for certification for chlortetracycline ophthalmic (chlortetracycline hydrochloride ophthalmic); tetracycline hydrochloride ophthalmic are described under § 446.310a of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 446.310a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for chlortetracycline ophthalmic (chlortetracycline hydrochloride ophthalmic); tetracycline hydrochloride ophthalmic are described under § 446.310a of this chapter.

§ 546.381 Tetracycline hydrochloride ophthalmic and topical dosage forms.

§ 546.381a Tetracycline hydrochloride-neomycin topical spray ointment.

(a) *Requirements for certification*—(1) The requirements for certification for tetracycline hydrochloride-neomycin spray topical ointment are described under § 446.581a of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 446.581a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline hydrochloride-neomycin spray topical ointment are described under § 446.581a of this chapter.

§ 546.381b Tetracycline hydrochloride-neomycin in oil suspension.

(a) *Requirements for certification.* The requirements for certification for tetracycline hydrochloride-neomycin in oil suspension are described under § 446.581b of this chapter, except, if it is intended solely for veterinary use, it may contain one or more suitable fungicides and miticides. If it contains such ingredients, the labeling shall bear the name and quantity of each contained in each milliliter.

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline hydrochloride-neomycin in oil suspension are described under § 446.581b(b) of this chapter, except, if it is intended solely for veterinary use, it may contain one or more suitable fungicides and miticides. If it contains such ingredients, the labeling shall bear the name and quantity of each contained in each milliliter.

Subpart D—Otic Dosage Forms

§ 546.481 Tetracycline hydrochloride otic.

(a) *Requirements for certification*—(1) The requirements for certification for tetracycline hydrochloride otic (tetracycline hydrochloride for ear solution) are described under § 446.481 of this chapter.

(2) When it is packaged for dispensing and it is intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 446.481(a)(3) of this chapter except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for tetracycline hydrochloride otic (tetracycline hydrochloride for ear solution) are described under § 446.481 of this chapter.

Subparts E and F [Reserved]

Subpart G—Rectal Dosage Forms

§ 546.713 Chlortetracycline/chlortetracycline hydrochloride/tetracycline hydrochloride suppositories.

(a) *Requirements for certification*—(1) The requirements for certification for chlortetracycline suppositories (chlortetracycline hydrochloride suppositories); tetracycline hydrochloride suppositories are described under § 446.610a of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 446.610a(a)(3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement, "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for chlortetracycline suppositories (chlortetracycline hydrochloride suppositories); tetracycline hydrochloride suppositories are described under § 446.610a of this chapter.

PART 548—CERTIFIABLE PEPTIDE ANTIBIOTIC DRUGS FOR ANIMAL USE

Subpart A—Oral Dosage Forms

Sec.
548.110 Bacitracin powder.
548.111 Feed grade manganese bacitracin powder oral.
548.112 Bacitracin methylene disalicylate oral dosage forms.
548.112a Soluble bacitracin methylene disalicylate.
548.112b Tablets bacitracin methylene disalicylate and streptomycin sulfate oral.
548.112c Capsules bacitracin methylene disalicylate and streptomycin sulfate oral.
548.112d Powder bacitracin methylene disalicylate and streptomycin sulfate oral.
548.113 Crude, unrefined, feed grade bacitracin/zinc bacitracin powder oral.
548.114 Zinc bacitracin oral.

Subpart B—Implantation or Injectable Dosage Forms

548.212 Bacitracin methylene disalicylate tablets; bacitracin/zinc bacitracin implantation pellets.

Subpart C—Ophthalmic and Topical Dosage Forms

548.310 Bacitracin ophthalmic and topical dosage forms.
548.310a Bacitracin ophthalmic.
548.310b Bacitracin - polymyxin - neomycin ointment.
548.313 Bacitracin/zinc bacitracin ophthalmic and topical dosage forms.
548.313a Bacitracin/zinc bacitracin-neomycin-polymyxin powder topical.
548.313b Bacitracin/zinc bacitracin ointment.
548.314 Zinc bacitracin ophthalmic and topical dosage forms.
548.314a Zinc bacitracin, polymyxin B sulfate, neomycin sulfate ophthalmic ointment.
548.314b Zinc bacitracin, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate, ophthalmic ointment.

AUTHORITY: Secs. 507, 512, 59 Stat. 463 as amended, 82 Stat. 343-351 (21 U.S.C. 357, 360b).

Subpart A—Oral Dosage Forms

§ 548.110 Bacitracin powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Bacitracin powder is bacitracin, with or without suitable and harmless buffer substances, preservatives, diluents, colorings, and flavorings. It contains the equivalent of not less than 10 grams of the bacitracin master standard per pound. Its moisture content is not more than 5 percent. The bacitracin used conforms to the standards prescribed therefor by § 448.10a(a)(1) of this chapter, except paragraph (a)(1)(ii), (iv), and (viii) of that section. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as herinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(*a*) The batch mark.

(*b*) The number of units of bacitracin per gram, the number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(*c*) The statement "Expiration date _____", the blank being filled in with the date that is 18 months after the month during which the batch was certified.

(*d*) The statement "For oral veterinary use only."

(*e*) If it is intended for use in animals raised for food production, it shall be labeled in accordance with the requirements of paragraph (c) of this section and Part 558 of this chapter.

(ii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Units of bacitracin per gram, and moisture.

(*b*) The bacitracin used in making the batch: Potency, toxicity, moisture, pH, and ash content.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 immediate containers in the batch, but in no case less than six 30-gram portions or more than twelve 30-gram portions. Such samples shall be collected by taking single immediate containers or 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(*b*) The bacitracin used in making the batch: 6 packages, each containing approximately equal portions of not less than 500 milligrams, packaged in accordance with the requirements of § 448.10a(a)(2) of this chapter.

(*c*) In case of an initial request for certification, each other substance used in making the batch: 1 package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(*b*) of this section, and no sample referred to in paragraph (a)(4)(iii)(*b*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 448.10a(b)(1)(i) of this chapter, except in lieu of the directions for preparing the sample in § 448.10a(b)(1)(i)(*b*) of this chapter, prepare the sample as follows: Place an accurately weighed sample of approximately 1 to 5 grams in a 100-milliliter volumetric flask, dissolve in 1 percent phosphate buffer, and dilute to 100 milliliters with 1 percent phosphate buffer. Dilute a suitable aliquot with 1-percent phosphate buffer to a concentration of 1 unit per milliliter (estimated). Its potency is satisfactory if it contains not less than 85 percent of the number of units of bacitracin per pound that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Bacitracin is the antibiotic substance produced by growth of *Bacillus subtilis var. Tracy* or the same antibiotic substance produced by other means, and for the purpose of this section refers to bacitracin or feed grade bacitracin.

(2) *Sponsor.* See No. 032707 in § 510.600(c) of this chapter.

(3) *Special considerations.* Antibiotic activities authorized are expressed in this section in terms of the weight of the appropriate antibiotic standard.

(4) *Related tolerances.* See § 556.70 of this chapter.

(5) *Conditions of use.* It is used in drinking water as follows:

(i) *Chickens*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).

(*2*) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 to 1,000 milligrams.

(*1*) *Indications for use.* Treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).

(*2*) *Limitations.* Prepare a fresh solution daily.

(ii) *Swine*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Aid in prevention of bacterial swine enteritis (scours).

(*2*) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 milligrams.

(*1*) *Indications for use.* Treatment of bacterial swine enteritis (scours).

(*2*) *Limitations.* Prepare a fresh solution daily.

(iii) *Turkey*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Prevention of infectious sinusitis; blue comb (mud fever).

(*2*) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 to 1,000 milligrams.

(*1*) *Indications for use.* Treatment of infectious sinusitis; blue comb (mud fever).

(*2*) *Limitations.* Prepare a fresh solution daily.

§ 548.111 Feed grade manganese bacitracin powder oral.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality and purity.* Feed grade manganese bacitracin powder oral is a mixture of the manganese salt of a kind of bacitracin or a mixture of two or more such salts, with or without one or more essential vitamins and mineral substances for nutritive purposes and with or without one or more suitable and harmless diluents. It contains the equivalent of not less than 5 grams of the bacitracin master standard per pound. Its moisture content is not more than 8.0 percent. The manganese bacitracin used in making the batch has a potency of not less than 2.0 units per milligram, it contains not more than 1.0 gram of manganese for each gram of bacitracin, and its moisture content is not more than 6.0 percent. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging; labeling; requests for certification, samples.* Feed grade manganese bacitracin powder oral conforms to all requirements and procedures prescribed for feed grade zinc bacitracin powder oral by § 548.113(a)(2), except:

(i) Its expiration date shall be 12 months.

(ii) Its labeling is such that, when the drug is mixed with animal feed according to the directions contained therein, such medicated feed complies with the requirements of § 510.510 of this chapter and the requirements of regulations in Part 558 of this chapter.

(b) *Tests and methods of assay*—(1) Proceed as directed in § 448.10a(b) (1) of this chapter, except in lieu of paragraph (b) (1) (i) (*b*) of that section prepare the sample as follows:

(i) Place 2 grams of the sample in a 150-milliliter beaker, add 5 milliliters of 10 percent HCl and stir 1 minute. Check pH with test paper. If pH is greater than 2 add more acid until pH 2 is reached. Add 45 milliliters of pyridine-buffer solution (mix 9 volumes pyridine and 31 volumes pH 6.0 buffer) and transfer the mixture to a centrifuge tube. Shake well for 5 minutes then centrifuge for 15 minutes at 2,000 r.p.m. Dilute an aliquot of the clear solution with enough pH 6.0 buffer to obtain an estimated concentration of 0.20 unit per milliliter.

(ii) Prepare the following dilutions in 0.1 *M* pH 6 buffer from the stock solution for the standard curve: 0.025, 0.05, 0.1, 0.2, 0.4, and 0.8 unit per milliliter with 0.2 unit per milliliter as the reference concentration. Also add 10 milliliters of agar to each petri dish instead of 21 milliliters.

Its potency is satisfactory if it contains not less than 85 percent of the number of grams of manganese bacitracin per pound that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(3) *Manganese bacitracin used in making the batch*—(i) Potency. Proceed as directed in § 448.13(b) (1) of this chapter.

(ii) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(iii) *Manganese content*—(*a*) *Reagents.*

Nitric acid (69.0 percent–71.0 percent) A.C.S.[1]
Sulfuric acid (95.0 percent–98 percent) A.C.S.
Phosphoric acid (85 percent) A.C.S.
Potassium periodate (99.8 percent).

(*b*) *Manganese standard solution.* Dissolve in a flask about 300 milligrams of potassium permanganate (A.C.S.) in 100 milliliters of water and boil the solution for about 15 minutes. Stopper the flask, allow it to stand for at least 2 days, and filter through asbestos. Standardize the solution as follows: Weigh accurately about 20 milligrams of sodium oxalate, previously dried at 110° C. to constant weight, and dissolve it in 25 milliliters of water. Add 1 milliliter of sulfuric acid, heat to about 70° C., and slowly add the permanganate solution from a buret, with constant stirring until a pale-pink color is produced that persists for 15 seconds. The temperature at the conclusion of the titration should not be less than 60° C. Calculate the concentration of the manganese in the standard. Store it in a glass-stoppered, amber-colored bottle.

(c) *Procedure.* Accurately weigh 200 milligrams to 300 milligrams of the sample into a 30-milliliter kjeldahl flask. Add 5 milliliters of nitric acid and 2 milliliters of sulfuric acid, and heat with a full flame, adding nitric acid dropwise as needed to prevent charring of sample until SO_3 fumes appear. Cool, dilute with water, and boil until SO_3 fumes reappear. After cooling, dilute the sample to 50 milliliters. To a 5-milliliter aliquot add 3 milliliters of phosphoric acid, 3 milliliters of sulfuric acid, 0.3 gram of potassium periodate and water to a volume of 75 milliliters. Boil for 5 minutes and continue heating in a boiling water bath for an additional 30 minutes. When cool, dilute the sample to 100 milliliters and determine the permanganate color on a spectrophotometer against a water blank at 525 millimicrons. The amount of manganese that is present can be determined by comparing the absorbance to a standard curve prepared by pipetting 3.0-, 5.0-, 10.0-, and 15.0-milliliter aliquots of the manganese standard solution into separate 100-milliliter volumetric flasks. Add 3.0 milliliters of phosphoric acid and 3.0 milliliters of sulfuric acid to each, and dilute to mark. In a suitable spectrophotometer, determine the absorbance of the solutions at 525 millimicrons, using water as a blank.

§ 548.112 Bacitracin methylene disalicylate oral dosage forms.

§ 548.112a Soluble bacitracin methylene disalicylate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Soluble bacitracin methylene disalicylate is a mixture of bacitracin methylene disalicylate, sodium carbonate, and sodium bicarbonate, with or without suitable and harmless diluents. It contains the equivalent of not less than 25 grams of the bacitracin master standard per pound. Its moisture content is not more than 8.5 percent. Its pH in an aqueous solution containing 200 units per milliliter is not less than 8.5 and not more than 9.5. The bacitracin methylene disalicylate used conforms to the requirements of § 539.310a(a) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

[1] American Chemical Society.

(2) *Packaging; labeling; requests for certification, samples.* Soluble bacitracin methylene disalicylate conforms to all requirements and procedures prescribed for bacitracin methylene disalicylate by § 539.310a (b), (c), and (d) of this chapter, except that the person who requests certification of a batch shall submit with his request (unless previously submitted) a sample consisting of five immediate containers, each containing approximately 5 grams, of the bacitracin methylene disalicylate used in making the batch.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 448.10a(b) (1) (i) of this chapter, except in lieu of the directions for preparing the sample in § 448.10a(b) (1) (i) (*b*) of this chapter, prepare the sample as follows: Place an accurately weighed sample of approximately 1 gram in a blending jar, add 99 milliliters of an aqueous solution of 2 percent sodium bicarbonate and 1 milliliter of polysorbate 80 and blend for 3 minutes in a high-speed blender. Allow the foam to subside. Dilute a suitable aliquot with 1 percent phosphate buffer to a concentration of one unit per milliliter. Its potency is satisfactory if it contains not less than 85 percent of the bacitracin activity per pound that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(3) *pH.* Proceed as directed in § 440.80a(b) (5) (ii) of this chapter, using a solution containing 200 units per milliliter.

(c) *Conditions of marketing*—(1) *Specifications.* Bacitracin methylene disalicylate is the methylene disalicylate salt of the antibiotic substance produced by growth of *Bacillus subtilis var. Tracy* or the same antibiotic substance produced by any other means and, for the purposes of this section, refers to bacitracin methylene disalicylate or feed grade bacitracin methylene disalicylate.

(2) *Sponsor.* See No. 000794 in § 510.600(c) of this chapter.

(3) *Special considerations.* Antibiotic activities authorized in paragraph (c) (5) of this section are expressed in terms of the weight of the appropriate antibiotic standard.

(4) *Related tolerances.* See § 556.70 of this chapter.

(5) *Conditions of use.* It is used in drinking water as follows:

(i) *Chickens*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).

(*2*) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 to 400 milligrams.

(*1*) *Indications for use.* Treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).

(*2*) *Limitations.* Prepare a fresh solution daily.

(ii) *Swine*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Aid in prevention of bacterial swine enteritis (scours).

(*2*) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 milligrams.

(*1*) *Indications for use.* Treatment of bacterial swine enteritis (scours).

(*2*) *Limitations.* Prepare a fresh solution daily.

(iii) *Turkeys*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Prevention of infectious sinusitis; blue comb (mud fever).

(*2*) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 to 400 milligrams.

(*1*) *Indications for use.* Treatment of infectious sinusitis; blue comb (mud fever).

(*2*) *Limitations.* Prepare a fresh solution daily.

§ 548.112b Tablets bacitracin methylene disalicylate and streptomycin sulfate oral.

(a) *Requirements for certification.* Tablets bacitracin methylene disalicylate and streptomycin sulfate oral are tablets that conform to all requirements and are subject to all procedures prescribed by § 548.112d(a) for powder bacitracin methylene disalicylate and streptomycin sulfate oral, except that:

(1) Each tablet shall contain not less than 150 units of bacitracin activity and not less than 15 milligrams of streptomycin activity. Tablets not exceeding 15 millimeters in diameter, or not intended only for preparing solutions, shall disintegrate within 1 hour.

(2) In lieu of the directions for labeling prescribed by § 548.112d(a) (3) (i) (*b*), each package shall bear on the outside wrapper or container and the immediate container the quantity of each antibiotic in each tablet.

(3) In lieu of the directions for sampling the batch as prescribed in § 548.112d(a) (4) (iii) (*a*), the batch shall be sampled as follows:

(i) For potency and moisture: One tablet for each 5,000 tablets in the batch, but in no case less than 30 tablets, collected by taking single tablets throughout the entire time of tableting so that the quantities tableted during the intervals are approximately equal.

(ii) For disintegration-time studies: 6 tablets.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Bacitracin content.* Use 5 finely powdered tablets and proceed as directed in § 548.112d(b) (1) (i). Its bacitracin activity is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(ii) *Streptomycin content.* Proceed as directed in § 544.173a(b) (1) (i) of this chapter. Its streptomycin activity is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 440.180a(b) (3) of this chapter.

§ 548.112c Capsules bacitracin methylene disalicylate and streptomycin sulfate oral.

(a) *Requirements for certification.* Capsules bacitracin methylene disalicylate and streptomycin sulfate oral are capsules that conform to all requirements and are subject to all procedures prescribed by § 548.112b(a) for tablets bacitracin methylene disalicylate and streptomycin sulfate oral.

(b) *Tests and Methods of assay*—(1) *Potency*—(i) *Bacitracin content.* Using a representative number of capsules (usually five) in a blending jar, proceed as directed in § 548.112d(b) (1) (i). Its bacitracin content is satisfactory if it contains not less than 85 percent of that which it is represented to contain.

(ii) *Streptomycin content.* Using the contents of a representative number of capsules (usually six), proceed as directed in § 444.70a(b) (1) (i) through (ix), of this chapter, and use 0.1 *M* potassium phosphate buffer, pH 8.0, for preparing the sample instead of sterile distilled water as directed in § 444.70a (b) (1) (v). Its content of streptomycin is satisfactory if it contains not less than 85 percent of that which it is represented to contain.

(2) *Moisture.* Proceed as directed in § 440.80a(b) (5) (i) of this chapter.

§ 548.112d Powder bacitracin methylene disalicylate and streptomycin sulfate oral.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Powder bacitracin methylene disalicylate and streptomycin sulfate oral is a mixture of bacitracin methylene disalicylate and streptomycin sulfate oral, with or without one or more suitable and harmless adsorbent ingredients, diluents, colorings, and flavorings. Each gram contains not less than 200 units of bacitracin activity and not less than 20 milligrams of streptomycin activity. Its moisture content is not more than 7.5 percent. The bacitracin methylene disalicylate used conforms to the requirements prescribed by § 539.310(a) (1) of this chapter. The streptomycin sulfate oral used conforms to the standards prescribed by § 539.170(a) (1) of this chapter. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. and shall be of such composition that they will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(3) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(a) The batch mark.

(b) The number of units of bacitracin activity and the number of milligrams of streptomycin activity per gram and the total number of grams in the immediate container.

(c) The statement "Expiration date ---------", the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 36 months, 48 months, or 60 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(d) The statement "For oral veterinary use only".

(e) The statement, "Warning: Not for use in animals which are raised for food production".

(f) If it contains adsorbent ingredients, the name of each.

(ii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the bacitracin methylene disalicylate and streptomycin sulfate oral used in making such batch were completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor by this section.

(ii) Except as otherwise provided by paragraph (a)(4)(iv) of this section, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(a) The batch; units of bacitracin activity per gram, milligram of streptomycin activity per gram, and moisture.

(b) The bacitracin methylene disalicylate and the streptomycin sulfate oral veterinary used in making the batch; potency, toxicity, moisture, and pH.

(iii) Except as otherwise provided by paragraph (a)(4)(iv) of this section such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 immediate containers in the batch, but in no case less than six 30-gram portions. Such samples shall be collected by taking single immediate containers or 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(b) The bacitracin methylene disalicylate used in making the batch; 5 packages containing approximately equal portions of not less than 5 grams each, packaged in accordance with the requirements of § 539.310(a)(2) of this chapter.

(c) The streptomycin sulfate oral veterinary used in making the batch; 5 packages containing approximately equal portions of not less than 1.0 gram each, packaged in accordance with the requirements of § 539.170(a)(2) of this chapter.

(d) In case of an initial request for certification, the other ingredient used in making the batch; 1 package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a)(4)(ii)(b) of this section, and no sample referred to in paragraph (a)(4)(iii)(b) and (c) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay.* (1) *Potency*—(i) *Bacitracin content.* Proceed as directed in § 443.10a(b)(1)(i) of this chapter, except paragraph (b)(1)(i)(b) and (c) of that section. In lieu of the directions in § 443.10a(b)(1)(i) of this chapter, prepare the sample as follows: Place an accurately weighed sample of approximately 5 grams in a blending jar. Add sufficient dimethylformamide so that when the sample is diluted to its reference point the concentration of dimethylformamide in the final blank is no greater than 20 percent. Blend for 3 to 5 minutes. Filter through filter paper immediately. Remove an aliquot of the filtrate at once and dilute to 1 unit per milliliter with 1.0 percent phosphate buffer, pH 6.0. Add sufficient dimethylformamide to the working solution of the standard so that the concentration of dimethylformamide is the same as that in the sample being tested. In lieu of the directions in § 448.10a(b)(1)(i)(c) of this chapter, use one of the test organisms described in § 436.505(a)(2)(ii) of this chapter.

NOTE: Pyridine may be substituted for dimethylformamide in the procedure described in paragraph (b)(1)(i).

Its potency is satisfactory if it contains not less than 85 percent of the units of bacitracin activity that it is represented to contain.

(ii) *Streptomycin content.* Proceed as directed in § 444.70a(b)(1) of this chapter. Its content of streptomycin is satisfactory if it contains less than 85 percent of the number of milligrams of streptomycin activity per gram that it is represented to contain.

(2) *Moisture.* Using a 1.0-gram sample, proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 548.113 Crude, unrefined, feed grade bacitracin/zinc bacitracin powder oral.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Feed grade bacitracin powder oral is bacitracin with or without one or more essential vitamins and mineral substances for nutritive purposes and with or without one or more suitable and harmless diluents. Feed grade zinc bacitracin powder oral is a mixture of zinc bacitracin and zinc proteinates, with or without one or more essential vitamins and mineral substances for nutritive purposes and with or without one or more suitable and harmless diluents. They contain the equivalent of not less than 2.5 grams of the bacitracin master standard per pound, except that if it is zinc bacitracin powder it contains the equivalent of not less than 5 grams of the bacitracin master standard per pound. Their moisture content is not more than 5 percent. The bacitracin used in making the batch has a potency of not less than 5 units per milligram, and its moisture content is not more than 5 percent. The zinc bacitracin used in making the batch has a potency of not less than 2 units per milligram, not more than 2 grams of zinc for each gram of bacitracin, and its moisture content is not more than 6 percent. Each other substance used, if its name is recognized in the U.S.P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling*—Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(a) The batch mark.

(b) The number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(c) The statement "Expiration date ----------", the blank being filled in with the date that is 18 months after the month during which the batch was certified, except that an expiration date of 24 months or 36 months may be used if the manufacturer has submitted to the Commissioner results of tests and essays showing that, after having been stored for such period of time, such drug as prepared by him complies with the standards prescribed by paragraph (a)(1) of this section.

(d) The statement "For oral veterinary use only".

(e) If it is intended for use in animals raised for food production, it shall be labeled in accordance with the requirements of paragraph (c) of this section and Part 558 of this chapter.

(ii) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity.

(3) *Request for certification; samples.* (i) In addition to complying with the requirements of § 514.50 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor, by this section.

(ii) Except as otherwise provided by paragraph (a)(3)(iv) of this section, such person shall submit, in connection with his request, results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(*a*) The batch: Grams of bacitracin per pound and moisture.

(*b*) The bacitracin used in making the batch: Potency, moisture, and zinc content, if the bacitracin used is zinc bacitracin.

(iii) Except as otherwise provided by paragraph (a)(3)(iv) of this section, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(*a*) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams of each 5,000 immediate containers in the batch, but in no case less than six 30-gram portions or more than twelve 30-gram portions. Such samples shall be collected by taking single immediate containers of 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(*b*) The bacitracin used in making the batch: Three packages consisting of a composite of 6 portions of approximately 500 milligrams each taken at random from different locations in the batch, packaged in accordance with the requirements of § 510.45 of this chapter.

(*c*) In case of an initial request for certification, each other substance used in making the batch: 1 package of each containing approximately 5 grams.

(iv) No result referred to in paragraph (a)(3)(ii)(*b*) of this section, and no sample referred to in paragraph (a)(3)(iii)(*b*) of this section, is required if such result or sample has been previously submitted.

(b) *Tests and methods of assay*—(1) *Feed grade bacitracin or zinc bacitracin powder oral*—(i) *Potency.* Proceed as directed in § 548.110(b)(1), except if it is feed grade zinc bacitracin powder oral proceed as directed in § 448.13(b)(1) of this chapter. Their potency is satisfactory if they contain not less than 85 percent of the number of grams of bacitracin or zinc bacitracin per pound that they are represented to contain.

(ii) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

(2) *Bacitracin or zinc bacitracin used in making the batch*—(i) *Potency.* Proceed as directed in § 448.10a(b)(1) of this chapter, except if it is zinc bacitracin proceed as directed in § 448.13(b)(1) of this chapter.

(ii) *Zinc content (if zinc bacitracin is used).* Proceed as directed in § 448.13(b)(5) of this chapter.

(iii) *Moisture.* Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

(c) *Conditions of marketing.* If it is feed grade bacitracin powder, its conditions of marketing are described in § 548.110(c). If it is feed grade zinc bacitracin powder, oral, its conditions of marketing are described in § 548.114(c).

§ 548.114 Zinc bacitracin oral.

(a) *Requirements for certification.* The requirements for certification for zinc bacitracin oral are described under § 548.113(a).

(b) *Tests and methods of assay.* The tests and methods of assay for zinc bacitracin oral are described under § 548.113(b).

(c) *Conditions of marketing*—(1) *Specifications.* Zinc bacitracin is the zinc salt of the antibiotic substance produced by growth of *Bacillus subtilis var. Tracy* or the same antibiotic substance produced by any other means, and for the purposes of this section refers to zinc bacitracin or feed grade zinc bacitracin.

(2) *Sponsor.* See No. 012769 in § 510.600(c) of this chapter.

(3) *Special considerations.* Quantities of zinc bacitracin expressed in paragraph (c)(5) of this section refer to the weight of an appropriate antibiotic standard.

(4) *Related tolerances.* See § 556.70 of this chapter.

(5) *Conditions of use.* It is used in drinking water as follows:

(i) *Chickens*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).

(2) *Limitations.* Prepare a fresh solution daily.

(b) *Amount per gallon.* 200 to 1,000 milligrams.

(*1*) *Indications for use.* Treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).

(2) *Limitations.* Prepare a fresh solution daily.

(ii) *Swine*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Aid in prevention of bacterial swine enteritis (scours).

(2) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 milligrams.

(*1*) *Indications for use.* Treatment of bacterial swine enteritis (scours).

(2) *Limitations.* Prepare a fresh solution daily.

(iii) *Turkeys*—(*a*) *Amount per gallon.* 100 to 200 milligrams.

(*1*) *Indications for use.* Prevention of infectious sinusitis; blue comb (mud fever).

(2) *Limitations.* Prepare a fresh solution daily.

(*b*) *Amount per gallon.* 200 to 1,000 milligrams.

(*1*) *Indications for use.* Treatment of infectious sinusitis; blue comb (mud fever).

(2) *Limitations.* Prepare a fresh solution daily.

Subpart B—Implantation or Injectable Dosage Forms

§ 548.212 Bacitracin methylene disalicylate tables; bacitracin/zinc bacitracin implantation pellets.

(a) *Requirements for certification.* The requirements for certification for bacitracin methylene disalicylate tablets; bacitracin implantation pellets; zinc bacitracin implantation pellets are described under § 448.110a of this chapter, with the following exceptions:

(1) Standards of identity, strength, quality, and purity: The bacitracin methylene used conforms to the standards of § 539.310(a)(1) of this chapter.

(2) Labeling: When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 448.110a(a)(3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity and the statement, "Warning—Not for use in animals which are raised for food production."

(3) Request for certification; samples: As prescribed in § 448.110a(a)(4)(iii) of this chapter, a person shall submit with his request accurately representative samples of the bacitracin methylene disalicylate used in making the batch; 5 packages containing approximately equal portions of not less than 5 grams each, packaged in accordance with the requirements of § 539.310(a)(2) of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin methylene disalicylate tablets are described under § 448.110a of this chapter, except for the potency test described in § 448.110a(b)(1) of this chapter, use 99 milliliters of an aqueous solution of 2-percent sodium bicarbonate and 1 milliliter of polysorbate 80. For the disintegration time as described in § 448.110a(b)(3) of this chapter, proceed as directed in § 540.173b(b)(3) of this chapter.

Subpart C—Ophthalmic and Topical Dosage Forms

§ 548.310 Bacitracin ophthalmic and topical dosage forms.

§ 548.310a Bacitracin ophthalmic.

(a) *Requirements for certification*—(1) The requirements for certification for

bacitracin ophthalmic are described under § 448.310a(a) of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all requirements prescribed by § 448.310a(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin ophthalmic are described under § 448.310a(b) of this chapter.

§ 548.310b Bacitracin - polymyxin - neomycin ointment.

(a) *Requirements for certification.* The requirements for certification for bacitracin - polymyxin - neomycin ointment are described under § 448.510e(a) of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin - polymyxin - neomycin ointment are described under § 448.510e(b) of this chapter.

§ 548.313 Bacitracin/zinc bacitracin ophthalmic and topical dosage forms.

§ 548.313a Bacitracin/zinc bacitracin-neomycin-polymyxin powder topical.

(a) *Requirements for certification*—(1) The requirements for certification for bacitracin-neomycin-polymyxin powder topical; zinc bacitracin-neomycin-polymyxin powder topical are described under § 448.510f(a) of this chapter.

(2) When it is packaged for dispensing and intended solely for veterinary use, its label and labeling shall comply with all the requirements prescribed by § 448.510f(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity.

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin-neomycin-polymyxin powder topical; zinc bacitracin-neomycin-polymyxin powder topical are described under § 448.510f(b) of this chapter.

§ 548.313b Bacitracin/zinc bacitracin ointment.

(a) *Requirements for certification.* The requirements for certification for bacitracin ointment and zinc bacitracin ointment are described under § 448.510a(a) of this chapter, with the following exceptions:

(1) *Standards of identity, strength, quality, and purity.* When it is conspicuously labeled for veterinary use, it may contain one or more suitable antifungal agents or rotenone.

(2) *Labeling.* (i) It is packaged for dispensing; it contains cortisone or a suitable derivative of cortisone; and it is intended solely for veterinary use: Its label and labeling shall comply with the requirements of § 201.105 of this chapter (regulations issued under section 502(f) of the act) and with the requirements of § 448.510a(a)(3) of this chapter.

(ii) It is packaged for dispensing, it does not contain cortisone or a derivative of cortisone and it is intended solely for veterinary use: Its label and labeling shall comply with the requirements of paragraph (b)(1) of this section except that in lieu of the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" each package shall include information containing directions and warnings adequate for the veterinary use of the drug by the laity except that drugs complying with § 548.314a shall bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian".

(b) *Tests and methods of assay.* The tests and methods of assay for bacitracin ointment and zinc bacitracin ointment are described under § 448.510a(b) of this chapter.

§ 548.314 Zinc bacitracin ophthalmic and topical dosage forms.

§ 548.314a Zinc bacitracin, polymyxin B sulfate, neomycin sulfate ophthalmic ointment.

(a) *Specifications.* The drug conforms to the provisions of § 448.510e of this chapter.

(b) *Sponsor.* To firm(s) as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter, approvals of drugs as specified:

(1) To 000009: approval of a drug which contains in each gram 500 units of bacitracin, 3.5 milligrams of neomycin base, and 5,000 units of polymyxin B.

(2) To 010616: approval of a drug which contains in each gram 400 units of zinc bacitracin, 3.5 milligrams of neomycin base, and 5,000 units of polymyxin B.

(c) *Conditions of use.* (1) The drug is used in the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to the antibiotics contained in the ointment.

(2) Apply a thin film over the cornea 3 or 4 times daily. Laboratory tests should be conducted including in-vitro culturing and susceptibility tests on sample collected from animals prior to treatment with the drug.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 548.314b Zinc bacitracin, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate, ophthalmic ointment.

(a) *Requirements for certification.* The requirements for certification for zinc bacitracin, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate, ophthalmic ointment are described under § 448.510e(a) of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for zinc bacitracin, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate, ophthalmic ointment are described under § 448.510e(b) of this chapter.

(cv) *Conditions of marketing*—(1) *Specifications.* The drug conforms to the specification requirements in § 448.510e(a) of this chapter and is subject to the tests and methods of assay prescribed in § 548.310b of this chapter. Each gram of the drug contains the following active ingredients: 400 units of zinc bacitracin, 5,000 units of polymyxin B sulfate, 5 milligrams of neomycin sulfate (equivalent to 3.5 mg of neomycin base), and 10 milligrams of hydrocortisone acetate.

(2) *Sponsor.* See No. 010616 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) The drug is administered to dogs and cats for treating acute or chronic conjunctivitis caused by organisms susceptible to the antibiotics contained in this ointment.

(ii) Apply a thin film over the cornea three or four times daily.

(iii) All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

Subpart A—Oral Dosage Forms

Sec.
555.110 Chloramphenicol oral dosage forms.
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555.310e Chloramphenicol - prednisolone - tetracaine-squalane topical suspension.
555.310f Chloramphenicol-prednisolone ophthalmic ointment.
555.310g Fibrinolysin and desoxyribonuclease, combined (bovine) with chloramphenicol ointment.

Subpart D—Otic Dosage Forms

555.410 Chloramphenicol otic.

AUTHORITY: Secs. 507, 512, 59 Stat. 463 as amended, 82 Stat. 343-351 (21 U.S.C. 357, 360b).

Subpart A—Oral Dosage Forms

§ 555.110 Chloramphenicol oral dosage forms.

§ 555.110a Chloramphenicol tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol tablets are composed of chloramphenicol

col with or without one or more suitable diluents, lubricants, binders, colorings and coating substances. Each tablet contains 100 milligrams of chloramphenicol. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of chloramphenicol that it is represented to contain. Tablets shall disintegrate within 1 hour. The chloramphenicol used conforms to the standards prescribed by § 455.10(a) (1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, safety, pH, specific rotation, melting range, absorptivity, and crystallinity.

(*b*) The batch for potency and disintegration time.

(ii) Samples required.

(*a*) The chloramphenicol used in making the batch: 10 packages each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological turbidimetric assay shall be conclusive.

(i) *Microbiological turbidimetric assay.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing 100 milliliters of 95 percent ethyl alcohol. Blend for 2 minutes. Add 400 milliliters of 1 percent potassium phosphate buffer, pH 6.0 (solution 1), and blend again for 2 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(ii) *Spectrophotometric assay*—(*a*) *Preparation of working standard solution.* Dissolve approximately 50 milligrams of the working standard in 100 milliliters of distilled water. Warm if necessary to hasten dissolution. Transfer 10 milliliters into a 250-milliliter volumetric flask and fill to volume with distilled water.

(*b*) *Procedure.* Weigh accurately a counted number of not less than 10 tablets and determine the average weight per tablet. Reduce 10 tablets to a fine powder in a mortar and transfer an amount of powder containing 500 milligrams (estimated) of chloramphenicol to a 1,000-milliliter glass-stoppered volumetric flask. Add 50 milliliters of redistilled methanol to the flask and shake for at least 1 minute. Fill to volume with distilled water and mix thoroughly. Transfer exactly 10 milliliters of this solution into a 250-milliliter glass-stoppered volumetric flask. Fill to volume with distilled water and mix thoroughly. Determine the absorbance of this solution on a suitable spectrophotometer in a 1-centimeter quartz cell at 278 nanometers against a blank of distilled water. Calculate the potency of the sample as follows:

$$\text{Milligrams of chloramphenicol per tablet} = \frac{\text{Absorbance of sample solution} \times \text{Concentration of working standard solution (mg/ml)} \times \text{Potency of working standard (mcg/mg)} \times 25{,}000 \times \text{Average tablet weight (mg/tab)}}{\text{Absorbance of working standard solution} \times \text{Weight of sample (mg)} \times 1000}$$

(2) *Disintegration time.* Proceed as directed in § 436.212 of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Chloramphenicol tablets contain 100 milligrams of chloramphenicol and conform to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is administered to dogs for oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) The drug is administered at 25 milligrams per pound of body weight every 6 hours.

(iii) Laboratory tests should be conducted including in-vitro culturing and susceptibility tests on samples collected prior to treatment. If no response to chloramphenicol therapy is obtained in 3 to 5 days, discontinue its use and review diagnosis.

(iv) The label bears a statement that the product is not to be used in animals which are raised for food production.

(v) Chloramphenicol products must not be used in meat, egg, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 555.110b Chloramphenicol capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol capsules are composed of chloramphenicol with or without one or more suitable diluents and lubricants. Each capsule contains 50, 100, 250, or 500 milligrams of chloramphenicol. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of chloramphenicol that it is represented to contain. The chloramphenicol used conforms to the standards prescribed by § 455.10(a) (1) of this chapter.

(2) *Labeling.* In addition to the labeling requirements of paragraph (c) of this section and § 510.55 of this chapter, its label and labeling shall bear the statement, "Warning: Not for use in animals which are raised for food production".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, safety, pH, specific rotation, melting range, absorptivity, and crystallinity.

(*b*) The batch for potency.

(ii) Samples required:

(*a*) The chloramphenicol used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay; potency.* Proceed as directed in § 455.110(b) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Chloramphenicol capsules contain 50, 100, 250, and 500 milligrams of chloramphenicol and conform to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* (i) For chloramphenicol capsules containing 50, 100, 250 and 500 milligrams chloramphenicol see Nos. 000071, 000196, 000172 and 000345 in § 510.600(c) of this chapter.

(ii) For chloramphenicol capsules containing 100 and 250 milligrams of chloramphenicol see No. 000022 in § 510.600 (c) of this chapter.

(iii) [Reserved]

(3) *Conditions of use.* (i) The drug is administered to dogs for oral treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) The drug is administered at 25 milligrams per pound of body weight every 6 hours.

(iii) Laboratory tests should be conducted including in-vitro culturing and susceptibility tests on samples collected prior to treatment.

(iv) This product must not be used in meat, egg, or milk producing animals. The length of time that residues persist in milk or tissues has not been determined.

(v) For use by or on the order of a licensed veterinarian.

§ 555.110c Chloramphenicol oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol oral solution is a solution containing chloramphenicol and one or more suitable and

harmless buffers and preservatives in a suitable and harmless solvent. Each milliliter contains 100 milligrams of chloramphenicol. The chloramphenicol content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of chloramphenicol that it is represented to contain. The pH is not less than 6.5 and not more than 8.5. The chloramphenicol used conforms to the standards prescribed in § 455.10(a)(1) of this chapter.

(2) *Packaging.* It shall be packaged in accordance with the requirements of § 510.45 of this chapter.

(3) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.-55 of this chapter.

(4) *Requests for certification; samples.* In addition to the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, safety, pH, specific rotation, melting point, absorptivity, and crystallinity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The chloramphenicol used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Transfer an accurately measured portion of the sample into a volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0, (solution 1). Further dilute with solution #1 to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.-202 of this chapter, diluting the sample with an equal volume of distilled water.

(c) *Conditions of marketing*—(1) *Specifications and special considerations.* The product complies with the requirements of paragraph (a) of this section.

(2) *Sponsor.* See Nos. 010271 and 011757 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs for the treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.

(ii) It is administered orally to dogs at a dosage level of 25 milligrams per pound of body weight every 6 hours. In severe infections, 4 to 6 hour treatment intervals may be desirable the first day of treatment. If no response is obtained in 3 to 5 days, discontinue use of the drug and review the diagnosis.

(iii) The label bears a statement that this produce is not to be used in animals which are raised for food production.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Subpart B—Implantation or Injectable Dosage Forms

§ 555.210 Chloramphenicol injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol injection is a solution containing chloramphenicol and one or more suitable and harmless buffers and preservatives in ethyl alcohol and propylene glycol base. Each milliliter contains 100 milligrams of chloramphenicol. The chloramphenicol content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of chloramphenicol that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. It contains no histamine or histaminelike substances. Its pH is not less than 6.5 and not more than 8.5. The chloramphenicol used conforms to the standards prescribed by § 455.10a(a)(1) of this chapter.

(2) *Packaging.* It shall be packaged in accordance with the requirements of § 510.45 of this chapter.

(3) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.-55 of this chapter.

(4) *Requests for certification; samples.* In addition to the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, pH, specific rotation, melting point, absorptivity, and crystallinity.

(*b*) The batch for potency, sterility, pyrogens, safety, histamine content, and pH.

(ii) Samples required:

(*a*) The chloramphenicol used in making the batch: 10 packages each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 8 immediate containers.

(*2*) For sterility testing: 20 immediate containers collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assays*—(1) *Potency.* Proceed as directed in § 436.-106 of this chapter, preparing the sample for assay as follows: Transfer an accurately measured portion of the sample into a volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1). Further dilute with solution 1 to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except transfer 1 milliliter from each container directly to the dry filter, thus eliminating the preliminary solubilization step.

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter.

(4) *Safety.* Proceed as directed in § 436.33 of this chapter.

(5) *Histamine.* Proceed as directed in § 436.35 of this chapter, omitting the application of heat.

(6) *pH.* Proceed as directed in § 436.202 of this chapter, diluting the sample with an equal volume of distilled water.

(c) *Conditions of marketing*—(1) *Specifications.* The product complies with the requirements of paragraph (a) of this section.

(2) *Sponsor.* See Nos. 010271 and 011757 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) It is used in dogs for the treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.

(ii) It is administered intramuscularly or intravenously at a dosage level of 5 to 15 milligrams per pound of body weight every 6 hours. In severe infections, 4 to 6 hour treatment intervals may be desirable the first day of treatment. If no response to treatment is obtained in 3 to 5 days, use should be discontinued and the diagnosis reviewed.

(iii) The label bears a statement that the product is not to be used in animals which are raised for food production.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Subpart C—Ophthalmic and Topical Dosage Forms

§ 555.310 Chloramphenicol ophthalmic and topical dosage forms.

§ 555.310a Chloramphenicol ophthalmic.

(a) *Requirements for certification*—(1) The requirements for certification for chloramphenicol ophthalmic are described under § 455.310b of this chapter.

(2) When it is intended solely for veterinary use, its label and labeling shall comply with all the requirements of § 455.310b(a)(3) of this chapter, except that in lieu of the statement "Caution: Federal law prohibits dispensing without prescription", it shall be labeled in accordance with the requirements prescribed by § 201.105 of this chapter (regulations issued under section 502(f) of the act).

(b) *Tests and methods of assay.* The tests and methods of assay for chloramphenicol ophthalmic are described in § 455.310b of this chapter.

§ 555.310b Chloramphenicol topical.

(a) *Requirements for certification.* (1) The requirements for certification for chloramphenicol topical are described under § 455.410(a) of this chapter.

(2) When it is intended solely for veterinary use, its label and labeling shall comply with all the requirements of § 455.410(a)(3) of this chapter, except that in lieu of the statement, "Caution: Federal law prohibits dispensing without prescription", it shall be labeled in accordance with the requirements of § 201.105 of this chapter (regulations issued under section 502(f) of the act) and bear on its label and labeling the

statement, "Warning—Not for use in animals which are raised for food production."

(b) *Tests and methods of assay.* The tests and methods of assay for chloramphenicol topical are described under § 455.410(b) of this chapter.

§ 555.310c Chloramphenicol ophthalmic ointment.

(a) *Requirements for certification.* The requirements for certification for chloramphenicol ointment (chloramphenicol cream) are described under § 455.310c (a) of this chapter.

(b) *Tests and methods of assay.* The tests and methods of assay for chloramphenicol ointment are described under § 455.310c(b) of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* The product conforms to the specification requirements in paragraph (a) of this section, and is subject to the tests and methods of assay prescribed in paragraph (b) of this section. Each gram of the product contains 10 milligrams chloramphenicol.

(2) *Sponsor.* See Nos. 000071 and 010616 in § 510.600(c) of this chapter for use in accordance with paragraph (c) (3) (i) (*a*) of this section and No. 017030 for use in accordance with paragraph (c) (3) (i) (*b*) of this section.

(3) *Conditions of use.*—(i) It is used in dogs and cats for the treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol as follows:

(*a*) It is applied every 3 hours around the clock for 48 hours after which night instillations may be omitted. Treatment should be continued for 2 days after the eye appears normal.

(*b*) It is applied to affected eye four to six times daily for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac. Continue treatment for 48 hours after eye appears normal.

(ii) Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection is suspected as the cause of a disease process, especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotics will be effective prior to applying ophthalmic preparations. This chloramphenicol product must not be used in animals producing meat, eggs, or milk. The length of time that residues persist in milk or tissues has not been determined.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 555.310d Chloramphenicol ophthalmic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol ophthalmic solution contains in each milliliter 5 milligrams of chloramphenicol with or without one or more suitable and harmless preservatives and surfactants in an aqueous solution. Its potency is not less than 90 percent and not more than 130 percent of the number of milligrams of chloramphenicol that it is represented to contain. It is sterile. Its pH is not less than 3 nor more than 6. The chloramphenicol used conforms to the standards prescribed by § 455.10(a) (1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, safety, pH, specific rotation, melting range, absorptivity, and crystallinity.

(*b*) The batch for potency, sterility, and pH.

(ii) Samples required:

(*a*) The chloramphenicol used in making the batch: 10 containers, each containing not less than 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of five immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological turbidimetric assay shall be conclusive.

(i) *Microbiological turbidimetric assay.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample in sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(ii) *Spectrophotometric assay.* Dilute a 1-milliliter aliquot of the sample in sufficient distilled water to make a solution containing 20 milligrams of chloramphenicol per milliliter. Dissolve an accurately weighed portion of the working standard in sufficient distilled water to give a solution containing 20 milligrams per milliliter. Warm if necessary to hasten solution of the working standard. Cool. Using a suitable spectrophotometer and distilled water as the blank, determine the absorbance of the sample and standard solutions at 278 nanometers. Calculate the potency of the sample as follows:

$$\text{Milligrams of chloramphenicol per milliliter} = \frac{\text{Absorbance of sample} \times \text{labeled potency per milliliter in milligrams}}{\text{Absorbance of standard}}$$

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e) (1) of that section.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(c) *Conditions of marketing*—(1) *Specifications.* The solution conforms to the certification requirements of paragraph (a) of this section. The solution contains as active ingredient, chloramphenicol 0.5 percent with cholorbutanol 0.5 percent as a preservative.

(2) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs and cats for the treatment of bacterial conjunctivitis caused by organisms susceptible to chloramphenicol.

(ii) Treat with one or two drops, 4 to 6 times a day for the first 72 hours, depending upon the severity of the condition. Intervals between applications may be increased after the first 2 days. Therapy should be continued for 48 hours after an apparent cure has been attained.

(iii) Therapy for cats should not exceed 7 days. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs, or if clinical improvement is not noted within a reasonable period, discontinue use, and institute appropriate therapy. Prolonged use in cats may produce blood dyscrasias. This chloramphenicol product must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined.

(iv) For use by or on the order of a licensed veterinarian.

§ 555.310e Chloramphenicol - prednisolone-tetracaine-squalane topical suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* This drug is a suspension composed of chloramphenicol, prednisolone, tetracaine, and squalane in a suitable and harmless vehicle. Each milliliter contains 4.2 milligrams of chloramphenicol, 1.7 milligrams of prednisolone, 4.2 milligrams of tetracaine, and 0.21 milliliter of squalane. Its moisture content is not more than 1 percent. Its antibiotic potency is not less than 90 percent and not more than 125 percent of the number of milligrams of chloramphenicol that it is represented to contain. The chloramphenicol used conforms to the standards prescribed by § 455.10(a) (1) of this chapter, except safety.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The chloramphenicol used in making the batch for potency, pH,

specific rotation, melting range, absorptivity, and crystallinity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The chloramphenicol used in making the batch: 10 containers, each containing approximately 300 milligrams.

(b) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Transfer an accurately measured portion of the sample into a separatory funnel containing 50 milliliters of petroleum ether. Shake the separatory funnel vigorously to bring about complete mixing of the sample and the petroleum ether. Add 20 milliliters of 1 percent potassium phosphate buffer, pH 6.0 (solution 1), and shake well. Remove the buffer layer and repeat the extraction with three additional 20-milliliter portions of solution 1. Combine the extractives and dilute to an appropriate volume with solution 1. Further dilute in solution 1 to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter, using 1 or 2 milliliters of the suspension.

(c) *Conditions of marketing*—(1) *Specification.* The suspension conforms to the certification requirements of paragraph (a) of this section. Each cubic centimeter of suspension contains 4.2 milligrams of chloramphenicol, 1.7 milligrams of prednisolone, 4.2 milligrams of tetracaine, and 0.21 milliliter of squalane in a petrolatum-mineral oil base.

(2) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(3) *Conditions of use.* It is used in the treatment of acute otitis externa and pyodermas (acute moist dermatitis, vulvar fold dermatitis, lip fold dermatitis, interdigital dermatitis, and juvenile dematitis) in dogs and cats. Laboratory tests should be conducted, including *in-vitro* culturing and susceptibility tests on samples collected prior to treatment. Treat with two or three applications daily or as needed for not more than 7 days. Severe infections should be supplemented by systemic therapy. The drug must not be used in the eyes. Prolonged use in cats may produce blood dyscrasias. Chloramphenicol products must not be used in meat, egg, or milk producing animals. The length of time that residues persist in milk or tissues has not been determined. For use by or on the order of a licensed veterinarian.

§ 555.310f Chloramphenicol - prednisolone ophthalmic ointment.

(a) *Requirements for certification.* The requirements for certification for chloramphenicol - prednisolone ophthalmic ointment are described under § 555.310c.

(b) *Tests and methods of assay.* The tests and methods of assay for chloramphenicol - prednisolone ophthalmic ointment are described under § 555.310c.

(c) *Conditions of marketing*—(1) *Specifications.* The product conforms to the specification requirements in § 555.310c(a) of this chapter and is subject to the tests and methods of assay prescribed in § 555.310c(b) of this chapter. Each gram of the product contains the following active ingredients: 10 milligrams of chloramphenicol and 2 milligrams of prednisolone.

(2) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used in dogs and cats for the treatment of bacterial conjunctivitis and ocular inflammation caused by organisms susceptible to chloramphenicol.

(ii) It is applied to the affected eye 4 to 6 times daily for the first 72 hours depending upon the severity of the condition. Continue treatment for 48 hours after an apparent cure has been attained.

(iii) Therapy for cats should not exceed 7 days, prolonged use in cats may produce blood dyscrasia. As with other antibiotics, prolonged use may result in overgrowth of nonsusceptible organisms. If superinfection occurs or if clinical improvement is not noted within a reasonable period, discontinue use and institute appropriate therapy. All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well under way. This chloramphenicol product must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined.

(iv) For use only by or on the order of a licensed veterinarian.

§ 555.310g Fibrinolysin and desoxyribonuclease, combined (bovine) with chloramphenicol ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Fibrinolysin and desoxyribonuclease, combined (bovine) with chloramphenicol ointment is fibrinolysin, desoxyribonuclease, and chloramphenicol in a suitable and harmless ointment base. It contains a suitable and harmless preservative. Each gram contains 1 unit of fibrinolysin, 666 units of desoxyribonuclease, and 10 milligrams of chloramphenicol. Its chloramphenicol content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of chloramphenicol that it is represented to contain. The chloramphenicol used conforms to the standards prescribed by § 455.10 of this chapter, except safety. In addition to the requirements prescribed by this paragraph, the drug satisfies the requirements designated therefor by the Division of Biologics Standards, National Institutes of Health, Department of Health, Education, and Welfare.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 510.55 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The chloramphenicol used in making the batch for potency, pH, specific rotation, melting range, absorptivity, and crystallinity.

(b) The batch for potency.

(ii) Samples required:

(a) The chloramphenicol used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 5 containers if it is packaged in immediate containers of tin or glass, and a minimum of 20 immediate containers if it is packaged in immediate containers other than tin or glass.

(b) *Tests and methods of assay; potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a high-speed glass blender jar containing 1 milliliter polysorbate 80 and sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 2.5 micrograms of chloramphenicol per milliliter (estimated).

Subpart D—Otic Dosage Forms

§ 555.410 Chloramphenicol otic.

The requirements for certification and the tests and methods of assay for chloramphenicol otic are described under § 555.310b.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

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Sec.

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Sec.
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556.360 Lincomycin.
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556.380 Melengestrol acetate.
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556.400 Methylprednisolone.
556.410 Metoserpate hydrochloride.
556.420 Monensin.
556.430 Neomycin.
556.440 Nequinate.
556.450 Nihydrazone.
556.460 Novobiocin.
556.470 Nystatin.
556.480 Oleandomycin.
556.490 Ormetoprim.
556.500 Oxytetracycline.
556.510 Penicillin.
556.520 Prednisolone.
556.530 Prednisone.
556.540 Progesterone.
556.550 Propylparaben.
556.560 Pyrantel tartrate.
556.570 Reserpine.
556.580 Robenidine hydrochloride.
556.590 Salicylic acid.
556.600 Spectinomycin.
556.610 Streptomycin.
556.625 Solium sulfachloropyrazine monohydrate.
556.630 Sulfachlorpyridazine.
556.640 Sulfadimethoxine.
556.650 Sulfaethoxypyridazine.
556.660 Sulfamerazine.
556.670 Sulfamethazine.
556.680 Sulfanitran.
556.690 Sulfathiazole.
556.700 Sulfomyxin.
556.708 Testosterone.
556.710 Testosterone propionate.
556.720 Tetracycline.
556.730 Thiabendazole.
556.740 Tylosin.
556.750 Virginiamycin.
556.760 Zeranol.
556.770 Zoalene.

AUTHORITY: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)).

Subpart A—General Provisions

§ 556.1 General considerations; tolerances for residues of new animal drugs in food.

(a) Tolerances established in this part are based upon residues of drugs in edible products of food-producing animals treated with such drugs. Consideration of an appropriate tolerance for a drug shall result in a conclusion either that:

(1) Finite residues will be present in the edible products—in which case a finite tolerance is required; or

(2) It is not possible to determine whether finite residues will be incurred but there is reasonable expectation that they may be present—in which case a tolerance for negligible residue is required; or

(3) The drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, has been shown to induce cancer in man or animal; however, such drug will not adversely affect the animals for which it is intended, and no residue of such drug will be found by prescribed methods of analysis in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal—in which case the accepted method of analysis shall be published or cited, if previously published and available elsewhere, in this part; or

(4) It may or may not be possible to determine whether finite residues will be incurred but there is no reasonable expectation that they may be present—in which case the establishment of a tolerance is not required; or

(5) The drug is such that it may be metabolized and/or assimilated in such form that any possible residue would be indistinguishable from normal tissue constituents—in which case the establishment of a tolerance is not required.

(b) No tolerance established pursuant to paragraph (a)(1) of this section will be set at any level higher than that reflected by the permitted use of the drug.

(c) Any tolerance required pursuant to this section will, in addition to the toxicological considerations, be conditioned on the availability of a practicable analytical method to determine the quantity of residue. Such method must be sensitive to and reliable at the established tolerance level or, in certain instances, may be sensitive at a higher level where such level is also deemed satisfactory and safe in light of the toxicity of the drug residue and of the unlikelihood of such residue's exceeding the tolerance.

Subpart B—Specific Tolerances for Residues of New Animal Drugs

§ 556.20 2-Acetylamino-5-nitrothiazole.

A tolerance of 0.1 part per million is established for negligible residues of 2-acetylamino-5-nitrothiazole in the edible tissues of turkeys.

§ 556.30 Aklomide.

Tolerances are established for combined residues of aklomide (2-chloro-4-nitrobenzamide) and its metabolite (4-amino-2-chlorobenzamide) in uncooked edible tissues of chickens as follows:

(a) 4.5 parts per million in liver and muscle.

(b) 3 parts per million in skin with fat.

§ 556.40 Ampicillin.

A tolerance of 0.01 p/m is established for negligible residues of ampicillin in the uncooked edible tissues of swine and cattle and in milk.

§ 556.50 Amprolium.

Tolerances are established as follows for residues of amprolium (1-(4-amino-2-*n*-propyl - 5 - pyrimidinylmethyl)-2-picolinium chloride hydrochloride):

(a) In the edible tissues and in eggs of chickens and turkeys:

(1) 1 part per million in uncooked liver and kidney.

(2) 0.5 part per million in uncooked muscle tissue.

(3) In eggs:

(i) 8 parts per million in egg yolks.

(ii) 4 parts per million in whole eggs.

(b) In the edible tissues of calves:

(1) 2.0 parts per million in uncooked fat.

(2) 0.5 part per million in uncooked muscle tissue, liver, and kidney.

§ 556.60 Arsenic.

Tolerances for total residues of combined arsenic (calculated as As) in food are established as follows:

(a) In edible tissues and in eggs of chickens and turkeys:

(1) 0.5 part per million in uncooked muscle tissue.

(2) 2 parts per million in uncooked edible by-products.

(3) 0.5 part per million in eggs.

(b) In edible tissues of swine:

(1) 2 parts per million in uncooked liver and kidney.

(2) 0.5 part per million in uncooked muscle tissue and byproducts other than liver and kidney.

§ 556.70 Bacitracin.

Tolerances for residues of bacitracin from bacitracin, zinc bacitracin, manganese bacitracin, or bacitracin methylene disalicylate are established at 0.5 part per million (0.02 unit per gram), negligible residue, in uncooked edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and in milk and eggs.

§ 556.80 Bambermycins.

Tolerances are established for residues of bambermycins in uncooked edible tissues of chickens as follows:

(a) In muscle tissues: 0.75 part per million.

(b) In liver: 0.50 part per million.

(c) In kidney, skin, and fat of chickens: 1.00 part per million.

§ 556.90 Buquinolate.

Tolerances are established for residues of buquinolate as follows:

(a) In edible tissues of chickens:

(1) 0.4 part per million in uncooked liver, kidney, and skin with fat.

(2) 0.1 part per million in uncooked muscle.

(b) In eggs:

(1) 0.5 part per million in uncooked yolk.

(2) 0.2 part per million in uncooked whole eggs.

§ 556.100 Carbadox.

No residues of carbadox (Methyl 3-(2-quinoxalinylmethylene) carbazate-N^1, N^4-dioxide) and its metabolite (quinoxaline-2-carboxylic acid) are found in the uncooked edible tissues of swine as determined by the following method of analysis:

I. REAGENTS

A. Benzene—Distilled-in-Glass grade, Burdick and Jackson Laboratories or equivalent.

B. Ethyl acetate—Distilled-in-Glass grade, Burdick and Jackson Laboratories or equivalent.

C. n-Hexane—Distilled-in-Glass grade, Burdick and Jackson Laboratories or equivalent.

D. 1-Propanol—reagent grade, dried over molecular sieve pellets (5A).

E. Citric acid monohydrate—U.S.P., Pfizer, Inc., or equivalent.

F. Potassium hydroxide—pellets, reagent grade.

G. Sodium hydroxide—pellets, reagent grade.

H. Hydrochloric acid—reagent, A.C.S.

I. Sulfuric acid—reagent, A.C.S.
J. Sodium sulfate—anhydrous, reagent grade.
K. Quinoxaline-2-carboxylic acid—Pfizer Inc., or equivalent.
L. Propyl quinoxaline-2-carboxylate—Pfizer, Inc., or equivalent.
M. Acridine—practical grade; Matheson. Coleman and Bell or equivalent.

II. Solutions

A. 1*M* Citric acid.
B. 5*M* Sodium hydroxide.
C. 3*M* Potassium hydroxide.
D. 0.5*M* Citric acid buffer. Adjust the pH of 100 milliliters of 1*M* citric acid to pH 6.0 with 5*M* sodium hydroxide (approximately 55 milliliters), using a previously calibrated pH meter. Adjust the final volume to 200 milliliters with distilled water. Before making the final pH adjustment, cool the buffer to room temperature.
E. 1-Propanol-sulfuric acid reagent (97:3). Dilute 3 milliliters of concentrated sulfuric acid to 100 milliliters with dried, filtered, and cooled 1-propanol.
F. Acridine solution. Dissolve 1 milligram of acridine in 100 milliliters of benzene.
G. Quinoxaline-2-carboxylic acid solutions:
1. *Stock solution A.* Dissolve 1.25 milligram of quinoxaline-2-carboxylic acid in enough 1-propanol to make 100.0 milliliters (concentration 12.5 micrograms per milliliter).
2. *Stock solution B.* Dilute 1.0 milliliter of stock solution A to 100.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 0.125 microgram per milliliter).
3. *Working standard solution C.* Dilute a 2.0 milliliter aliquot of stock solution B to 10.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 25.0 nanograms per milliliter).
4. *Working standard solution D.* Dilute a 3.0 milliliter aliquot of stock solution B to 10.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 37.5 nanograms per milliliter).
5. *Working standard solution E.* Dilute a 4.0 milliliter aliquot of stock solution B to 10.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 50.0 nanograms per milliliter).
6. *Fortification solution.* Dilute 3.0 milliliters stock solution A to 250 milliliters with distilled water (concentration 150 nanograms per milliliter).
7. *Propyl quinoxaline-2-carboxylate solution.* Dissolve 1.00 milligram of propyl quinoxaline-2-carboxylate in enough ethyl acetate to make 10 milliliters (concentration 100 micrograms per milliliter).

III. Apparatus

A. Column, glass-tapered at one end, 0.9 centimeters x 21.5 centimeters, prepared from a 10-milliliter serological pipette.
B. Centrifuge tubes, heavy duty—50-milliliter graduated (60-milliliter capacity), equipped with glass stoppers, R. C. Ewald, Inc., or equivalent.
C. Centrifuge tubes—50 milliliters graduated, equipped with glass stoppers.
D. Volumetric flasks—5 10 100 and 250-milliliter capacity, glass stoppered.
E. Pipettes, automatic transfer—10 15 and 25-milliliter delivery volume.
F. Pipettes, measuring—0.1 and 0.5 milliliter delivery volume.
G. Pipettes, volumetric—1 2 3 4 and 5-milliliter delivery volume.
H. Pipette, serological—10 milliliter delivery volume.
I. Pipettes—Pasteur, disposable.
J. Propipette bulb.
K. Syringe—10 microliter capacity, Hamilton or equivalent.
L. Crystallizing dish—190 millimeter (diameter) x 100 millimeter (height), for oil bath.
M. Test tube rack.
N. Test tube mixer—Vortex mixer or equivalent.
O. Lab jack—Cenco or equivalent.
P. Thermo-stir hotplate.
Q. Magnetic stirrer bar (teflon).
R. Thermometer—centigrade, 0° to 150° C. range.
S. Knife (for cutting frozen tissue).
T. Ultraviolet light—254 nanometers and 366 nanometers.
U. Scalpel.
V. Torsion balance—style RX-1, class A, Torsion Balance Co., or equivalent.
W. Cahn electrobalance—Cahn Model C-2 or equivalent.
X. Centrifuge—International, size 2, model K, or equivalent.
Y. Rotary evaporator equipped either with a water aspirator or with a vacuum pump and condenser.
Z. Alkacid test paper.
AA. Glassine paper.
BB. Glasswool.
CC. Flask—round bottom, 29/42 ST, 250 milliliters.
DD. Flask—round bottom, 19/22 ST, 65 milliliters.
EE. Funnel—burette.
FF. Hair dryer.
GG. pH meter.
HH. Tray—instrument, stainless steel.
II. Water bath.
JJ. Precoated thin layer plates—20 x 20 centimeters; 250 micron thickness, Silica gel GF, E. Merck, Darmstadt; distributed by Brinkmann Instruments Inc., Westbury, N.Y. 11590 or equivalent.
KK. Desaga multiplate developing tanks for five 20 x 20 centimeters plates-distributed by Brinkmann instruments Inc. or equivalent.
LL. Gas-liquid chromatograph—Micro Tek 220 model instrument (or equivalent) equipped with a Ni^{63} electron affinity pulsed detector and a 0–1 MV recorder. Conditions and operating parameters for the gas-liquid chromatograph are: Isothermal column temperature, 175° C.; inlet heater, 270° C.; EC detector temperature, 275° C.; argon-methane (95:5) flowrate, 100 milliliters per minute (40 pounds per square inch); chart speed, ½ inch per minute, attentuation, 10 x 64. Electrometer pulse parameters: RF mode; voltage output, 55; pulse rate, 270 microseconds; pulse width, 3.0 microseconds.
A glass sleeve injection port liner is installed for off-column injections.
MM. Packing—3 percent OV-17 on Gas Chrom Q, 60–80 mesh, Applied Sciences Laboratories, Inc. or equivalent.
NN. Column—pyrex glass, U-tube, 6 feet (length) x 4 millimeters (inside diameter). Condition the packed column at 280° C. for at least 72 hours with argon-methane (95:5) flow, detached from the detector input.
OO. Septum—high temperature type (HT-13), Applied Sciences Laboratories, Inc. or equivalent.
PP. Detector-$Nickel^{63}$ electron capture. The voltage current profile for this detector should plateau at 30 volts or less in the DC mode when a stream of nitrogen gas is passed through the column and the electron capture detector.

IV. Procedure

A. Dissolution and hydrolysis step

Transfer 5 grams of swine tissue (freshly sliced from frozen tissue) to a 50-milliliter centrifuge tube. Add 10 milliliters of 3*M* potassium hydroxide, stopper, and place in a 100° C. silicone oil bath for 1 hour.

Note: The level of the silicone oil bath should exceed that of the tissue sample. Stopper the tubes lightly in order to allow the digestion mixture to "breath". To determine the recovery of quinoxaline-2-carboxylic acid in swine tissue at the 30 p.p.b. level, fortify 5 grams of sample with 1 milliliter of fortification solution (concentration 150 nanograms per milliliter).

B. Extraction step

1. Cool the alkaline hydrolyzate in an ice bath and acidify to ≤ 1 pH 1 (deep red to alkacid test paper) with 4 milliliters of concentrated hydrochloric acid. Add 15 milliliters of ethyl acetate to the acidified hydrolyzate, stopper, and extract by shaking for 20 seconds. Centrifuge the mixture at 1,500 revolutions per minute for 5 minutes to clarify the ethyl acetate phase. Recover the ethyl acetate phase with a blowout pipette equipped with a propipette bulb, and transfer this extract to a 60-milliliter separatory funnel equipped with teflon stopcocks. Re-extract the hydrolyzate with two additional 15-milliliter portions of ethyl acetate, and combine the organic extracts.

Note: Do not contaminate the ethyl acetate phase with interfacial material during these extractions. Quinoxaline-2-carboxylic acid is unstable in strongly acidic solutions. Continue to process these extracts through the benzene extraction and evaporation steps.

2. Add 5 milliliters of 0.5*M* citric acid buffer (pH 6.0) to the ethyl acetate extract, shake, and allow the lower phase to clarify for about 20 minutes. Collect the aqueous phase in a 50-milliliter glass-stoppered centrifuge tube. Reextract the ethyl acetate phase with an additional 5 milliliters of pH 6 buffer, wait for the aqueous phase to clarify, and combine the aqueous extracts. Acidify (≤ pH 1) the aqueous extract with 2 milliliters of concentrated hydrochloric acid, stopper, and extract with 25 milliliters of benzene. Centrifuge to clarify the benzene layer and transfer the organic phase, using a blowout pipette equipped with a propipette bulb, to a 250-milliliter round bottom flask. Repeat the extraction and centrifugation steps three times. Combine the benzene extracts (about 100 milliliters) and evaporate to near-dryness, using a rotary evaporator equipped with a water aspirator and with a water bath set at 40° C.

Note: A rotary evaporator equipped with a vacuum pump and condenser may be used at this point. These residues may be stored overnight.

C. Esterification step

Reconstitute the residue from the previous step by rinsing the walls of the round bottom flask with 2 x 2 milliliters of 1-propanol-sulfuric acid reagent; transfer each rinse with a disposable pipette to a 50-milliliter centrifuge tube. Stopper and heat the tube in a silicone oil bath at 90° C. for 1 hour. Cool the reaction mixture in an ice bath before proceeding to the following extraction step.

Note: Samples and standards may be stored overnight at room temperature in the propanol-sulfuric acid medium.

D. Extraction of the ester derivative

Add 10 milliliters of water and 15 milliliters of n-hexane to the esterification mixture. Extract and centrifuge to clarify the n-hexane phase. Transfer the n-hexane extract to a 65-milliliter round bottom flask; reextract the aqueous-propanol phase with two additional 15-milliliter portions of n-hexane. Centrifuge after each extraction and combine the n-hexane extracts. (Note: Avoid taking any of the aqueous phase in this extraction step; otherwise, the n-hexane extracts will have to be washed with 3 x 10 milliliters of water and dried over sodium sulfate.) Concentrate this solution to 0.5

milliliter, using a rotary evaporator equipped with a water aspirator and with a water bath set at 25° C. (NOTE: A rotary evaporator equipped with a vacuum pump and condenser may be used at this point.) Fortify this solution with 0.1 milliliter of acridine marker (1 milligram per 100 milliliters benzene).

NOTE: Do not store the n-hexane extracts of the propyl ester derivative overnight. Continue to process these solutions by the following thin-layer chromatography step E.

E. THIN-LAYER CHROMATOGRAPHY

1. Quantitatively transfer the concentrated n-hexane extract to the "origin" of a 20-centimeters x 20-centimeters silica gel thin-layer plate, using a disposable pipette. When pipetting this extract, streak it in a uniform band approximately 15 centimeters across and approximately 20 millimeters above the lower edge of the plate, making sure not to scratch or remove appreciable portions of adsorbent and avoiding application of the sample to the sides of the plate. The applied band should not diffuse or penetrate to the end of the silica gel layer, but should remain 10 millimeters above the lower edge of the silica gel layer. Rinse the round bottom flask (containing residual n-hexane) with three portions of approximately 0.25 milliliter each of ethyl acetate; transfer each portion with the same pipette and cover the same area of the plate as described above. Following each application of the extract and ethyl acetate washes, evaporate the solvent from the plate by directing a stream of cool air to the sample zone ("origin"). Prior to chromatographic development, place an edge (approximately 5 millimeters deep) of the thin-layer plate into a tray of ethyl acetate so that the solvent will rise through the applied sample zone to form it into a narrow band approximately 10 millimeters above the "origin." Air dry this plate before chromatographic development.

2. Place the prepared plate in a chromatographic chamber lined with blotting paper and saturated with the benzene-ethyl acetate system (85:15). Develop the plate twice in this system, maintaining straight solvent fronts and allowing the solvent front to reach the top of the plate during each irrigation. Air dry the thin-layer plate for approximately 5 minutes between the first and second irrigations. Each irrigation takes approximately 75 minutes. Developed plates should not be stored overnight. Examine the developed plate under long wavelength (366 nanometers) ultraviolet light and locate the blue fluorescent band of acridine (R_f approximately 0.5). Mark out a 12-millimeters x 20-centimeters band of silica gel encompassing an area 5 millimeters above and 7 millimeters below the center of the acridine marker and extending from one side of the plate to the other.

NOTE: The relative mobilities of propyl quinoxaline-2-carboxylate and acridine must be checked in each laboratory to determine where a 12 milliliter x 20-centimeters zone of silica gel is to be excised in order to quantitatively recover the propyl ester derivative. This may be accomplished by mixing 0.1 milliliter of acridine solution (1 milligram per 100 milliliters) with 0.4 milliliter of propyl quinoxaline-2-carboxylate (100 micrograms per milliliter) and chromatographing this solution as directed above. Examine the developed plate under long wavelength (366 nanometers) ultraviolet light and locate the blue fluorescent band of acridine (R_f approximately 0.5). Examination of the plate under short wavelength (254 nanometers) ultraviolet light locates the blue absorbing band of propyl quinoxaline-2-carboxylate (R_f approximately 0.5).

3. Reduce the sample zone to a fine powder by making a series of horizontal cuts with a scalpel. Gently transfer this powder with the aid of a stainless steel spatula to glassine paper; pour this material into a burette funnel atop a small glass column packed with a glass wool plug. Elute the adsorbent with ethyl acetate (about 6 milliliters), and collect the eluate to mark in a 5-milliliter volumetric flask. Examine this eluate by gas-liquid chromatography.

NOTE: Contamination of thin-layer chromatographic plates can be checked by gas-liquid chromatographic examination of an eluate prepared by processing a blank plate as in paragraph 1 above, starting at the point: "place an edge (approximately 5 millimeters deep) of the thin-layer plate into a tray of ethyl acetate • • •." If the plate is contaminated, examine alternate lots of precoated thin-layer plates.

F. STANDARD CURVE

Pipette 4-milliliter aliquots of quinoxaline-2-carboxylic acid working standard solutions C, D, and E, respectively, and 4-milliliter portions of 1-propanol-sulfuric acid reagent into 50-milliliter centrifuge tubes; stopper, react, extract, and concentrate as directed in the esterification and extraction steps described in subsections C and D above; however, omit the addition of acridine to the n-hexane concentrate and do not chromatograph it by thin-layer chromatography. Instead, reconstitute the n-hexane concentrate with ethyl acetate and quantitatively transfer this solution to a 5-milliliter volumetric flask to give working standard solutions C, D, and E. The final concentrations of working standard solutions C, D, and E, are 20, 30, and 40 nanograms per milliliter, respectively, and are equivalent to 20, 30, and 40 p.p.b., respectively.

G. GAS-LIQUID CHROMATOGRAPHY

Separately inject 4 microliters of each of the working standard solutions C, D, and E (prepared as described above (F) into the gas-liquid chromatograph to determine the retention time of propyl quinoxaline-2-carboxylate and the relative response of the EC detector. Construct a standard curve by plotting concentration (p.p.b.) versus peak height (millimeters).

(NOTE: The reagent blank must show no interfering gas-liquid chromatographic peaks.) The peak height of propyl quinoxaline-2-carboxylate at the 30-p.p.b. level (working standard solution D) should approximate 10 percent of full-scale deflection with a retention time of 5 minutes. Follow these injections with 4-microliter injections of the tissue eluates, allowing 20 minutes between injections to clear the instrument of background peaks.

Measure the peak heights of samples and determine their concentration (p.p.b.) by reference to the standard curve.

H. CALCULATIONS

From the standard curve and the observed peak height of quinoxaline-2-carboxylic acid in the sample, determine its concentration (p.p.b.).

§ 556.110 Carbomycin.

A tolerance of zero is established for residues of carbomycin in the uncooked edible tissues of chickens.

§ 556.120 Chlorhexidine.

A tolerance of zero is established for residues of chlorhexidine in the uncooked edible tissues of calves.

§ 556.130 Chlormadinone acetate.

No residues of chlormadinone acetate (6 - chloro - 17 - hydroxypregna - 4,6 - diene-3,20-dione acetate) may be found in the uncooked edible tissues of beef heifers and beef cows as determined by the following method of analysis:

I. *Method of analysis.* Chlormadinone acetate (CAP) is extracted from muscle, liver, and kidney with methanol or from fat with hexane. The samples are purified by liquid-liquid extraction and by column chromatography. Final measurement is made by gas-liquid chromatography.

II. *Reagents.*

A. Methanol, analytical reagent (AR).

B. Carbon tetrachloride AR.

C. Dichloromethane AR (redistilled).

D. Benzene, nanograde.

E. Hexane AR.

F. Acetonitrile AR.

G. Chloroform AR.

H. Chloroform AR containing 50 percent by volume dichloromethane AR.

I. Silica gel 0.2 to 0.5 millimeter for column chromatography, Brinkmann Institute, Inc., or equivalent.

J. Activated Alumina. Alcoa F-20, Alcoa Corp., or equivalent.

K. Sodium sulfate, anhydrous.

L. Chlormadinone acetate standard, Elanco Products Co.

III. *Apparatus.*

A. Tissue blender—Hamilton Beach Model 8, or equivalent, equipped with blender heads to fit half-pint Mason jars.

B. Centrifuge—International Model V, or equivalent, equipped to receive 250-milliliter centrifuge tubes.

C. Separatory funnels—250 milliliters.

D. Glass chromatography columns—14 x 250 millimeters.

E. Rotary vacuum evaporator—Rinco, or equivalent.

F. Evaporating flasks—300 and 125 milliliters.

G. Assorted volumetric flasks, pipettes, and graduated cylinders.

H. Gas chromatograph—Jarrell-Ash Model 28-700, or equivalent, equipped with an electron affinity cell.

I. Preparation of column packing:

Gas chrom Q (80-100 mesh)—Applied Science Laboratories, Inc., or equivalent.

XE-60 (silicone gum [nitrile] G.E.)—F and M Scientific Corp. or Applied Science Laboratories, or equivalent.

Weigh 19.7 grams of the Gas Chrom Q, transfer to a 1-liter round-botom flask and add sufficient acetone to cover the solid support. Weigh 300 milligrams of the XE-60 in a 150-milliliter beaker, dissolve in 75 milliliters of acetone, and transfer to the flask containing the solid support. Rinse beaker several times with acetone and add rinses to he flask.

Evaporate the acetone in a rotary vacuum evaporator using continuous rotation. A warm water bath (40° C.) is used to hasten the evaporation.

"Caking" of the solid may occur during the evaporation before all the acetone is removed. On continued evaporation, the solid will tumbel freely. When the coated phase tumbles freely in the flask and no odor of acetone is detected, the phase is removed from the flask. (A Morton type flask may be substituted for the round-botom flask, if intermittent rotation is used during the evaporation.)

Pour the prepared phase on a 60-mesh screen sieve and collect that portion of the phase that passes the 60-mesh screen and is retained on the 100-mesh screen. Use gentle tapping during screening step to avoid breaking of particles. Discard that portion of the phase which is retained on the 60-mesh screen and that portion which passes through the 100-mesh screen.

IV. *Standard solutions.*

A. Chlormadinone acetate standard solution, 50 micrograms per milliliter—accurately

weight 5 milligrams of standard chlormadinone acetate and transfer quantitatively to a 100-milliliter volumetric flask. Dissolve the standard and dilute to the mark with nanograde benzene. Mix the solution thoroughly.

B. Chlormadinone acetate standard solution, 1 microgram per milliliter—pipette 2 milliliters of 50 mcg./ml. from A above into a 100-milliliter volumetric flask and dilute to the mark with methanol.

NOTE: Chlormadinone acetate is relatively stable in these solutions; however, it is recommended that solution A (50 mcg./ml. in benzene) be prepared fresh every month and that solution B be prepared fresh each week.

V. *Procedure.*

A. Extraction and purification of muscle and liver sample.

1. Thoroughly grind tissue and weigh a representative 20-gram sample of tissue into a half-pint Mason jar.

2. Add 2 milliliters of methanol per gram of sample.

3. Blend the sample until uniform.

4. Transfer as much of the sample as possible to a 250-milliliter centrifuge bottle and centrifuge for 20 minutes at about 2,000 r.p.m.

NOTE: Do not rinse with additional solvent since this would introduce an unknown in the volume from which the aliquot in step 5 below is taken.

5. Immediately transfer 30 milliliters of supernatant liquid (measured with a graduated cylinder) to a 250-milliliter separatory funnel.

NOTE: The aliquot should be taken soon after centrifuging. Otherwise the solids tend to expand and reduce the amount of supernate which can be decanted.

NOTE: Smaller aliquots may be taken in cases where the liquid yield is less than 30 milliliters. In a series of samples the calculations may be expedited by using a uniform aliquot size for all samples and standard recoveries in the series.

6. Extract the supernate from step 5 above about 20 seconds with 30 milliliters of carbon tetrachloride (CCl_4). Transfer the CCl_4 fraction (lower phase) to a 300-milliliter evaporating flask. Extract the aqueous methanol phase with two more 30-milliliter portions of CCl_4 and combine the extracts. *Stopping place.* Evaporate the combined CCl_4 fractions to dryness by rotary vacuum evaporation using a water bath at about 50° C.

NOTE: If the CCl_4 fractions are cloudy or appear to contain emulsion, the CCl_4 should be filtered through anhydrous sodium sulfate into the evaporating flask.

7. Prepare a silica gel column for each sample as follows:

a. Place about 10 milliliters of dichloromethane (CH_2Cl_2) into a 14 x 250-millimeter glass chromatographic column. Insert a glass wool pledget and tamp with a glass stirring rod to eliminate air bubbles.

b. Add 10 milliliters (about 4.8 grams) of silica gel to the column through a powder funnel.

c. Add about 5 milliliters of dichloromethane (CH_2Cl_2) to the top of the column and stir the silica gel with a stirring rod to eliminate air bubbles.

d. After the silica gel has settled, add about 2 centimeters of anhydrous sodium sulfate to the column layering it carefully to avoid disturbance of the silica gel surface.

e. Drain the CH_2Cl_2 to the top of the sodium sulfate.

8. Dissolve the sample from step 6 above in 10 milliliters of CH_2Cl_2 and charge the chromatographic column with the solution at a flow rate of about 3 milliliters per minute.

9. Rinse the flask with 10 milliliters of CH_2Cl_2 and transfer the rinse to the column after all solution from step 8 above has passed into the column.

10. Develop the column with 75 milliliters of 50/50 dichloromethane/chloroform (discard this fraction).

11. Place a 125-milliliter evaporating flask into position to receive the column eluate

12. Elute the column with 75 milliliters of chloroform.

13. Evaporate the eluate to dryness by rotary evaporation.

14. Transfer the sample to a 15-milliliter glass sample vial with the aid of about 5 milliliters of acetone (or chloroform) in 2 or 3 portions. Evaporate the acetone under a stream of compressed air and close the vial with an aluminum-lined screwcap.

15. Dissolve the sample in 1.0 milliliter of nanograde benzene.

16. Assay the sample by gas-liquid chromatography as described in E below.

B. Extraction and purification of kidney samples.

1. Process kidney samples exactly as described for muscle and liver in A, steps 1 through 6, above.

2. Prepare an alumina column for each sample as follows:

a. Place about 10 milliliters of CH_2Cl_2 into a 14 x 250-millimeter glass chromatographic column. Insert a glass wool pledget and tamp with a glass stirring rod to eliminate air bubbles.

b. Add 10 milliliters of alumina to the column through a powder funnel.

c. Add about 5 milliliters of CH_2Cl_2 to the top of the column and stir the alumina with a stirring rod to eliminate air bubbles.

d. After the alumina has settled, add about 2 centimeters or anhydrous sodium sulfate to the column, layering it carefully to avoid disturbance of the alumina surface.

e. Drain the CH_2Cl_2 to the top of the sodium sulfate.

3. Dissolve the kidney sample in 10 milliliters of CH_2Cl_2 and charge the chromatographic column with the solution at a flow rate of about 3 milliliters per minute.

4. Rinse the flask with 10 milliliters of CH_2Cl_2 and transfer the rinse to the column after all solution from step 3 above has passed into the column.

5. Develop the column with 75 milliliters of CH_2Cl_2 and discard this fraction.

6. Place a 125-milliliter evaporating flask into position to receive the column eluate.

7. Elute the column with 75 milliliters of chloroform.

8. Continue exactly as in steps 13 through 16 in A above.

NOTE: The suitability of each lot of alumina should be evaluated prior to its use for experimental samples. This is done by assaying duplicate 1-microgram chlormadinone acetate standard samples by the alumina column procedure as described in steps 2 through 7 above. The sample is then evaporated, dissolved in 1 milliliter of benzene, and subjected to gas chromatographic measurement. Percent recovery as compared to a 1 mcg./ml. standard should be 90 to 100 percent.

C. Extraction and purification of fat samples.

1. Weigh a representative 15-gram sample of fat into a 250-milliliter beaker.

2. Warm the fat on a steam bath until the sample melts or becomes semisolid.

3. Dissolve the fat in 125 milliliters of hexane and allow the sample to cool to room temperature. Mix the sample with a glass stirring rod to effect solution of the fat.

4. Prepare a funnel with approximately a 1½-inch bed of anhydrous sodium sulfate. Pass the hexane solution of fat through the sodium sulfate into a 250-milliliter separatory funnel.

NOTE: This step removes connective tissue and other hexane insoluble materials.

5. Wash the sodium sulfate with two 15-milliliter portions of hexane.

6. Extract the hexane fraction about 20 seconds with 30 milliliters of acetonitrile. Pass the acetonitrile (lower phase) through a sodium sulfate bed into a 300-milliliter evaporating flask.

7. Repeat step 6 above with 3 additional 30-milliliter portions of acetonitrile and combine the extracts.

8. Wash the sodium sulfate with 10 milliliter of acetonitrile and evaporate the acetonitrile fraction to dryness by rotary vacuum evaporation.

9. Dissolve the sample in 10 milliliters of dichloromethane and purify by silica gel column chromatography exactly as described in steps 7 through 14 under A above.

10. Assay the sample by gas-liquid chromatography as described in E below.

D. Preparation of control and standard recovery samples. If control tissues are available, one control and one standard recovery sample are assayed with each day's experimental samples. Control tissues are assayed exactly as described in A, B, and C above. Standard recovery samples are prepared by fortifying control tissues with chlormadinone acetate at a level of 0.05 part per million as follows:

1. Muscle, liver, and kidney—weigh 20 grams of tissue into a half-pint Mason jar and add 1.0 milliliter of a methanol solution containing 1 mcg./ml. chlormadinone acetate (standard solution B).

2. Fat—weigh 15 grams of fat into a 250-milliliter beaker and add 0.75 milliliter of 1 mcg./ml. standard solution B.

NOTE: A 1-milliliter measuring pipette graduated in 0.01-milliliter increments is ordinarily used for this purpose.

3. Process the standard recovery exactly as in A, B, and C above.

E. Measurement. Samples from A, B, and C above are measured by gas-liquid chromatography (GLC) using an instrument equipped and adjusted as described in H below.

1. Prepare a 1-mcg./ml. chlormadinone standard in benzene by pipetting 1 milliliter of standard solution B into a sample vial, evaporating to dryness under compressed air, and redissolving in 1 milliliter of nanograde benzene.

2. Condition the gas chromatographic column each day prior to assay of experimental samples.

a. Inject 1 microliter of the 50 mcg./ml. standard (solution A) into the GLC instrument.

b. Inject 1-microliter portions of nanograde benzene until the chromatogram shows no chlormadinone acetate peak.

3. Adjust the GLC instrument to give a peak height of about 3 centimeters (2.5 to 3.5) upon injection of 1 microliter of 1-mcg./ml. standard from step 1 above).

NOTE: The injection technique is "injection by difference" using plug injection as described in the "U.S. Health, Education, and Welfare Pesticide Analytical Manual," vol. I, July 1965, section 2.17, page 7.

4. Inject repeated 1-microliter samples of the 1-mcg./ml. standard (step 1) until successive injections show a reproducibility of peak height of about ±5 percent.

5. Inject 1 microliter of the 0.05 part per million standard recovery sample until successive injections shows a reproducibility of peak height of about ±5 percent.

6. Inject 1 microliter of each experimental sample.

NOTE: If an experimental sample gives a response in excess of twice that of the 1-mcg./ml. standard, the sample should be diluted with benzene and reassayed. This will

necessitate making the appropriate changes in the calculation.

7. Repeat injection of the 0.05 part per million standard recovery sample after each 4 or 5 experimental samples to compensate for slight changes in instrument parameters.

NOTE: If a standard recovery sample is not prepared, use periodic injections of the 1-mcg./ml. standard.

8. Measure the peak height of chlormadinone acetate in centimeters for all samples and standards.

F. Calculation of chlormadinone acetate in muscle, liver, and kidney.

1. Percent recovery $=\frac{\text{pH recovery sample}}{\text{pH direct standard}}\times 1.8\times 100$, where pH=peak height.

2. Calculation of residue in parts per million (mcg./g.) when standard recovery at 0.050 part per million are run with assay samples:

$$\frac{\text{Sample pH}}{\text{Standard recovery pH}}\times 0.05 \text{ mcg./g.}=\text{mcg./g. chlormadinone acetate in assay sample.}$$

This computation is recommended since the assay samples are compared directly to the 0.050-part per million standard recovery. This practice compensates for recovery factors encountered and aliquots taken during the assay procedure.

3. When a standard recovery sample is not prepared with the assay samples:

$$\text{Part per million}=\frac{\text{pH sample}}{\text{pH direct standard}}\times 1.0 \text{ mcg./ml.}\times\frac{\text{1.0 ml. benzene}}{\text{30 ml. aliquot}}\times\frac{(2.0\times\text{sample weight}+0.7\times\text{sample weight})}{\text{Sample weight}}$$

This equation reduces to:

$$\frac{\text{pH sample}}{\text{pH direct standard}}\times 0.09=\text{Parts per million of chlormadinone acetate in assay sample.}$$

The above equation is based on the assumption that muscle, liver, and kidney contain 70 percent water. Further, the total volume (milliliters) of liquid obtained after blending is assumed to be 2.7 times the tissue weight; for example, 2 milliliters of methanol per gram of tissue and 0.7 milliliter of water per gram of tissue. These assumptions are not absolutely correct because of slight differences in the water content of tissues and the slight volume change which occurs when methanol and water are combined; however, the assumptions are considered to be accurate enough for practical purposes.

G. Calculations of chlormadinone acetate in fat. Since the fat samples are sampled by exhaustive extraction rather than by aliquot, a different calculation is necessary.

1. Percent recovery $=\frac{\text{pH recovery sample}}{\text{pH direct standard}}\times 1.33\times 100$.

2. Calculation of residue in parts per million when a standard recovery sample at 0.05 part per million is included:

$$\frac{\text{pH sample}}{\text{pH standard recovery}}\times 0.05 \text{ mcg./g.}=\text{mcg./g. chlormadinone acetate.}$$

3. Calculation of residue when no standard recovery is included:

$$\frac{\text{pH sample}}{\text{pH direct standard}}\times\frac{1.0 \text{ mcg./ml.}}{1.0 \text{ ml.}}\times\frac{1}{\text{Sample weight}}=\text{mcg./chlormadinone acetate.}$$

H. Gas-liquid chromatography.

1. Instrument parameters.

a. Jarrell-Ash Model 28-700.

Column—16 inches of packing in 4-millimeter i.d. borosilicate glass.

Packing—1.5 percent XE-60 on Gas Chrom Q80/100 mesh.

Column temperature—220° C.

Cell temperature—210° C.

Injector temperature—250° C.

Electrometer range—1×10^{-9} amperes full scale.

Detector—electron affinity with plane parallel electrodes.

Detector voltage — to give 70 percent of standing current.

Carrier gas—prepurified nitrogen 170 ml./min.

b. F and M Model 402.

Column—16 inches of packing in 4-millimeter i.d. borosilicate glass column.

Column packing—1.5 percent XE-60 on Gas Chrom Q80/100 mesh.

Detector — electron capture — tritium source.

Column temperature—250° C.

Cell temperature—200° C.

Flash Heater—305° C.

Pulse—150 μsec.

Range and attenuation—to obtain a peak height of 2.5 to 3.5 centimeters with injection of 1.0 μl of a 1.0 mcg./ml. standard in benzene.

Carrier gas—argon/methane 90/10.

Gas flow—190-200 milliliters per minute.

Under these conditions, the retention time of chlormadinone acetate is approximately 5 minutes.

§ 556.140 Chlorobutanol.

A tolerance of zero is established for residues of chlorobutanol in milk from dairy animals.

§ 556.150 Chlortetracycline.

Tolerances are established for residues of chlortetracycline in food as follows:

(a) In edible tissues and in eggs of chickens, turkeys, and ducks:

(1) 4 parts per million in uncooked kidney.

(2) 1 part per million in uncooked muscle, liver, fat, and skin.

(3) Zero in eggs.

(b) In edible tissues of swine:

(1) 4 parts per million in uncooked kidney.

(2) 2 parts per million in uncooked liver.

(3) 1 part per million in uncooked muscle.

(4) 0.2 part per million in uncooked fat.

(c) In edible tissues of calves:

(1) 4 parts per million in uncooked liver and kidney.

(2) 1 part per million in uncooked muscle and fat.

(d) In edible tissues of beef cattle and nonlactating dairy cows:

(1) 0.1 part per million in uncooked kidney, liver, and muscle.

(2) Zero in uncooked fat.

(e) Zero in milk.

§ 556.160 Clopidol.

Tolerances for residues of clopidol (3,5 - dichloro-2,6-dimethyl-4-pyridinol) in food are established as follows:

(a) In cereal grains, vegetables, and fruits: 0.2 part per million.

(b) In chickens and turkeys:

(1) 15 parts per million in uncooked liver and kidney.

(2) 5 parts per million in uncooked muscle.

(c) In cattle, sheep, and goats:

(1) 3 parts per million in uncooked kidney.

(2) 1.5 parts per million in uncooked liver.

(3) 0.2 part per million in uncooked muscle.

(d) In swine: 0.2 part per million in uncooked edible tissues.

(e) In milk: 0.02 part per million (negligible residue).

§ 556.170 Decoquinate.

Tolerances are established for residues of decoquinate in the uncooked edible tissues of chickens as follows:

(a) 2 parts per million in tissues other than skeletal muscle.

(b) 1 part per million in skeletal muscle.

§ 556.180 Dichlorvos.

A tolerance of 0.1 part per million is established for negligible residues of dichlorvos (2,2-dichlorovinyl dimethyl phosphate) in the edible tissues of swine.

§ 556.190 Diethylstilbestrol.

(a) No residues of diethylstilbestrol may be found in the uncooked edible tissues of beef cattle and sheep after slaughter or in any food yielded by or derived from the living animal.

(b) The method of examination prescribed for the quantitative determination of estrogenic activity is the method of E. J. Umberger, G. H. Gass, and J. M. Curtis published in "Endocrinology," volume 63, page 806 (1958).[1]

(c) The method of examination prescribed for the qualitative identification of estrogenic activity as diethylstilbestrol is as follows:

(1) (i) Extract the diethylstilbestrol with alkali from a suitably prepared sample of fat dissolved in isooctane; or

(ii) Extract the diethylstilbestrol with ethyl alcohol from lean meat or liver, followed by hydrolysis of the alcohol extractive with dilute hydrochloric acid.

(2) Either of the solutions of diethylstilbestrol described in paragraph (c) (1) of this section is next extracted with

[1] Copies may be obtained from: Food and Drug Administration, Bureau of Foods, 200 C St. SW., Washington, DC 20204.

(3) The chloroform extractive of diethylstilbestrol is then extracted with 1 percent sodium hydroxide, and the resulting solution is acidified.

(4) The hormone is reextracted from the acidified solution with chloroform. If the solution is colored, the extraction procedures may be repeated.

(5) The chloroform is evaporated and the remaining residue is dissolved in a suitable volume of methyl alcohol for identification of the diethylstilbestrol, as follows:

(i) Impregnate Whatman No. 1 filter paper with a solution of 40 percent formamide in methyl alcohol, blot it lightly, and dry for 5 minutes.

(ii) Spot an aliquot of the methyl alcohol solution on the paper.

(iii) Similarly, spot an aliquot of methyl alcohol solution of Reference Standard diethylstilbestrol for identification comparison.

(iv) Place the paper in a chromatographic tank and develop, using the continuous ascending technique, either with the solvent system heptane: toluene::1:4 for 2.5 hours, or the solvent system cyclohexene:cyclohexanol::98:2 for 45 minutes.

(v) Remove the paper from the tank and, while still wet, irradiate it with ultraviolet light from a 15-watt germicidal lamp for 1 minute.

(vi) Observe fluorescence through a black-light viewing apparatus.

§ 556.200 Dihydrostreptomycin.

A tolerance of zero is established for residues of dihydrostreptomycin in uncooked edible tissues of calves, in milk from dairy animals, and in any food in which such milk has been used.

§ 556.210 Dimetridazole.

A tolerance of zero is established for residues of dimetridazole in the uncooked edible tissues and eggs of turkeys.

§ 556.220 3,5-Dinitrobenzamide.

No residues of 3,5-dinitrobenzamide may be found in the uncooked edible tissues of chickens as determined by the following method of analysis:

I. *Method of analysis—3,5-dinitrobenzamide.* A method for 3,5-dinitrobenzamide (3,5-DNBA) in chicken tissues is described with a cleanup step that removes most of the interfering materials, thus allowing uncompensated measurements to be read. The 3,5-DNBA is extracted from the sample with acetone and chloroform and prepared for chromatography by removing the aqueous phase in a separatory funnel and the solvents in a flash evaporator. The extract residue is chromatographed on alumina to remove several lipid components and residues of other drugs. The benzamide eluate is passed through a column of Dowex-50 resin, or equivalent, to remove arylamines; for example, 3-amino-5-nitrobenzamide. The 3,5-DNBA fraction is reduced, after removal of alcohol, with $TiCl_3$ in basic solution to an arylamine, presumably 3,5-diaminobenzamide. The reduced fraction is placed on another Dowex-50 column, most of the interfering substances are removed with washings of alcohol and water, and the arylamine residue is eluted with 4*N* HCl. Colorimetric measurement is made in a 100-millimeter cell at 530 millimicrons after reacting the residue with Bratton-Marshall reagents.

II. *Reagents.* A. Acetone.

B. Acetyl - (*p* - nitrophenyl) -sulfanilamide (APNPS) standard—melting point range 264° C.–267° C. Weigh and transfer 10 milligrams of APNPS to a 100-milliliter flask, dissolve and dilute to volume with acetone.

C. Alumina—activated F–20, 80–200 mesh, Aluminum Co. of America, or equivalent substance.

D. Ammonium sulfamate.

E. Ammonium sulfamate solution—1.25 grams of ammonium sulfamate per 100 milliliters of water. Refrigerate when not in use. Prepare fresh weekly.

F. Cation-exchange resin—Dowex 50W–X8, 200–400 mesh, Baker Analyzed Reagent, or equivalent, prepared as follows:

1. Place 500 grams of resin into a 3-liter beaker.

2. Add 2,000 milligrams of 6*N* HCl.

3. Heat and stir while on a bath at 80° C. for 6 hours. Discontinue heating and continue stirring overnight.

4. Filter the resin on a Buchner funnel (24 cm.) fitted with Whatman No. 1 paper.

5. Wash the resin bed with four 500-milliliter portions of 6*N* HCl.

6. Wash the resin bed with 500-milliliter portions of deionized water until the effluent has a pH or 5 of higher.

7. Wash the resin bed with three 400-milliliter portions of specially denatured alcohol 3A. Drain thoroughly.

8. Make a slurry of resin in 1,250 milliliters of specially denatured alcohol 3A.

G. Chloroform.

H. Coupling reagent—0.25 gram of *N*-1-naphthyl-ethylenediamine dihydrochloride per 100 milliliters of water. Refrigerate when not in use. Prepare fresh weekly.

I. 3,5-Dinitrobenzamide (3,5-DNBA standard). Add to boiling specially denatured alcohol 3A until a saturated solution is obtained and treat with activated carbon, filtered and crystallize by cooling to room temperature. The 3,5-DNBA therefrom is treated a second time with activated carbon and then recrystallized three more times from specially denatured alcohol 3A. The third crystallization is washed with diethyl ether and dried in a vacuum desiccator, melting point range 185° C.–186° C.

J. Ethyl alcohol—absolute, A.C.S.

K. Eluting reagent A. The formula and volume required in procedure step V–D is dependent on the adsorptive strength of the Al_2O_3. For each lot Al_2O_3, make the following test:

1. Prepare a column (see procedure step V–D for determining formula and volume to eluting reagent A).

2. Transfer 1 milliliter of APNPS standard (100 micrograms per milliliter) in 75 milliliters of chloroform to the column.

3. Wash the column with 100 milliliters of chloroform and discard the eluate.

4. Pass through 100 milliliters of solution consisting of specially denatured alcohol 3A and ethyl alcohol 1:1 (volume to volume). Collect one 50-milliliter and five 10-milliliter portions; these make up the first, second, third, fourth, fifth, and sixth portions of eluate.

5. Place in beakers under a stream of air on a water bath (90° C.) until the solvents are evaporated.

6. Add 10 milliliters of 4*N* HCl to each, cover with watch glasses and heat (90° C.) for 30 minutes; cool to room temperature.

7. Add the Bratton-Marshall reagents.

8. All fractions show a slight color. Note the portion containing the first significant increase in pink color.

a. If the color increases in the second, third, or fourth portions of eluate, the formula in procedure step V–D is suitable and, depending on the portion, 45, 55, or 65 milliliters, respectively, should be used in procedure step V–D4. Thereby, the APNPS is retained on the column and the benzamides are eluted.

b. If the color increases in the first portion, the eluting strength of the reagent is too strong. Return the test, substituting 1:4 (volume to volume) in procedure step V–D4. If 1:4 (volume to volume) is too strong, rerun with ethyl alcohol in procedure step V–D. If none of these are suitable, another lot of Al_2O_3 should be used.

c. If the color increases in the fifth or sixth portion, the eluting strength of the reagent is too weak. Rerun the test, substituting in procedure step V–D4, respectively, 4:1 (volume to volume), specially denatured alcohol 3A: methyl alcohol, 4:1 (volume to volume), until a suitable formula is found. If none of these are suitable, another lot of Al_2O_3 should be used.

L. Hydrochloric acid, 4*N*. Add two volumes of water to one volume of HCl.

M. Diatomaceous earth—Hyflo Super Cel, Johns-Manville Co., or equivalent substance.

N. *N*-1-Naphthylethylenediamine dihydrochloride.

O. Sodium hydroxide solution, 10*N*. Dissolve 100 grams of sodium hydroxide in water and dilute to 25 milliliters.

P. Sodium nitrite solution—0.25 grams of sodium nitrite per 100 milliliters of water. Refrigerate when not in use. Prepare fresh weekly.

Q. Specially denatured alcohol, formula 3A–100 parts of 190-proof ethyl alcohol plus 5 parts of commercial methyl alcohol.

R. Titanium(ous) chloride—20 percent solution.

III. *Special apparatus.* A. Absorption cells—Beckman No. 75195 matched set of two cylindrical silica cells with 100 millimeter optical length, or equivalent cells.

B. Autotransformer—type 500B, or equivalent. To regulate speed of mixer.

C. Centrifuge.

D. Centrifuge tubes—50-milliliter size with glass stopper.

E. Chromatography tubes—Corning No. 38460, 20 millimeters x 400 millimeters and having a tapered 29/42 joint with coarse, fritted disc, or equivalent tubes.

F. Evaporator—vacuum, rotary, thin film.

G. Ion-exchange column—as described by Thiegs et al. in "Determination of 3-amino-5-nitro-o-toluamide (ANOT) in chicken tissues" published in "Journal of Agricultural and Food Chemistry," volume 9, pages 201–204 (1961).

H. Glycerol manostat. For regulating pressure on columns: To Al_2O_3 columns, 15-inch head pressure; to ion-exchange columns, 30-inch head pressure.

I. Motor speed control. For regulating speed on 1-quart blendor.

J. Volumetric flasks—50 milliliter size, actinic ware.

K. Mixer—Vortex Jr. Model K–500–1, Scientific Industries, Inc., or equivalent mixer.

L. One-quart blendor.

M. Water bath (45° C.–50° C.).

N. Water bath (90° C.).

IV. *Standard curve.* A. 1. Weigh 100 milligrams of 3,5-DNBA and transfer to a 1-liter volumetric flask with acetone.

2. Dissolve and dilute with acetone to volume.

3. Dilute 1 milliliter to 100 milliliters.

4. Add 5.0 milliliters of water to each of six centrifuge tubes.

5. Add standard to each of the tubes to contain one of the following amounts: 0.0, 1.0 2.0, 3.0, 5.0, and 10.0 micrograms of 3,5-DNBA.

B. Prepare each tube for colorimetric measurement as follows:

1. Place the tube in a hot water bath (90° C.) until 5.0 milliliters remain. Cool to room temperature.

2. While mixing on Vortex mixer, or equivalent, regulated with an autotransformer, add 2 drops of $TiCl_3$ and 4 drops of 10*N* NaOH. Continue mixing until chalky-white in appearance.

3. Add 2 milliliters of HCl, mix, and allow to stand for 5 minutes.

4. Transfer to 50-milliliter volumetric flask and dilute with 4*N* HCl to 40–45 milliliters.

5. Cool to 0° C.–5° C. by placing in a freezer or ice bath.

6. Perform the Bratton-Marshall reaction in subdued light as follows:

a. Add 1 milliliter of sodium nitrite reagent, mix, and allow to stand for 1 minute.

b. Add 1 milliliter of ammonium sufamate reagent, mix, and allow to stand for 1 minute.

c. Add 1 milliliter of coupling reagent, mix, and allow to stand for 10 minutes.

d. Dilute to volume with 4*N* HCl.

C. Perform colorimetric measurement at 530 millimicrons as follows:

1. Fill two matched 100-millimeter cells with 4*N* HCl and place into spectrophotometer.

2. Adjust dark current.

3. Adjust to zero absorbance.

4. Replace acid in cell of sample side of compartment with standard to be measured.

5. The standard curve should be run five different times. Plot equivalent concentration in tissue versus mean absorbance at each concentration. If computer is available, a better procedure is to calculate the equation of the standard curve by means of least squares.

V. *Procedure.* A. Extraction. 1. Mince 350 grams of tissue in a 1-quart blending jar for 3 minutes. Use samples obtained from either freshly killed or quickly frozen birds. The latter should be analyzed as soon as thawed. For fibrous meats (for example, muscle, skin) put through a meat grinder before mincing.

2. Weigh 100±0.5 grams of each replicate sample in a 150-milliliter beaker. Analyze each sample in triplicate and average the results. Reproducibility of ±10 percent between such analyses has been obtained.

3. Transfer the sample to a 1-quart blendor jar. For kidney and liver tissues, make a slurry with acetone in the weighing beaker. Transfer with several rinses of acetone.

4. Blend the sample for 5 minutes with 250 milliliters of acetone and a 100-milliliter beakerful of diatomaceous earth.

5. Filter through a Buchner funnel containing a wetted Whatman No. 5 filter paper (12.5 cm.) into a 1-liter suction flask.

6. Rinse the blendor jar into the funnel with three 25-milliliter portions of acetone.

7. Transfer the pulp and paper from the funnel to the aforementioned blendor jar.

8. Add 250 milliliters of chloroform.

9. Blend for 3 minutes.

10. Filter through the aforementioned apparatus of procedure step V–A5. For rapid filtration of skin and blood samples, prepare funnel by adding diatomaceous earth and tamping evenly over paper to a thickness of 3 to 5 millimeters.

11. Rinse the blendor jar into the funnel with three 25-milliliter rinses of chloroform.

B. Phasic separation. 1. Pour the combined filtrates into a 1-liter separatory funnel.

2. Rinse the suction flask twice with 25 milliliters of chloroform.

3. Mix the funnel contents by gently rocking and swirling for 30 seconds.

4. Let stand 10 minutes to allow phases to separate.

a. The upper (aqueous) phase (30 to 50 milliliters) is not always emulsion-free. Losses from emulsions have not been significant.

b. If an upper (aqueous) phase does not appear, add an additional 100 milliliters of chloroform and 10 milliliters of water and repeat procedure step V–B3.

5. Withdraw the lower phase into a 1-liter round-bottom flask, and discard upper phase. Withdraw nearly all of the lower phase, let stand for 2 to 3 minutes, then withdraw the remainder.

C. Evaporation. Attach the flask on a thin-film rotary evaporator connected to a vacuum supply, and place in a water bath maintained at 45° C.–50° C. until an oily residue remains. Do not overheat the sample or allow to go to dryness.

D. Adsorption chromatography. 1. Prepare a chromatography column using a column with calibrated etchings to indicate appropriate adsorbent and solvent levels as follows:

a. Fill tube to a depth of 60 millimeters with Al_2O_3.

b. Tap walls gently with hands.

c. Add anhydrous sodium sulfate to an additional depth of 25 millimeters.

d. Wet and wash column with 50 milliliters of chloroform.

i. During chromatography, make each addition to the tube when the liquid level has reached the top of the sodium sulfate layer.

ii. Increase the percolation rates by applying a slight air pressure to the top of the column.

2. Transfer the residue from procedure step V–C to the column with four 15-milliliter rinses of chloroform. Then rinse the walls of the tube and sodium sulfate layer with three 5-milliliter portions of chloroform. Percolation rate: 15 to 25 milliliters per minute. No color from sample should be seen in sodium sulfate layer after final rinse.

3. Wash column with 100 milliliters of chloroform. Discard eluate.

4. Add 75 milliliters of eluting reagent A and collect eluate A in a 250-milliliter beaker for cation-exchange chromatography.

a. Refer to "Eluting reagent A" under "Reagents" (II–K) for determining formula and volume.

b. Percolation rate: 8 to 12 milliliters per minute.

E. Cation-exchange chromatography—No. 1. 1. Prepare an ion-exchange column as follows:

a. Add a uniform slurry of resin to the column to obtain a 4 to 5 centimeter bed depth after settling.

i. Obtain a uniform slurry using a magnetic stirrer. To add the required amount of resin, calibrate the slurry and transfer it with a 10-milliliter pipette to deliver a reproducible volume.

ii. Increase the flow rate to 2 to 4 milliliters per minute by applying air pressure to the column. A glycerol manostat adjusted to 30 inches and attached between an air supply and column provides adequate pressure.

b. Wash the resin with 10 milliliters of eluting reagent A. Discard eluate.

2. Pass eluate A from procedure step V–D4 through the column. Collect in a 250-milliliter beaker.

3. Pass 50 milliliters of specially denatured alcohol 3A through the column. Combine with the eluate of procedure step V–E2.

F. Reduction. 1. Place the eluate A fraction from procedure step V–E3 on a hot water bath (90° C.) and evaporate with a stream of air until 5 to 10 milliliters remain. Do not overheat the sample or allow the sample to go to dryness.

2. Transfer to centrifuge tube and rinse beaker three times with 3 milliliters of specially denatured alcohol 3A.

3. Evaporate on a hot water bath (90° C.) under a stream of air until alcohol has evaporated. Do not overheat the sample or allow the sample to go to dryness.

4. Remove the tube from the water bath and immediately add 5.0 milliliters of water.

5. While mixing, add 2 drops of titanium chloride and 4 drops of 10*N* sodium hydroxide. Continue mixing until greyish color disappears.

a. Mix on Vortex Jr. mixer, or equivalent, regulated with autotransformer.

b. Precipitate of insoluble tissue substances and white titanium salts is present after reduction is complete.

6. Dilute to 50 milliliters with specially denatured alcohol 3A and mix.

7. Centrifuge for 5 minutes at 2,000 r.p.m.

G. Cation-exchange chromatography—No. 2. 1. Prepare resin column by procedure step V–E.

2. Pass the centrifugate of procedure step V–F7 through column. Use three rinses of specially denatured alcohol 3A, each 5 milliliters, to aid in transferring of sample.

3. Pass 50 milliliters of specially denatured alcohol 3A through the column.

4. Pass 50 milliliters of deionized water through the column.

5. Elute arylamine residue from the resin with 40 to 43 milliliters of 4*N* HCl into a 50-milliliter volumetric flask (actinic ware) for 3,5-DNBA analysis. Avoid direct sunlight. The arylamine has been found to be photosensitive.

H. Color development and measurement. 1. Cool to 0° C.–5° C. by placing in a freezer or ice bath.

2. Perform the Bratton-Marshall reaction in subdued light as follows:

a. Add 1 milliliter of sodium nitrite reagent, mix, and allow to stand for 1 minute.

b. Add 1 milliliter of ammonium sulfamate reagent, mix, and allow to stand for 1 minute.

c. Add 1 milliliter of coupling reagent, mix, and allow to stand for 10 minutes.

d. Dilute to volume with 4*N* HCl.

3. Perform colorimetric measurement at 530 millimicrons as follows:

a. Fill two matched 100-millimeter cells with 4*N* HCl and place into instrument.

b. Adjust dark current.

c. Adjust to zero absorbance.

d. Replace acid in cell of sample side of compartment with sample to be measured.

e. Record absorbance observed.

I. Calculations. Determine parts per billion (observed) from the standard curve.

§ 556.230 Erythromycin.

Tolerances for residues of erythromycin in food are established as follows:

(a) 0.1 part per million (negligible residue) in uncooked edible tissues of swine.

(b) Zero in the uncooked edible tissues of beef cattle and in milk.

(c) 0.025 part per million in uncooked eggs.

(d) 0.125 part per million (negligible residue) in uncooked edible tissues of chickens and turkeys.

§ 556.240 Estradiol benzoate.

(a) No residues of estradiol benzoate may be found in the uncooked edible tissues of heifers, lambs, and steers.

(b) The method of examination prescribed for the quantitative determination of estradiol benzoate is as follows: Incorporate the finely ground tissues in the diet of immature mice, and assay by the mouse uterine weight method of E. J. Umberger, G. H. Gass, and J. M. Curtis, published in "Endocrinology." Volume 63, page 806 (1958).[1]

[1] See footnote on p. 13950.

§ 556.250 Estradiol monopalmitate.

(a) No residues of estradiol monopalmitate may be found in the uncooked edible tissues of chickens.

(b) The method of examination prescribed for the quantitative determination of estradiol monopalmitate is as follows: Incorporate finely ground tissues of the treated chickens in the diet of immature mice and assays by the mouse uterine weight method of E. J. Umberger, J. H. Gass, and J. M. Curtis published in "Endocrinology," volume 63, page 806 (1958).[1]

§ 556.260 Ethopabate.

Tolerance for residues of ethopabate converted to metaphenetidine are established in the edible tissues of chickens as follows:

(a) 1.5 parts per million in uncooked liver and kidney.

(b) 0.5 part per million in uncooked muscle.

§ 556.270 Ethylenediamine.

A tolerance of zero is established for residues of ethylenediamine in milk.

§ 556.280 Furaltadone.

A tolerance of zero is established for residues of furaltadone in milk of dairy cows.

§ 556.290 Furazolidone.

A tolerance of zero is established for residues of furazolidone in the uncooked edible tissues of swine.

§ 556.300 Gentamicin sulfate.

A tolerance of 0.1 part per million is established for negligible residues of gentamicin sulfate in the uncooked edible tissues of turkeys.

§ 556.310 Haloxon.

A tolerance of 0.1 part per million is established for negligible residues of haloxon (3-chloro-7-hydroxy-4-methylcoumarin bis(2-chloroethyl) phosphate) in the edible tissues of cattle, sheep, and goats.

§ 556.320 Hydrocortisone.

A tolerance is established for negligible residues of hydrocortisone (as hydrocortisone sodium succinate or hydrocortisone acetate) in milk at 10 parts per billion.

§ 556.330 Hygromycin B.

A tolerance of zero is established for residues of hygromycin B in or on eggs and the uncooked edible tissues of swine and poultry.

§ 556.340 Ipronidazole.

No residues of ipronidazole (2-isopropyl-1-methyl-5-nitroimidazole) and its metabolite (1-methyl-5-nitroimidazole-2-isopropanol) are found in the uncooked edible tissues of turkeys as determined by the following method of analysis:

[1] Copies may be obtained from: Food and Drug Administration, Bureau of Foods, 200 C St. SW., Washington, DC 20204.

I. METHOD OF ANALYSIS

A. The assay procedure is suitable for the recovery and analysis of ipronidazole (1-methyl-2-isopropyl-5-nitroimidazole) and its metabolite 1-methyl-5-nitroimidazole-2-isopropanol from turkey tissue with a lower limit of 2 parts per billion using a 100-gram sample. Ipronidazole and its metabolite are extracted from muscle, liver, kidney, skin, fat, and blood with benzene in the presence of borax. The extract is purified by column chromatography on silica gel and the two compounds are determined separately by gas-liquid chromatography (GLC).

B. The following aspects of the procedure must be carefully observed to insure good recoveries and reproducible results:

1. The sample in solution must be protected from light at all times.

2. The ether-eluent from the column must be shaken before division, and the division must be performed carefully to insure two equal portions.

3. No solution should be allowed to go to dryness during an evaporation step.

4. The compounds should not stand in or in contact with a basic solution or phase for any prolonged period of time.

5. The electron-capture detector should be standardized daily for both compounds.

6. For best results, the assay procedure must be completed in one working day.

II. REAGENTS

A. Sodium borate, tetra (Borax), AR.

B. Sodium chloride, AR.

C. Benzene, nanograde, Burdick & Jackson, or equivalent.

D. Ethyl ether, anhydrous, AR, Mallinckrodt, or equivalent. Open a fresh 1-pound can each day.

E. Silica gel, 100–200 mesh, Davision (Grace), or equivalent.

F. Hydrochloric acid, AR, 3N.

G. Sodium hydroxide, AR, 6N.

NOTE: Wash reagents F and G three times with an approximately equal volume of benzene. Check purity by injecting 10 microliters of the third benzene wash onto GLC column for 1-methyl-5-nitroimidazole-2-isopropanol. If necessary, repeat benzene wash until interfering peaks are no longer detected.

III. APPARATUS

A. Grinders, Hobart KitchenAid Model 5A and Intedge Model C–2, or equivalent.

B. Centrifuge, International, Model K, or equivalent.

C. Lab-Line, Super-Mixer, variable speed, or equivalent.

D. pH-Meter with combination microelectrode.

E. Virtis Homogenizer, Model 45, with 500-milliliter capacity amber flasks, or equivalent.

F. Centrifuge bottle, heavy duty, 500-milliliter, amber.

G. Centrifuge tubes, heavy duty, 50 milliliter and 15-milliliter, amber, glass-stoppered.

H. Chromatographic column, 9 millimeters I.D. x 150 millimeters long, Teflon stopcock, sintered glass disc, clamp, Teflon seal, amber.

I. Chromatographic reservoir, amber, 500-milliliter.

J. Graduated cylinder, 250-milliliter, amber.

K. Disposable Pasteur pipette connected to a 1-liter vacuum flask by means of Tygon tubing.

L. Tracor Microtek MT–220 Gas Chromatograph, or equivalent, equipped with electron capture detection (130μc Nickel-63 source) and 10-inch strip chart recorder or equivalent instrument.

M. 10-microliter syringe.

N. 4 feet of ¼-inch O.D. stainless steel tubing.

O. Anakrom ABS 90–100 mesh (Analabs, or equivalent).

P. OV–17 phenyl methyl silicone (Applied Science Laboratories, Inc., or equivalent).

Q. G.C. Peakometer (Alltek Associates, or equivalent).

R. 6 feet of ¼-inch O.D. glass U-tube column.

S. Packing: 6 percent SE–30 silicone ultraphase (Pierce Chemical Co.) on Gaschrom Q, 80–100 mesh (Applied Science Laboratories, Inc.).

NOTE: Wash glassware with detergent (Alkonox, or equivalent) and rinse with water, distilled water, and acetone. Prior to use, rinse with ether followed by benzene and drain thoroughly.

IV. GAS-LIQUID CHROMATOGRAPHIC PROCEDURES

A. IPRONIDAZOLE

1. Preparation of GLC Column: Prepare the packing of 4.2 percent of OV–17 on Anakrom ABS 90–100 mesh using the filtration-fluidization technique (Bulletin No. 2A, Applied Science Laboratories, Inc.). The packed 4-foot x ¼-inch stainless steel column should be conditioned for 2 days at 250° C. with nitrogen flowing through it.

2. GLC Analysis: Use a 10-microliter sample for injection. Area of the peak is used for the determination and is obtained as the product of the peak width at the half height and the peak height. This is accomplished with the G.C. Peakometer or a conventional ruler. Instrument parameters for maximum sensitivity of 0.5 nanogram are shown below:

a. Column temperature: 190° C. ±1°.

b. Detector temperature: 265° C. ±1°.

c. Injection port temperature: 225° C. ±1°.

d. Carrier gas: ProPurified Nitrogen (Matheson).

e. Carrier gas flow (outlet): 60 cubic centimeters per minute.

f. Electrometer: 1 x 10^{-9}.

g. Attenuation setting: 10^3 x 16.

h. Recorder range: 1 millivolt.

i. Detector voltage: Adjusted daily according to Tracor operation and service manual to obtain the optimum voltage for operating the detector.

j. Approximate retention time: 1.5 minutes (uncorrected).

B. 1-METHYL-5-NITROIMIDAZOLE-2-ISOPROPANOL

1. Preparation of GLC Column: Prepare the packing of 6 percent SE-30 ultraphase (Pierce Chemical Co., or equivalent) on Gaschrom Q, 80–100 mesh (Applied Science Laboratories, Inc., or equivalent) by the same method as described for the GLC column for ipronidazole. Silanizing of the inside of the 6-foot x ¼-inch O.D. glass column is recommended. Prepare a fresh solution of dimethyldichorosilane in toluene (10 percent volume for volume) and pour into the U-tube to the top of both legs. Allow the column to stand for 10 minutes, remove the solution, and rinse the column with 300 milliliters of toluene. Then fill it with methanol, leave for 5 minutes, rinse with an additional 100 to 200 milliliters of methanol, and leave to dry. The column is now ready for use. The packed column should be conditioned overnight at 300° C. with low flow rate of nitrogen.

2. GLC Analysis: Use a 10-microliter sample for injection. Area of the peak is used for the determination and is obtained as the product of the peak width at half height and the peak height. Instrument parameters for maximum sensitivity of 0.5 nanogram are shown below:

a. Column temperature: 189° C. ±1°.
b. Detector temperature: 265° C. ±1°.
c. Injection port temperature: 225° C. ±1°.
d. Carrier gas: PrePurified Nitrogen (Matheson).
e. Carrier gas flow (outlet): 60 cubic centimeters per minute.
f. Electrometer: 1 x 10^{-9}.
g. Attenuation setting: 10^{2} x 16.
h. Recorder range: 1 millivolt.
i. Detector voltage: Adjusted daily according to Tracor operation and service manual to obtain the optimum voltage for operating the detector.
j. Approximate retention time: 1.95 minutes (uncorrected).

V. Preparation of External Reference Standard Solutions

The standard solutions for both ipronidazole and 1-methyl-5-nitroimidazole-2-isopropanol are prepared so as to be equivalent to 2 and 4 parts per billion levels of the compounds from 100-gram tissue samples. Amber glassware must be used. The stock solutions may be kept for up to 1 week in the refrigerator.

A. Ipronidazole

1. *Solution 1.* 1 x 10^{-4} gram per milliliter: 10 milligrams analytical standard ipronidazole in 100 milliliters of methyl alcohol (amber flask).
2. *Solution 2.* 1 x 10^{-6} gram per milliliter: 1.0 milliliter of stock Solution 1 in 100-milliliter amber volumetric flask to volume with glass-distilled benzene.
3. *Solution 3.* 1 x 10^{-7} gram per milliliter: 5 milliliters of stock Solution 2 in 50-milliliter amber volumetric flask to volume with glass-distilled benzene. Inject 10 microliters on GC column for 2 parts per billion.
4. *Solution 4.* 2 x 10^{-7} gram per milliliter: 5 milliliters of stock Solution 2 in 25-milliliter amber volumetric flask to volume with glass-distilled benzene. Inject 10 microliters on GC column for 4 parts per billion.

B. 1-Methyl-5-nitroimidazole-2-isopropanol

1. *Solution 1.* 1 x 10^{-4} gram per milliliter: 10 milligrams analytical standard 1-methyl-5-nitroimidazole-2-isopropanol in 100 milliliters of methyl alcohol (amber flask).
2. *Solution 2.* 1 x 10^{-6} gram per milliliter: 1.0 milliliter of stock Solution 1 in 100-milliliter amber volumetric flask to volume with glass-distilled benzene.
3. *Solution 3.* 0.5 x 10^{-7} gram per milliliter: 5.0 milliliters of stock Solution 2 in 100-milliliter amber volumetric flask to volume with glass-distilled benzene. Inject 10 microliters on GC column for 2 parts per billion.
4. *Solution 4.* 1.0 x 10^{-7} gram per milliliter: 5.0 milliliters of stock Solution 2 in 50-milliliter amber volumetric flask to volume with glass-distilled benzene. Inject 10 microliters on GC column for 4 parts per billion.

VI. Recovery Study

For those using the method for the first time, a recovery study using fortified (spiked) tissue is recommended. The standard solutions for fortification are prepared from the basic stock solutions of ipronidazole and of 1-methyl-5-nitroimidazole-2-isopropanol with distilled water as the diluent. Amber glassware must be used. The following volumes of solutions were added to the 100-gram tissue sample prior to initial homogenization:

Spike level for ipronidazole	Milliliters of ipronidazole solution 3 (see VI, A)	Concentration per gram of tissue
2 parts per billion.	2	2 X 10^{-6} gram.
4 parts per billion.	4	4 X 10^{-6} gram.

Spike level for 1-methyl-5-nitroimidazole-2-isopropanol	Milliliters of 1-methyl-5-nitroimidazole-2-isopropanol solution 3 (see VI, B)	Concentration per gram of tissue
2 parts per billion.	2	2 X 10^{-6} gram.
4 parts per billion.	4	4 X 10^{-6} gram.

A. Ipronidazole

1. *Solution 1.* 1 x 10^{-4} gram per milliliter: 10 milligrams analytical standard ipronidazole in 100 milliliters of methyl alcohol (amber flask). This is the same stock solution used for the preparation of the external standard solutions.
2. *Solution 2.* 1 x 10^{-6} gram per milliliter: 1.0 milliliter of stock Solution 1 in 100-milliliter amber volumetric flask to volume with distilled water.
3. *Solution 3.* 1 x 10^{-7} gram per milliliter: 5 milliliters of Solution 2 in 50-milliliter amber volumetric flask to volume with distilled water.

B. 1-Methyl-5-nitroimidazole-2-isopropanol

1. *Solution 1.* 1 x 10^{-4} gram per milliliter: 10 milligrams analytical standard 1-methyl-5-nitroimidazole-2-isopropanol in 100 milliliters of methyl alcohol (amber flask). This is the same stock solution used for preparation of the external standard solutions.
2. *Solution 2.* 1 x 10^{-6} gram per milliliter: 1.0 milliliter of stock Solution 1 in 100-milliliter amber volumetric flask to volume with distilled water.
3. *Solution 3.* 1 x 10^{-7} gram per milliliter: 5 milliliters of Solution 2 in 50-milliliter amber volumetric flask to volume with distilled water.

VII. Preparation of Silica Gel Column

A. Assemble the amber glass column according to the manufacturer's instructions and pour 1.3–1.7 grams of dry activated silica gel (dried for 1 hour at 110° C.) in the column. The silica gel column should be 3 to 4 centimeters long after gently tapping the outside of the column to insure close packing. Clamp into place the 500-milliliter amber reservoir (made from a 500-milliliter round bottom flask and a column end) and allow 35 milliliters of benzene to run through the column. If air bubbles are present, stir contents of column with a thin glass rod. The column is now ready for use and should be prepared fresh for each tissue sample.

B. Purify each new batch of silica gel prior to use. Wash 20 grams of silica gel with six portions of 75 milliliters of water-saturated ether. Activate overnight at 110° C. Material not used the same day should be reactivated for 1 hour prior to use and cooled in desiccator. After filling column, wash silica gel with 70 milliliters of anhydrous ether, followed by 4 x 10 milliliters of benzene. A sample column is checked out by starting with step 12 of IX, A, and proceeding directly to step 1 of IX, C, without dividing the sample.

VIII. Tissue Sample Preparation

A. Allow muscle, liver, or kidney tissue to come to room temperature, grossly subdivide, and grind using a meat grinder. Size of tissue sample dictates the size grinder to be used: Hobart K5–A (small samples) or Intedge C–2 (large samples).

B. Grind fat and skin tissue samples in a semifrozen condition after gross subdivision of the sample.

IX. Extraction Procedure

A. Initial Procedure

1. Weigh a 100-gram sample of ground tissue into a 500-milliliter amber centrifuge bottle and add 10 grams of borax and salt. Homogenize the sample with the Virtis for 1 minute to provide a homogeneous mixture.
2. Add 100 milliliters of glass-distilled benzene to the mixture and homogenize at moderate speed for 2 minutes. The use of high homogenizing speeds after benzene is added sometimes results in emulsions that are difficult to break. Special caution is needed with liver, and it may be preferable to use manual shaking only.
3. Stopper the bottle and shake by hand for 2 minutes. Centrifuge the sample for 15 minutes at 1,500 revolutions per minute. The use of a refrigerated centrifuge may be helpful in breaking emulsions.
4. Following centrifugation, decant the benzene layer into a storage 500-milliliter amber Virtis flask.
5. Add 100 milliliters of glass-distilled benzene to the tissue in the 500-milliliter bottle. Break up the compacted tissue with a spatula. Stopper the bottle and shake by hand for 2 minutes.
6. Centrifuge the mixture for 15 minutes at 1,500 revolutions per minute.
7. Following centrifugation, decant the benzene layer into the 500-milliliter storage Virtis flask and pool with the first extract.
8. Add 100 milliliters of glass-distilled benzene to the tissue in the 500-milliliter bottle. Break up the compacted tissue with a spatula. Stopper the bottle and shake by hand for 2 minutes.
9. Centrifuge the mixture for 15 minutes at 1,500 revolutions per minute.
10. Following centrifugation, decant the benzene layer into the 500-milliliter storage flask and pool with the first and second extracts. At least 270 milliliters of benzene should be recovered.
11. Transfer 250 milliliters of the total pooled benzene extract to the reservoir or the previously prepared silica gel column, allow to run through the column, follow by 20 milliliters of benzene as a wash, and discard the benzene.
12. Strip the silica gel column by the addition of 25 milliliters of water-saturated ethyl ether (prepared fresh daily using an unopened can of anhydrous ether and distilled water) and allow the ether to pass through the column. Wash column with an additional 5 milliliters of water-saturated ether. Pressurize the column using a hand bulb or nitrogen to insure that all the ether goes through the column and is caught in the 40-milliliter amber centrifuge tube.
13. Mix the combined ether eluent well and divide into two equal portions (designated A and B) in 15-milliliter amber centrifuge tubes. Portion A is used for the analysis of ipronidazole (IX, B, 1–5); portion B is used for the analysis of 1-methyl-5-nitroimidazole-2-isopropanol (IX, C, 1–6).

B. Procedure for Ipronidazole

1. Reduce volume of ether portion A to approximately 10 milliliters in a stream of nitrogen. Add 3 milliliters of 3N·HCl to the ether, stopper, and shake for 30 seconds on a Vortex mixer.
2. Allow the layers to separate and discard the ether layer by aspiration making sure that none of the aqueous layer is removed.
3. Wash the aqueous layer with 2 x 2-milliliter portions of glass-distilled benzene. Remove benzene by aspiration. Care must be taken during this washing step that none of the aqueous layer is removed.
4. To the HCl layer, add small amount of borax and adjust the pH of the solution to approximately 8 with 6N NaOH using a pH meter. The compounds should not be left at alkaline pH any longer than necessary, each sample being extracted with benzene as soon as the pH has been adjusted (2–5 minutes).
5. Add 1 milliliter of glass-distilled benzene, shake well, and allow the layers to sepa-

rate. A 10-microliter sample of the benzene layer is used for GLC analysis of ipronidazole.

C. PROCEDURE FOR 1-METHYL-5-NITROIMIDAZOLE-2-ISOPROPANOL

1. Reduce volume of ether portion B to approximately 10 milliliters in a stream of nitrogen. Add 2 milliliters of glass-distilled benzene to the ether in the 15-milliliter amber centrifuge tube.

2. Evaporate the ethyl ether from the tube using a stream of dry nitrogen at room temperature until a volume of approximately 2 cubic centimeters remains in the tube.

3. Add 1.4 milliliters of 3N·HCl to the tube, shake for 30 seconds on a Vortex mixer, and allow the layers to separate. Discard the upper benzene layer by aspiration insuring that none of the aqueous layer is removed.

4. Wash the aqueous layer with 2 x 2-milliliter portion of glass-distilled benzene. Remove the benzene by aspiration. Care must be taken that, during the washing step, none of the aqueous layer is removed.

5. To the aqueous layer, add small amount of borax and adjust the pH of the solution to approximately 8 with 6N NaOH using a pH meter. The compounds should not be left at alkaline pH any longer than necessary, each sample being extracted with benzene as soon as the pH has been adjusted (2–5 minutes).

6. Add 2 milliliters of glass-distilled benzene, shake well, and allow the layers to separate. A 10-microliter sample of the benzene layer is used for GLC analysis of 1-methyl-5-nitroimidazole-2-isopropanol.

X. CALCULATION

A. The gas chromatograph must be calibrated daily by the repeated injection of 2 and 4 parts per billion external reference standards of both compounds and calculation of the peak areas. Recovery of compounds from spiked control tissues is calculated as follows:

$$\frac{\text{(Observed response, ng/10 mcl.) (Conversion Constant) (100)}}{\text{(Quantity spiked into 100g. tissue sample, ng.)}} = \text{Percent recovery}$$

$$\text{Observed response, ng/10 mcl.} = \frac{\text{Peak area of spiked sample}}{\text{Peak area of reference standard}} \times \text{Concentration of reference standard}$$

The conversion constant for ipronidazole is 240. It is obtained as follows:

Conversion Constant = (Volume conversion, 10 mcl. to 1 ml.) (Correction for 1:1 split of column effluent) (Extract volume aliquot 300 ml. total/250 ml. used).

$$\text{Conversion Constant} = \frac{(1\times10^{-3})}{(10\times10^{-6})}(2)\frac{(300)}{(250)} = 240$$

The conversion constant for 1-methyl-5-nitroimidazole-2-isopropanol is 480. It is obtained as follows:

Conversion Constant = (Volume conversion, 10 mcl. to 2 ml.) (Correction for 1:1 split of column effluent) (Extract volume aliquot 300 ml. total/250 ml. used)

$$\text{Conversion Constant} = \frac{(2\times10^{-3})}{(10\times10^{-6})}(2)\frac{(300)}{(250)} = 480$$

B. The method is capable of quantitatively determining both compounds at levels as low as 2 parts per billion. In the case of tissue samples containing either compound at levels in excess of 6 parts per billion, an appropriate dilution with glass-distilled benzene of the final solution is made prior to gas chromatography. The calculation to determine parts per billion in a tissue sample is shown below:

$$\frac{\text{(Observed response, ng./10 mcl.) (Conversion Constant) (Dilution factor, if needed)}}{\text{Weight of tissue sample}} = \text{p.p.b.}$$

§ 556.350 Levamisole hydrochloride.

A tolerance of 0.1 part per million is established for negligible residues of levamisole hydrochloride in the edible tissues of cattle, sheep, and swine.

§ 556.360 Lincomycin.

Tolerances are established for residues of lincomycin as follows: 0.15 part per million for negligible residues in milk; and 0.1 part per million for negligible residues in the edible tissues of chickens and swine.

§ 556.370 Medroxyprogesterone acetate.

(a) No residues of medroxyprogesterone acetate (17-hydroxy-6α-methylpregn-4-ene-3,20-dione 17-acetate) may be found in the uncooked edible tissues of sheep and cattle or in milk.

(b) The method of examination used in the quantitative determination of medroxyprogesterone acetate to establish that there were no residues present in tissues or milk in an exaggerated study is as follows:

(1) *Apparatus.* A Lourdes Tissue Homogenizer or equivalent; dialyzer tubing, Visking No. 30, 32, or equivalent.

(2) *Reagents.* Methylene chloride, redistilled in all-glass equipment, using a Vigreaux distilling lead (store in brown bottles); Skellysolve B (distill and store in brown bottles); chromatographic alumina; Woelm acid, activity grade 1, for chromatography.

(3) *Preparation of samples*—(i) *Tissue.* Grind fresh tissue in a household meat grinder. If analysis is delayed, the ground tissue must be stored in a deep freeze and thawed just prior to analysis. Transfer 10 grams of tissue to a 60-milliliter stainless steel can, add 40–45 milliliters of 95 percent ethyl alcohol and two 4.25-centimeter circles of Whatman No. 4 filter paper. Attach can to the tissue homogenizer, immerse in an ice bath, and homogenize for 5 minutes. Filter with suction through a Büchner funnel using a Whatman No. 4 filter paper. Return the filter cake to the stainless steel can, add 40 to 45 milliliters of 95 percent ethyl alcohol and homogenize for 5 minutes as before. Filter as before, adding the second filtrate to the first. Repeat the extraction a third time and combine the filtrate with the first two.

(ii) *Bone marrow or fat.* Extract as under subdivision (i) of this subparagraph, using 4:1 Skellysolve B-absolute ethyl alcohol instead of 95 percent ethyl alcohol.

(iii) *Brain tissue.* Extract as under subdivision (i) of this subparagraph, using 95 percent ethyl alcohol for the first extract, 4:1 Skellysolve B-absolute ethyl alcohol for the second extract, and 95 percent ethyl alcohol for the third extract. Transfer the combined extracts to a 500-milliliter separator, add an equal volume of water, and extract with four successive 50-milliliter volumes of methylene chloride. Evaporate the combined extracts to dryness. Dissolve the oily residue in 20 milliliters Skellysolve B and retain for the chromatographic separation.

(iv) *Milk.* Transfer 180 milliliters of milk to a beaker, add 20 milliliters of absolute methyl alcohol, and mix by stirring. Transfer the solution to a pre-extracted No. 30 or 32 Visking tubing. Tie both ends of the tubing with double overhand knots. Care must be exercised to avoid making the milk-filled casing too taut. Place the filled casing carefully in a large Soxhlet extractor, add 350 milliliters of absolute methyl alcohol, and extract for 48 hours. Transfer the extract into a rotary evaporator and evaporate with vacuum until the volume is reduced to 50 to 100 milliliters. This will remove all the methyl alcohol. Transfer the aqueous residue to a 500-milliliter separator, using sufficient wash water to produce a volume of about 150 milliliters. Extract with four successive 50-milliliter portions of methylene chloride, and evaporate the combined extracts until only an oily residue remains. Dissolve the residue in 20 milliliters of Skellysolve B and retain for the chromatographic separation.

(4) *Preparation of chromatographic column.* Partially fill the column with chloroform. Slurry 15 grams of chromatographic alumina with chloroform and transfer to the column. Place a small plug of glass wool on top of the alumina. (NOTE: Keep exposure of the alumina to air to a minimum.) Wash the column with a total of 125 milliliters of chloroform, including the volume used to make the slurry. Follow with a second wash, using 100 milliliters of Skellysolve B.

(5) *Determination* (i) When the final portion of the Skellysolve B wash passes into the column, transfer the reserved sample solution to the column with the aid of two additional 20-milliliter portions of Skellysolve B. Add each rinse to the column when the solvent level has just reached the glass wool plug over the alumina. Pass an additional 50-milliliter portion of Skellysolve B through the column and follow it with 50 milliliters of 2 percent acetone in

Skellysolve B. Discard these washings. Elute the medroxyprogesterone acetate with 75 milliliters of 1:1 chloroform-Skellysolve B. Evaporate the effluent to dryness. Dissolve the residue in 10 milliliters of Skellysolve B saturated with 70 percent methyl alcohol and transfer to a 125-milliliter separator. Rinse the container with a second 10-milliliter portion of the above solvent and add to the separator. Rinse the container with 20 milliliters of 70 percent methyl alcohol, add to the separator, shake, and allow the two phases to separate. Transfer the lower layer to a second 125-milliliter separator containing 20 milliliters of Skellysolve B saturated with 70 percent methyl alcohol. Shake, allow the phases to separate, and transfer the lower layer to a 250-milliliter beaker. Extract the two separators serially with four successive 20-milliliter portions of 70 percent methyl alcohol, and add the washings to the beaker. Evaporate the combined extracts just to dryness on a steam bath. Dissolve the residue in 2 milliliters of 1:1 methyl alcohol-methylene chloride, and transfer to a 5-milliliter beaker. Complete the transfer with three additional 2-milliliter portions of the solvent (evaporate the solvent in the 5-milliliter beaker between addition of washings). Reduce the volume to 0.1 milliliter in preparation for paper chromatography.

(ii) *Paper chromatographic analysis*—(*a*) *Apparatus.* A descending paper chromatographic apparatus designed to use a series of strips; Whatman No. 1 paper, washed overnight with 95 percent ethyl alcohol.

(*b*) *Reagents*—(*1*) *Immobile solvent.* Diethylene glycol monoethyl ether.

(2) *Mobile solvent.* Diethylene glycol monoethyl ether-saturated methylcyclohexane.

(3) *Standard solution.* Dissolve a weighed amount of medroxyprogesterone acetate standard in 1:1 methyl alcohol-methylene chloride, and dilute to a concentration of 100 micrograms per milliliter. Saturate a sheet of washed chromatographic paper with diethylene glycol monoethyl ether and remove the excess by blotting between sheets of filter paper. Transfer the total sample to a spot on the starting line, using a micro pipette Spot a 100-microliter portion of the standard solution in the same manner. Place paper in tank and develop for 6 hours. Following development, air dry the papers at room temperature over night. Locate and mark the zones under ultraviolet light. Remove the zones, cut into small pieces, and place each in a 10-milliliter beaker. Add 5 milliliters of 95 percent methyl alcohol to each beaker, cover, and heat on steam bath for 10 minutes. Cool and transfer solutions to 10-milliliter volumetric flasks. Wash paper residues and beakers with small amounts of 95 percent ethyl alcohol and use washing to make to volume. Determine the absorbance *A*, of sample and standard solutions at 242 mμ relative to an ethyl alcohol blank, using matched 1-centimeter cells.

$$\text{1 part per million of medroxyprogesterone acetate} = \frac{A \text{ sample solution}}{A \text{ standard solution}} \times \frac{100}{\text{weight sample}}.$$

§ 556.380 Melengestrol acetate.

No residues of melengestrol acetate (17-hydroxy-6-methyl-16-methylene-pregna-4,6-diene-3,20-dione acetate) may be found in uncooked edible tissues of cattle as determined by the following method of analysis:

I. *Method of analysis—melengestrol acetate.* A gas-liquid chromatographic (GLC) method for melengestrol acetate (MGA) in frozen bovine tissue is described which removes, through several partition and chromatography cleanup steps, most interfering materials before injection of the sample onto the column for detection. MGA is extracted from lean tissues with ethanol and transferred, after dilution with water, into chloroform. MGA in fatty tissues is extracted with hexane and transferred first into aqueous methanol, then into methylene chloride. The residue from either extract, after evaporation of solvent, is chromatographed on silica gel to remove lipid materials using hexane and a mixture of ethyl ether-benzene. MGA is eluted with ethyl acetate. The residue, after evaporation, is dissolved in hexane and transferred first into aqueous methanol and then into methylene chloride. The dried residue is transferred to aluminum oxide thin layer chromatography (TLC) plates which are developed in a benzene-chloroform-ethyl acetate system. The zone containing MGA is removed and eluted with ethanol. The ethanol is evaporated and the MGA is dissolved into an exact volume of chloroform. MGA is injected onto a 3-percent QF-1 column in an all-glass system and quantitated by peak height measurements from a flame ionization detector.

MGA can be detected at a level of 25 parts per billion with negligible interference from tissues or reagents. Observed recovery ± estimated standard deviation at 25 parts per billion in muscle, liver, and fat is 74.4±8.0 percent.

II. *Reagents.* All solvents must be GLC pure when processed through the entire procedure in the absence of tissue, see VII *Recovery study* below.

A. Air—20 pounds per square inch purified by passage through a Linde Molecular Sieve, type 4A, 1/16-inch pellets or equivalent.

B. Aluminum oxide GF254, Brinkman Instruments, or equivalent

C. Benzene—Burdick and Jackson Laboratories, Distilled-in-Glass grade, or equivalent.

D. Chloroform—Burdick and Jackson Laboratories, Distilled-in-Glass grade, or equivalent.

E. Column packing—3-percent QF-1 on Gas Chrom Q, 100–120 mesh. Applied Science Laboratories, Inc., or equivalent.

F. Dry ice.

G. Ethanol—absolute, synthetic, Gold Shield, Commercial Solvents Corp., or equivalent. A 25-milliliter portion roto-evaporated to dryness, taken up in 0.1 milliliter chloroform and 10 microliters injected into the gas chromatograph should show no contaminants. Contaminated alcohol must be redistilled in an all-glass system and retested.

H. Ethanol—190 proof, synthetic, Gold Shield, Commercial Solvents Corp., or equivalent.

I. Ethyl acetate—Burdick and Jackson Laboratories, Distilled-in-Glass grade, or equivalent.

J. Ethyl ether—anhydrous, Mallinckrodt AR, 1-pound can, or equivalent.

K. Glassware cleaner—Haemo-Sol, Scientific Products, or equivalent.

L. Helium—99.5 percent minimum, The Matheson Co., or equivalent.

M. Hexane—Burdick and Jackson Laboratories, Distilled-in-Glass grade, or equivalent.

N. Hydrogen—99.5 percent minimum, Ohio Chemical Co., or equivalent.

O. Melengestrol acetate—MGA Standard, 99.5 percent purity, The Upjohn Co.

P. Methanol—Burdick and Jackson Laboratories, Distilled-in-Glass grade, or equivalent.

Q. Methylene chloride—Burdick and Jackson Laboratories, Distilled-in-Glass grade, or equivalent.

R. Nitrogen—filtered, see III-D below, The Matheson Co., or equivalent.

S. Progesterone—The Upjohn Co., or equivalent.

T. Silica gel—for chromatographic columns, 50–200 mesh, G. Frederick Smith Chemical Co., or equivalent.

U. Sodium sulfate—anhydrous, Mallinckrodt AR, granular, or equivalent.

V. Water—double distilled in glass or deionized.

W. Solvent mixtures—ratios by volume:

1. 10:1:1 benzene-chloroform-ethyl acetate.
2. 1:1 chloroform-methanol.
3. 19:1 ethanol, absolute-double distilled water.
4. 1:19 ethyl ether-benzene.
5. Hexane saturated with 7:3 methanol-water.
6. 7:3 methanol-water.
7. 9:1 methanol-water.
8. Saturated sodium sulfate solution, aqueous.

III. *Special apparatus.* A. Adapters—24/40, No. 5225. Ace Glass, Inc., or equivalent.

B. Blender—Waring Blender, or equivalent.

C. Chromatography columns—glass columns 28 (inside diameter) x 600 millimeters, fitted with Teflon stopcocks and medium porosity, sintered glass disks, Fisher and Porter 274–100, or equivalent.

D. Filters—Koby "Junior," air purifier and flow equilizer, low pressure, The Koby Corp., or equivalent.

E. Filtrator—Fisher Filtrator, Fisher Scientific Co., or equivalent.

F. Gas chromatograph—Micro Tek 220, or P and M 402, or equivalent. Instrument must have an all-glass on-column injection system and a flame detector. Electrometer sensitivity of 10^{-12} amperes and recorder sensitivity of 1 millivolt.

G. Gas chromatography columns—use borosilicate glass tubing, 0.2362±0.013 inch outside diameter and 0.118±0.01 inch inside diameter. Wilkens Anderson Co., or equivalent. Bend 2-foot and 3-foot pieces of tubing into the proper design for the instrument to be used. Pack the columns with 16 and 28 inches, respectively, of 3-percent QF-1 and plug both ends with 0.5 centimeter of loosely packed, silanized glass wool. Pack far enough from the ends so that no part of the column packing or glass wool will be inside the heated injection port or outlet fitting. Insert column into the GLC oven and condition with carrier gas off for 2 hours at 240° C., then at 220° C. overnight with the carrier gas on at a rate of 10 milliliters per minute.

H. Micropipettes—5 and 25 microliters, Microcap Disposable Pipettes, Drummond Scientific Co., or equivalent.

I. Micropipette—500 microliters, Kirk type, Microchemical Specialties Co., or equivalent.

J. Miniature jet evaporator—several transfer pipettes (see III-L below) connected through a manifold to a nitrogen supply.

K. Oven—110° C.

L. Pipettes—transfer pipettes, 9-inch disposable pipettes, Scientific Products, or equivalent.

M. Roto-evaporator—four to six small size Rinco evaporators, or equivalent, controlled with 4-millimeter bore stopcocks connected to a manifold which leads to two condensation traps (1–2 liters) connected in series to a vacuum pump of 140 liters per minute free air capacity. The traps are cooled with a dry ice-solvent mixture. The time for roto-evaporation of 200 milliliters of 7:3 methanol-water is 35–40 minutes. Each sample in around-bottomed flask is connected with two adapters (see III–A above) in a series to an evaporator and heated in a thermostatically controlled water bath at 45° C.

N. Separatory funnels—fitted with Teflon stopcocks, 125, 500, and 2,000 milliliters.

O. Shevky-Stafford tubes—6.5 milliliters, Arthur H. Thomas Co., or equivalent. Must be calibrated at the 0.100 milliliter mark to contain 0.100±0.002 milliliters.

P. Silanized glass wool—Applied Science Laboratories, or equivalent.

Q. Sintered glass Buchner funnels—fine porosity 2.5 x 5.0 centimeters.

R. Syringe—25-Microliter, Hamilton No. 702, Hamilton Co., Inc., or equivalent.

S. Thin layer chromatography equipment—spreader suitable for preparing five plates, 0.75-millimeter thickness. Glass tanks for developing TLC plates.

T. TLC plates—200 x 200 millimeters, prepared as follows:

1. Place 5 plates (200 x 200 millimeters) in the template, wipe the surface with absolute ethyl alcohol and dry with lintless tissue.

a. TLC plates are best cleaned by immersion in a sonic-oscillation bath.

b. Hand washing is not recommended unless absolutely necessary.

2. Adjust the spreader for 0.75 millimeters.

3. Weigh out 90 grams of aluminum oxide and place in a clean, dry blender jar.

a. Add 140 milliliters of distilled water and blend at low speed for 30 seconds.

b. Remove the jar from the blender and swirl the contents.

c. After 90 seconds has elapsed from the time the blender was turned on, pour the slurry into the spreader and coat the five plates.

d. It may be necessary to make minor operational changes such as amount of water and mixing time in order to obtain plates of uniform thickness free of checks and bubbles.

i. If checks or cracks appear, decrease the amount of water.

ii. If bubbles appear, decrease blending time or speed.

4. Allow the plates to dry 2 days or longer at room temperature.

a. Plates aged 2 to 4 weeks show less tendency to flake in the mobile solvent systems.

b. Plates may be stored on the bench exposed to laboratory air if it can be demonstrated that no air contaminants are present as shown by a TLC blank run through the GLC starting with procedure step V–G9.

5. Activate the plates for 1 hour at 110° C. in a hot air oven, cool 30 minutes in laboratory air.

a. Use plates the same day they are activated.

b. Oven should be free of contaminants that may be absorbed by the plates as shown by a TLC blank run through the GLC starting with procedure step V–G9.

c. Relative humidity of 40–60 percent aids in dissipating the static charge which appears to be characteristic of heated alumina plates. Unless this charge is dissipated, attraction of alumina for the spotting pipette causes disruption of the surface.

d. If humidity conditions cannot be met, longer standing will suffice to dissipate the charge.

6. Scribe the TLC plates at right angles to the direction in which they are poured in the following manner:

a. Remove 2 millimeters alumina from vertical edges of each plate.

b. Scribe the rest of the plate with 2-millimeter wide lines so as to give two 80-millimeter strips and one 20-millimeter vertical strip between them.

U. Tissue homogenizer—Lourdes tissue homogenizer with 300-milliliter stainless steel cups fitted with silicone rubber gaskets. Do not use any lubricant. Reduce wear between cup head and shaft bushings with Teflon-fiberglass washers made from Teflon tape impregnated with 15 percent glass, 0.015 inch thick, Detroit Ball Bearing Co., or equivalent.

V. Ultraviolet lamp—Mineralight Model 2L–2537 (shortwave), or equivalent.

W. Vacuum oven—20–35° C., 20–30 millimeters mercury.

X. Volumetric flasks—1 milliliter.

Y. Vortex mixer—Fisher Mini-Shaker, or equivalent.

IV. *Standard solutions.* A. Stock solution A—6.00 milligrams of MGA in 100 milliliters of absolute ethanol.

B. Stock solution B—dilute 5 milliliters of stock solution A to 200 milliliters with absolute ethanol.

C. Stock solution C—20 milligrams of MGA in 100 milliliters of absolute ethanol.

D. Stock solution D—Dilute 5 milliliters stock solution C to 100 milliliters with chloroform.

E. Stock solution E—10 milligrams of MGA and 10 milligrams of progesterone in 10 milliliters of absolute ethanol:

F. Stock solution F—10 milligrams of MGA in 10 milliliters of absolute ethanol.

V. *Procedure.* A. Preparation of glassware. All glassware should be washed in detergent to remove contaminants and rinsed in water to remove traces of cleaning agent. Rinse with solvents before using.

B. Preparation of sample:

1. Grind the fresh tissue in a meat grinder and store in a suitable container in a deep freeze.

2. Chill the leg bones in the refrigerator for 24 hours, saw them lengthwise (commercial meat bandsaw), remove the bone marrow, and place in the deep freeze.

3. Steam the tripe for 5 minutes and strip off the muscle layer and store in deep freeze.

C. Extraction procedure for muscle, liver, kidney, and tripe:

1. Clean homogenizer by disassembling mixer heads completely and soaking in detergent with the cups. Keep all parts from each mixer head separated from those of the other assemblies. Brush all parts and rinse thoroughly with tap water and then with distilled water. Let dry and reassemble the mixer heads without using a lubricant.

2. Weigh 60 grams of the partially thawed tissue into a 300-milliliter homogenizing cup and refreeze the unused portion immediately.

3. Add 175 milliliters of 190 proof ethanol and a circle of Whatman filter paper No. 40, 12.5 centimeters, as a filter aid.

4. Homogenize for 2 minutes in an ice bath.

5. Filter the slurry through Whatman filter paper No. 40, 12.5 centimeters, in a Buchner funnel into a 1-liter filter flask using a vacuum supply.

6. Wash the cut with 20–25 milliliters of 190 proof ethanol using a wash bottle and filter the washings through the Buchner funnel.

7. Transfer the dry filter cake with its filter paper to the cup and add 175 milliliters of 190 proof ethanol.

8. Homogenize for 2 minutes and filter the slurry.

9. Repeat step 7, but this time homogenize the dry cake without its filter paper for 2 minutes and filter.

10. Mark the level of the combined alcohol eluates in the 1-liter filter flask and quantitatively transfer it to a 2-liter separatory funnel.

11. Add water to the marked level; add 100 milliliters of water and 20 milliliters of saturated sodium sulfate solution to the flask, mix, and transfer the mixture to the separatory funnel.

12. Add 100 milliliters of chloroform and shake the separatory funnel vigorously for 1 minute.

13. Let stand for 30 minutes or until complete phase separation takes place. If the chloroform layer is less than 50 milliliters, add 25 milliliters more of chloroform and shake again.

14. Drain the chloroform phase into a 1-liter round-bottomed flask.

15. Repeat procedure steps V–12, 13, and 14 three more times.

16. Roto-evaporate the combined chloroform extracts and remove the last trace of water in the following manner avoiding violent bubbling during roto-evaporation.

a. This can be done by restricting the vacuum supply by partially opening the stopcock slowly or by starting the roto-evaporator with the round-bottomed flask out of the water bath. When flask is cool or shows frosting, place it into water bath.

b. To the flask add with swirling 25 milliliters of hexane followed by 25 milliliters of absolute ethanol.

c. Swirl until the solids and/or oil are dissolved or suspended in the solvents and roto-evaporate.

d. Add 25 milliliters of absolute ethanol and roto-evaporate until 15 minutes after the solvent has been removed.

17. Close the stopcock and open the system at the glass joint between the two adapters.

a. This prevents back-flushing of contaminants from the roto-evaporator.

b. *Stopping place.* Leave the adapter in place, stopper, and store in refrigerator or deep freeze.

c. Storage of sample in the solvent should be avoided.

D. Extraction procedure for fat and bone marrow:

1. Clean homogenizer cups and heads, procedure step V–C1; weigh samples as in procedure step V–C2.

2. Add 150 milliliters of hexane and warm on a steam bath without boiling.

3. Stir the solution with a spatula until the fat dissolves.

4. Filter the warm solution through Whatman No. 40 filter paper, 12.5 centimeters, into a 1-liter filter flask.

5. Transfer the filter cake, including filter paper, to the cup and add 150 milliliters of hexane.

6. Homogenize for 2 minutes in an ice bath, rewarm the cup, and filter the warm solution into the filter flask.

7. Repeat the homogenization and extraction of the filter cake one more time.

8. Warm the filter flask until the solution is relatively clear and transfer the warm hexane solution into a 2-liter separatory funnel.

9. Add 500 milliliters of hexane, 250 milliliters of 9:1 methanol-water, and shake vigorously for 1 minute.

10. Let stand 30 minutes and drain the lower phase into a 2-liter separatory funnel.

11. Extract with three 250-milliliters portions of 9:1 methanol-water and combine the extracts.

12. To the combined filtrates in the 2-liter separatory funnel, add 500 milliliters of water and 2 milliliters of saturated sodium sulfate

solution to give 55 to 60 percent aqueous methanol.

13. Shake vigorously for 1 minute the aqueous methanol with 300 milliliters of methylene chloride. If the phases do not separate well, add 2 milliliters of saturated sodium sulfate solution and shake again.

14. Let phases stand 20 minutes and drain into a 1-liter round-bottomed flask.

15. Extract with three successive portions of 100 milliliters of methylene chloride.

16. Roto-evaporate the combined extracts as in procedure step V–C16.

17. *Stopping place.* Leave adapter in place, stopper, and store in the refrigerator or deep freeze.

E. Defatting on silica gel columns: 1. Prepare silica gel column as follows:

a. Clean the column with 50 milliliters of absolute ethanol, allowing it to flow through the sintered disk. Aspirate air through the column until dry.

b. Half fill a column with hexane, slurry 20 grams silica gel in hexane, and pour it into the column.

c. Rinse the sides of the beaker and column with hexane.

d. Adjust the flow rate to 8–10 milliliters per minute.

e. While maintaining at least 15 centimeters of solvent, slowly add anhydrous sodium sulfate to a depth of 3 centimeters. The sodium sulfate layer should be free of air bubbles and should not disrupt the silica gel surface.

2. Take residue from procedure steps V–C17b and V–D17. Remove and rinse adapter with stopper in place as follows:

a. Invert and pour 20 milliliters of hexane into the adapter and swirl.

b. Pour the contents onto the residue.

c. Rinse the adapter twice with hexane using a wash bottle and transfer the washings to the residue.

3. Swirl and transfer the hexane solution to the silica gel column.

4. Allow the solution to be completely absorbed into the column, but do not allow the column to go to dryness.

5. Maintain a flow rate of 8–10 milliliters per minute.

6. Rinse the round-bottomed flask twice with 10-milliliter portions of hexane and transfer to the column.

7. Wash the column with the following solvents, discarding the effluents:

a. Rinse the round-bottomed flask with 75 milliliters of hexane and pour onto the column.

b. 350 milliliters of 1:19 ethyl ether-benzene (prepared daily from fresh ether, do not reuse opened cans).

8. Elute MGA fraction with 350 milliliters of ethyl acetate into a 1-liter round-bottomed flask and roto-evaporate off the solvent.

a. Discard the adapters.

b. *Stopping place.* Stopper and store in refrigerator or deep freeze.

F. Solvent partition: 1. Transfer the residue to a 125-milliliter separatory funnel using two 20-milliliter portions of hexane saturated with 7:3 methanol-water.

2. Extract the hexane phase with 40 milliliters of 7:3 methanol-water, first rinsing the round-bottomed flask with the aqueous methanol.

a. Shake the funnel vigorously for 1 minute; let the phases separate at least 1 hour.

b. Drain the lower phases into a 500-milliliter separatory funnel containing 50 milliliters of methylene chloride, 80 milliliters of water, and 0.5 milliliter of saturated sodium sulfate solution.

3. Repeat step 2 four more times combining all extracts in the 500-milliliter separatory funnel.

4. Stopper the 500-milliliter separatory funnel, invert carefully, and vent immediately. Shake the funnel cautiously, venting frequently. When all pressure subsides, shake the funnel vigorously for 1 minute, wait 20–30 minutes, and drain the lower phase into a 500-milliliter round-bottomed flask. This precaution does not apply to the subsequent shakings.

5. Extract with three more 50-milliliter portions of methylene chloride, each time draining the lower phase into the flask.

6. Roto-evaporate the combined extracts until all the solvent has been removed. *Stopping place.* Stopper and store in refrigerator or deep freeze.

G. Thin layer chromatography. 1. Transfer the residue to a 1-milliliter volumetric flask using five 2-milliliter portions of 1: 1 chloroform-methanol.

a. A 1-milliliter volumetric flask holds over 2 milliliters.

b. After each transfer, place the 1-milliliter flask in a water bath at 35–40° C. and evaporate the solvents on the miniature jet evaporator, see apparatus III–J.

c. Evaporate the last portion under nitrogen to just below the 1-milliliter mark.

d. Label this flask "A".

e. Bring the volume back to the 1-milliliter mark, stopper, and mix.

2. Accurately transfer 500 microliters from flask "A" into another 1-milliliter volumetric flask and evaporate to dryness under nitrogen.

a. Label this flask "B".

b. This will ultimately be the portion of the split sample that is assayed by GLC.

3. Add 25 microliters of stock solution F to volumetric flask "A" and evaporate the solvents under nitrogen.

a. This half will be used to locate the MGA area on the plate.

b. All samples are split and fortified as described above in procedure steps V–G2 and V–G3.

c. *Stopping place.* Stopper and store in refrigerator or deep freeze.

4. To the residue in flasks "A" and "B", add 10–12 drops of 1: 1 chloroform-methanol.

5. Apply the entire sample in flask "A" across the entire 80-millimeter band 3 centimeters from the bottom of the plate.

a. Apply the sample in 10- to 20-microliter portions using a 25-microliter pipette. Apply the residue as a band 10 to 15 millimeters wide and 80 millimeters long. Flow the solution onto the plate as rapidly as possible with no forced drying.

b. Label this side of the plate "A".

6. Rinse the flask with 10 drops of 1: 1 chloroform-methanol and apply to the same streaked area as soon as possible.

7. Repeat once more with 5 drops.

8. Place sample "B" on the other 80-millimeter strip in a similar manner as in procedure step V–G 5, 6, and 7, and label this side of the plate "B"

9. Spot 5 microliters of stock solution E on the 20-millimeter strip.

10. Allow the plate to dry for 15 minutes at room temperature.

11. Place the plate in a tank containing fresh 1: 1 chloroform-methanol. Saturation of tank atmosphere is not necessary.

12. Remove the plate from the tank when the solvent front has moved 5 centimeters from the bottom of the plate. MGA and similar substances concentrate as a narrow band at the solvent front.

13. Remove and air dry the plate in a horizontal position on a cork ring for all subsequent plate-drying steps.

14. Dry for 15 minutes at room temperature and for another 15 minutes in a vacuum oven.

15. Place the plate in a tank containing fresh 10:1:1 benzene-chloroform-ethyl acetate. Saturation of tank atmosphere is unnecessary.

16. Allow the solvent to rise 17 centimeters from the botom of the plate.

17. Determine the position of MGA on the plate in section A with UV radiation referring to the lower spot in the center section. MGA will be below progesterone.

18. Scribe horizontal lines on section B above and below the MGA area using section A as a guide to determine the width of the band to be removed. Do not disturb section A.

19. Wash a sintered glass funnel with chloroform, hexane, and alcohol using a vacuum supply.

20. Scrape the MGA zone with a clean razor blade onto a piece of weighing paper and transfer the scrapings to the sintered glass funnel.

a. Do not rinse the weighing paper with alcohol.

b. Clean razor blade with hexane before and after each sample.

21. Add four 5-milliliter portions of 19:1 ethanol-water, stir with a glass rod, let stand 5 minutes, and filter with vacuum into a 50-milliliter round-bottomed flask using a filtrator.

22. Roto-evaporate the combined filtrates. *Stopping place.* Stopper and store in a refrigerator or deep freeze.

H. Gas liquid chromatography:

1. Transfer the residue from the round-bottomed flask to a Shevky-Stafford tube with four 1-milliliter portions of chloroform

2. Place the tubes into a water bath (35–40° C.) and evaporate the solvent with a gentle stream of nitrogen, using the miniature jet evaporator.

3. Rinse the sides down with approximately 1 milliliter of chloroform and once again evaporate the solvent.

4. Remove the tube from the evaporator as soon as possible after solvent has been removed.

5. Bring the volume up to the 0.1 milliliter mark with chloroform and swirl with a vortex mixer.

6. On a 2-foot conditioned column, adjust the gas flow and oven temperature to give a 10–15 minute retention time and adjust attenuation to give a peak height of 20–35 millimeters for 0.1 micrograms of MGA.

a. Suggested parameters are: Oven temperature, 210°–225° C; detector temperature, 275°–280° C; inlet temperature, 255° C; carrier gas flow for helium, 60–120 milliliters per minute, for hydrogen, 40–60 milliliters per minute, for air, 300 milliliters per minute; chart speed, 0.25–0.5 inch per minute.

b. Do not exceed an oven temperature of 230° C.

7. Inject 10 microliters of stock solution D and measure the peak height in millimeters.

8. Inject 10 microliters of the sample and measure the peak height in millimeters.

9. For fat samples or problem samples use the 3-foot column providing a longer retention time of 16–20 minutes.

VI. *Calculations.* Calculate the parts per billion MGA by the following formula:

$$\text{Parts per billion} = \frac{\text{Peak height of unknown}}{\text{Peak height of standard}} \times 33.3$$

VII. *Recovery study.* A. Fortification of reagent blank:

1. For those using this method for the first time either for recovery study or tissue assay, a solvent blank and solvent fortified with MGA should be processed through the entire procedure. This preliminary operation will establish whether or not the procedure is free from contamination arising from solvents and glassware and demonstrate the level of recovery of standard MGA. Level of recovery should be in the same range as the samples.

2. Place 175 milliliters of 190 proof ethanol into the homogenizer.

3. To another 175 milliliters of 190 proof ethanol in a homogenizer cup add 1 milliliter of stock solution B.

4. Assay both samples as described in the procedure beginning with the extraction step V–C4.

B. Fortification of the samples:

1. Weigh 60-gram portions of the unfortified tissue into homogenizer cups and set half of them aside to serve as tissue blanks.

2. Add to the remaining samples 1 milliliter of stock solution B to serve as fortified samples to which 25 parts per billion have been added.

3. Assay both fortified and unfortified tissue as described in the procedure section beginning with the extraction step V–C3 or the extraction step V–D2, whichever is appropriate.

§ 556.390 Methylparaben.

A tolerance of zero is established for residues of methylparaben in milk from dairy animals.

§ 556.400 Methylprednisolone.

A tolerance is established for negligible residues of methylprednisolone in milk at 10 parts per billion.

§ 556.410 Metoserpate hydrochloride.

A tolerance of 0.02 part per million is established for negligible residues of metoserpate hydrochloride (methyl-*o*-methyl-18-epireserpate hydrochloride) in uncooked edible tissues of chickens.

§ 556.420 Monensin.

A tolerance of 0.05 part per million is established for negligible residues of monensin, in the edible tissues of chickens.

§ 556.430 Neomycin.

Tolerances are established for residues of neomycin in food as follows: 0.25 part per million (negligible residue) in edible tissues of calves; and 0.15 part per million (negligible residue) in milk.

§ 556.440 Nequinate.

A tolerance of 0.1 part per million is established for negligible residues of nequinate in the uncooked edible tissues of chickens.

§ 556.450 Nihydrazone.

A tolerance of zero is established for residues of nihydrazone (5-nitro-2-furaldehyde acetylhydrazone) in the uncooked edible tissues and eggs of chickens.

§ 556.460 Novobiocin.

A tolerance of zero is established for residues of novobiocin in milk from dairy animals, in eggs, and in the uncooked edible tissues of chickens and turkeys.

§ 556.470 Nystatin.

A tolerance of zero is established for residues of nystatin in or on eggs and the uncooked edible tissues of swine and poultry.

§ 556.480 Oleandomycin.

Tolerances are established for negligible residues of oleandomycin in uncooked edible tissues of chickens, turkeys, and swine at 0.15 part per million.

§ 556.490 Ormetoprim.

A tolerance of 0.1 part per million is established for negligible residues of ormetoprim in the edible tissues of chickens and turkeys.

§ 556.500 Oxytetracycline.

Tolerances are established for residues of oxytetracycline in food as follows:

(a) In edible tissues of chickens and turkeys:

(1) 3 parts per million in uncooked kidney.

(2) 1 part per million in uncooked muscle, liver, fat, and skin.

(b) 0.1 part per million in uncooked edible tissues of swine.

(c) 0.1 part per million in uncooked elible tissues of cattle, beef calves, nonlactating dairy cattle and dairy calves.

(d) A tolerance of 0.1 part per million is established for negligible residues of oxytetracycline in uncooked edible tissues of salmonids and catfish.

§ 556.510 Penicillin.

Tolerances are established for residues of penicillin and the salts of penicillin in food as follows:

(a) 0.05 part per million (negligible residue) in the uncooked edible tissues of cattle.

(b) Zero in the uncooked edible tissues of chickens, pheasants, quail, and swine; in eggs; and in milk or in any processed food in which such milk has been used.

(c) 0.01 part per million in the uncooked edible tissues of turkeys.

§ 556.520 Prednisolone.

A tolerance of zero is established for residues of prednisolone in milk from dairy animals.

§ 556.530 Prednisone.

A tolerance of zero is established for residues of prednisone in milk from dairy animals.

§ 556.540 Progesterone.

(a) No residue of progesterone may be found in the uncooked edible tissues of lambs and steers.

(b) The method of examination prescribed for the quantitative determination of progesterone is as follows: Prepare an extractive of the tissues as described in this paragraph, and bioassay the extractive in a vegetable oil vehicle by the method of Hooker and Forbes, published in "Endocrinology," volume 41, page 158 (1947).[1]

[1] Copies may be obtained from: Yale University, Department of Anatomy, New Haven, CT 06520.

(1) Extraction procedure for liver, lean meat, and kidney tissue:

(i) Extract 1 kilogram of finely minced tissue with 20 volumes of a mixture of chloroform:methyl alcohol::2:1 in a tissue homogenized.

(ii) Separate the insoluble material by filtration with suction and reextract with two volumes of the chloroform-methyl alcohol mixture.

(iii) Again separate the insoluble material, and extract it with one-fifth volume of water. Separate the water from the insoluble material and extract the water two times with two volumes of chloroform.

(iv) Combine the chloroform-methyl alcohol and the chloroform extractives from paragraph (b)(1) (i), (ii), and (iii) of this section and evaporate to dryness in vacuum under a stream of nitrogen. Redissolve the residue in chloroform-methyl alcohol mixture, separate any insoluble protein, and again evaporate to dryness in vacuum under a stream of nitrogen.

(v) Dissolve the residue from paragraph (b)(1)(iv) of this section in three volumes of petroleum ether, and extract four times with equal volumes of fresh portions of 70 percent methyl alcohol in water. Combine the 70 percent methyl alcohol extractives, and wash the methyl alcohol solution with one-fourth volume of petroleum ether. Discard the petroleum ether.

(vi) Concentrate the aqueous methyl alcohol solution from paragraph (b)(1)(v) of this section under vacuum to remove the methyl alcohol, and extract the aqueous solution four times with equal volumes of ethyl ether.

(vii) Combine the ethyl ether extractives, and evaporate to dryness. The residue is dissolved in a suitable amount of solvent for bioassay.

(2) Extraction procedure for fatty tissue:

(i) Extract 1 kilogram of finely minced tissue two times with five volumes of a mixture of hexane:benzene::1:1 and one time with one volume of the same solvent.

(ii) Combine hexane-benzene extractives and evaporate to dryness.

(iii) Dissolve the residue from subdivision (ii) of this subparagraph in 12 liters of petroleum ether and extract five times with ½-liter of 70 percent ethyl alcohol in water. Combine the 70 percent ethyl alcohol extractive, and concentrate by evaporation to remove most of the ethyl alcohol. Discard the petroleum ether.

(iv) Extract the aqueous solution from paragraph (b)(1)(iii) of this section four times with one-half volume of ethyl ether.

(v) Combine the ethyl ether extracts and evaporate to dryness. The residue is dissolved in a suitable amount of solvent for bioassay.

§ 556.550 Propylparaben.

A tolerance of zero is established for residues of propylparaben in milk from dairy animals.

§ 556.560 Pyrantel tartrate.

Tolerances are established for residues of pyrantel tartrate in edible tissues of swine as follows:

(a) 10 parts per million in liver and kidney.

(b) 1 part per million in muscle.

§ 556.570 Reserpine.

A tolerance of zero is established for residues of reserpine and its metabolites in or on the uncooked edible tissues and eggs of turkeys.

§ 556.580 Robenidine hydrochloride.

Tolerances are established for residues of robenidine hydrochloride in edible tissues of chickens as follows:

0.2 part per million in skin and fat.

0.1-part per million (negligible residue) in edible tissues other than skin and fat.

§ 556.590 Salicylic acid.

A tolerance of zero is established for residues of salicylic acid in milk from dairy animals.

§ 556.600 Spectinomycin.

A tolerance of 0.1 part per million is established for negligible residues of spectinomycin in the uncooked edible tissues of chickens.

§ 556.610 Streptomycin.

A tolerance of zero is established for residues of streptomycin in the uncooked edible tissues of chickens, turkeys, and swine, and in eggs.

§ 556.625 Sodium sulfachloropyrazine monohydrate.

A tolerance of zero is established for residues of sodium sulfachloropyrazine monohydrate in the uncooked edible tissues of chickens.

§ 556.630 Sulfachlorpyridazine.

A tolerance of 0.1 part per million is established for negligible residues of sulfachlorpyridazine in uncooked edible tissues of calves and swine.

§ 556.640 Sulfadimethoxine.

Tolerances are established for residues of sulfadimethoxine in edible products of animals as follows:

(a) In the uncooked edible tissues of chickens, turkeys, and cattle at 0.1 part per million (negligible residue).

(b) In milk at 0.01 part per million (negligible residue).

§ 556.650 Sulfaethoxypyridazine.

Tolerances for residues of sulfaethoxypyridazine in food are established as follows:

(a) Zero in the uncooked edible tissues of swine and in milk.

(b) 0.1 part per million (negligible residue) in uncooked edible tissues of cattle.

§ 556.660 Sulfamerazine.

A tolerance of zero is established for residues of sulfamerazine (N^1-[4-methyl-2-pyrimidinyl]sulfanilamide) in the uncooked edible tissues of trout.

§ 556.670 Sulfamethazine.

A tolerance of 0.1 part per million is established for negligible residues of sulfamethazine in the uncooked edible tissues of cattle and swine.

§ 556.680 Sulfanitran.

A tolerance of zero is established for residues of sulfanitran (acetyl(*p*-nitrophenyl) sulfanilamide) and its metabolites in the uncooked edible tissues of chickens.

§ 556.690 Sulfathiazole.

A tolerance of 0.1 part per million is established for negligible residues of sulfathiazole in the uncooked edible tissues of swine.

§ 556.700 Sulfomyxin.

A tolerance of zero is established for residues of sulfomyxin (N-sulfomethylpolymyxin B sodium salt) in uncooked edible tissues from chickens and turkeys.

§ 556.708 Testosterone.

(a) No residues of testosterone may be found in the uncooked edible tissues of beef cattle.

(b) The method of examination prescribed for the quantitative determination of testosterone is as follows: Prepare an extract of the tissues as described in § 556.540 (1) and (2) and bioassay the extractive in an ethyl alcohol vehicle by inunction of the day-old chick's comb by the method published in "Methods in Hormone Research," New York, Academic Press, volume II, page 286 (1962).[1]

§ 556.710 Testosterone propionate.

(a) No residues of testosterone propionate may be found in the uncooked edible tissues of heifers.

(b) The method of examination prescribed for the quantitative determination of testosterone propionate is as follows: Prepare an extract of the tissues as described in § 556.540(b) (1) and (2) and bioassay the extractive in an ethyl alcohol vehicle by inunction on the day-old chick's comb by the method published in "Methods in Hormone Research," New York, Academic Press, volume II, page 286 (1962).[1]

§ 556.720 Tetracycline.

A tolerance of 0.25 part per million is established for negligible residues of tetracycline in uncooked edible tissues of calves, swine, sheep, chickens, and turkeys.

§ 556.730 Thiabendazole.

Tolerances are established at 0.1 part per million for negligible residues of thiabendazole in uncooked edible tissues of cattle, goats, sheep, and swine, and at 0.05 part per million for negligible residues in milk.

§ 556.740 Tylosin.

Tolerances are established for residues of tylosin in edible products of animals as follows:

(a) In chickens and turkeys: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

(b) In cattle: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

(c) In swine: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

(d) In milk: 0.05 part per million (negligible residue).

(e) In eggs: 0.2 part per million (negligible residue).

§ 556.750 Virginiamycin.

A tolerance of 0.1 part per million is established for negligible residues of virginiamycin in the edible tissues of swine.

§ 556.760 Zeranol.

No residues of zeranol (6-(6,10-dihydroxyundecyl-β-resorcylic acid-μ-lactone may be found in the uncooked edible tissues of cattle and sheep as determined by the following method of analysis:

I. Method of Analysis—Zeranol

A gas chromatographic method for the determination of the drug in frozen beef tissues is described. Tissue is frozen and stored in a deep freezer until ready for examination. A weighed portion of wet tissue (with exception of fat) is homogenized and lyophilized to dry solid. The drug is recovered from dry tissue by an extraction with methanol in a Soxhlet extractor. The methanol extract is digested in the presence of hydrochloric acid to hydrolyze conjugates should any be present. Elimination of impurities is brought about by liquid partition transfer successively to chloroform to 1*N* sodium hydroxide, to carbon tetrachloride, to 1*N* sodium hydroxide, to ethyl ether, and, finally, to a dry residue. The residue is reacted with a silane mixture to create a volatile derivative which is quantitated by peak area measurements from a flame ionization detector. The drug can be detected at a level of 20 parts per billion with negligible interference from tissues or reagents.

II. Reagents

A. Carbon tetrachloride, N.F., Fisher Scientific C-188, or equivalent.

B. Chloroform, N.F., Fisher Scientific C-296, or equivalent.

C. Chromatograph gases, flow rates adjusted to maximize sensitivity for specific chromatograph.

1. Carrier gas, conventional tank helium.

2. Flame makeup gas.

a. Oxygen, conventional tank oxygen.

b. Hydrogen, Linde high purity, or equivalent.

D. Column packing, 3 percent GE SE-52 (Applied Science Laboratories) on P.E. Celite 60-80 mesh (Johns Manville Product No. 154-0048), or equivalent.

E. Ether, anhydrous, Fisher Scientific E-138, or equivalent.

F. Hexamethyldisilazane, Dow-Corning, Peninsular, or equivalent.

G. Hydrochloric acid, analytical reagent grade.

H. Methanol, certified A.C.S., spectranalyzed, Fisher Scientific A-403, or equivalent.

I. Phosphoric acid, analytical reagent grade.

J. Pyridine, anhydrous, A.C.S. reagent grade.

K. Silating reagent mixture: Pipet 8 milliliters each of pyridine and hexamethyldisilazane and 4 milliliters of trimethylchlorosilane into a clean glass vial with a

[1] Copies may be obtained from: Academic Press Inc., 111 Fifth Ave., New York, N.Y. 10003.

polyethylene cap and mix thoroughly. Let stand overnight and decant supernatant liquid into a vial. Cap and store at room temperature for daily use. If kept dry, the reagent is stable for more than a month. Blanks are scanned by gas chromatography on each new bottle of J, F, and N material used in the silating reagent mixture for possible peak interference in the region of zeranol derivative.

L. Sodium chloride, analytical reagent grade.

M. Sodium hydroxide, analytical reagent grade.

N. Trimethylchlorosilane, Dow-Corning, Peninsular, or equivalent.

O. Water, distilled in glass.

P. Zeranol, primary standard.

Q. Solutions.

1. 2*N* Hydrochloric acid in water.
2. 3*N* Phosphoric acid in water.
3. 2 percent w/v solium chloride in water.
4. 1*N* Sodium hydroxide in water.

III. Apparatus

A. Extraction assemblies, Soxhlet, improved, standard taper grindings, Pyrex brand glass, 1,000 milliliters capacity, Sargent Catalog S-31265D, or equivalent.

B. Flasks, freeze drying, widemouth, 1,000 milliliters capacity, 24/40 standard taper grindings, Pyrex brand glass, Sargent Catalog S-28875-20-F, or equivalent.

C. Flasks, homogenizing, 250 milliliters, Sargent Catalog S-61716, or equivalent.

D. Funnels, separatory, Squibb stopper, with Teflon stopcock plug, Pyrex brand glass, 250- and 500-milliliter capacities, Sargent Catalog S-35815-20-F or G, or equivalent.

E. Gas chromatograph, F and M Model 5750 with flame ionization detector, or equivalent.

F. Gas chromatography column: Stainless steel tubing, 6 feet by 3/16 inch packed with 3 percent by weight GE SE-52 (Applied Science Laboratories) deposited on P.E. Celite 60-80 mesh (product No. 154-0048), or equivalent. Condition the column by baking for 40-80 hours at 325° C. with a helium flow, but detached from the detector input. Injections of 1-2 microliters of a 50/50 mixture of hexamethyldisilazane and trimethylchlorosilane will help remove active sites in the column.

1. Prepare a TMS derivative of a 1,000-microgram zeranol standard as described in the procedure section. Inject 1-microliter quantities to determine whether the column is responding to the conditioning. After the column shows a response at the 1,000-microgram level, proceed to smaller quantities to optimize conditions.

2. The column and chromatograph must be conditioned to achieve a minimum sensitivity response so that a peak 5 millimeters in height results from an injection of 5 microliter of standard preparation containing 1 microgram of zeranol in the derivative preparation. This criterion must be met before tissue assay is attempted.

3. The column is brought to 250° C. after conditioning and held at that temperature for at least 12 hours before making a run.

G. Heating mantle, electric, Glas-Col, Sargent Catalog S-40866H, or equivalent.

H. Hot plate, with gradient rheostat heat control.

I. Meat grinder, manually operated or equivalent.

J. Steam bath.

K. Syringe, Hamilton Micro Syringe Model 701, 10-microliter capacity, or equivalent.

L. Torsion balance, 0.1 gram sensitivity, 500 grams capacity.

M. Vials, 1-dram glass with plastic tops, Owens-Illinois, Opticlear, or equivalent.

N. Virtis freeze drier, Sargent Catalog S-28881-80, or equivalent.

O. Virtis homogenizing mill, macro, Virtis No. 45, Sargent Catalog S-61700, or equivalent.

IV. Standard Solutions

A. Stock solution A: Accurately weigh 0.1000 gram of zeranol, primary standard, into a 250-milliliter beaker. Dissolve the standard in 80 milliliters of methanol and accurately dilute to 100 milliliters in a volumetric flask with methanol. By preparation, the solution contains 1,000 micrograms per milliliter.

B. Stock solution B: Dilute 10.0 milliliters of stock solution A to 100 milliliters with methanol to provide a standard containing 100 micrograms of the drug per milliliter.

C. Stock solution C: Dilute 5.0 milliliters of stock solution B to 100 milliliters with methanol to provide a standard of 5 micrograms per milliliter.

D. Stock solution D: Dilute 2.0 milliliters of stock solution B to 100 milliliters with methanol to provide a standard of 2 micrograms per milliliter. Transfer 1.0 milliliter of stock solution D to a 1-dram glass vial, evaporate to a dry residue in a vacuum desiccator at reduced pressure. The residue contains 2 micrograms of zeranol to be used as a calibration standard in operation of the gas chromatograph.

V. Procedure

A. Preparation of glassware: Glassware should be washed in detergent or chromic acid solution to remove contaminants and rinsed in water to remove traces of cleaning agent. Rinse with methanol before using.

B. Preparation of sample.

1. Collect muscle, liver, kidney, and tripe from a freshly sacrificed animal under the cleanest conditions possible.

2. Grind the fresh tissue in a meat grinder, divide into 100-gram portions, and wrap in aluminum foil. Store wrapped tissue in a deep freeze. Fat should be wrapped in foil and stored in deep freeze.

C. Extraction procedure for muscle, liver kidney, and tripe.

1. Weight 100 grams of partially thawed tissue into a 250-milliliter homogenizing flask, add 60 milliliters of water, and attach to a Virtis "45" Tissue Mill, or equivalent.

2. Mix the materials at 45,000 r.p.m. for 5 minutes to obtain a thin homogenate.

3. Transfer the homogenate to a 1-liter, widemouth, freeze drying flask using 10-20 milliliters of water for a rinse.

4. Place the flask on its side in a nearly horizontal position in a slurry of dry ice and acetone. Rotate the flask on its side as the homogenate cools to set down a uniform frozen solid layer on the wall of the flask.

5. Mount the flask on a Virtis freeze drier, or equivalent, and lyophilize to dry solids. This operation usually requires 20-24 hours. *Stopping place.*

6. Transfer the solid cake to a clean sheet of paper and crumble by hand to a size convenient for transfer to an extraction thimble.

7. Transfer the solids to a single thickness 60 x 180 milliliters Soxhlet extraction thimble and compact the solids sufficiently to guarantee complete immersion during solid extraction.

8. Transfer 600 milliliters of methanol to a 1-liter pot of a Soxhlet extraction assembly and place the thimble in the extractor. Mount a large glass funnel in the neck of the extractor with the stem extending into the thimble. Rinse the 1-liter freeze drying flask with three 50-milliliter portions of fresh methanol and transfer the rinses through the funnel into the thimble. Mount the condenser in the extractor and extract the solids for 15 hours. The extractor should be heated with the electric heating mantle so that a fill-empty cycle requires 18-24 minutes.

9. Drain the methanol from the thimble. Composite the methanol from the extractor and pot in an 800-milliliter beaker.

10. Rinse the pot with 10 milliliters of methanol and add to the methanol composite. Transfer 50 milliliters of 2*N* HCl down the pot side wall, and add to methanol composite. Concentrate to 125 milliliters by boiling on a hotplate.

D. Extraction procedure for fat.

1. Cut fat into ¼-inch cubes. The lyophilization of fat is unnecessary since it is essentially water free.

2. Transfer 100 grams of the prepared fat to a 60- x 180-millimeter extraction thimble and extract with 750 milliliters of methanol for 15 hours in the Soxhlet extractor. The extractor should be heated with the electric heating mantle so that a fill-empty cycle requires 18-24 minutes.

3. Drain the methanol from the thimble. Composite the methanol from the extractor and pot in an 800-milliliter breaker.

4. Rinse the pot with 10 milliliters of methanol and add to the methanol composite. Transfer 50 milliliters of 2*N* HCl down the pot side wall, and add to methanol composite. Concentrate to 125 milliliters by boiling on a hot plate.

E. Solvent partition.

1. Transfer the methanol concentrate to a 500-milliliter separatory funnel, identified by number as 1, with 70 milliliters of chloroform rinse and mix.

2. Add 300 milliliters of water and without shaking allow liquid phases to separate.

3. Withdraw the chloroform layer into a separatory funnel, identified by number as 2, containing 100 milliliters of 2 percent aqueous sodium chloride.

4. Gently mix the contents of funnel 2 horizontally end to end 30 times and allow phases to separate. Usually about 20 minutes are required to obtain maximum chloroform separation.

5. Withdraw the chloroform layer into a beaker.

6. Extract with shaking the contents of funnels 1 and 2 successively with three more 50-milliliter portions of chloroform.

7. Composite the chloroform extracts and concentrate to 125 milliliters by evaporation on a steam bath and cool to room temperature.

8. Transfer the chloroform composite to a 250-milliliter separatory funnel, fitted with a Teflon stopcock, using 10 milliliters of chloroform as a rinse.

9. Extract the chloroform with three separate 20-milliliter portions of 1*N* sodium hydroxide solution retaining the emulsion in the sodium hydroxide phase. Agitation of sodium hydroxide with the chloroform extract for the first time is accompanied by the appearance of emulsion.

10. Perform an extraction by gently inverting the closed funnel and returning the funnel to an upright position.

11. Repeat phase mixing 30 times per extraction.

12. Allow phases to separate for 10 minutes. The time delay allows for gradual dissipation of the emulsion to improve phase separation. The zeranol transfers from the chloroform to the upper sodium hydroxide phase in this operation.

13. Composite the sodium hydroxide extracts.

14. Wash the sodium hydroxide extract with three 50-milliliter portions of chloroform using the technique as in step 9 and the same 10-minute interval for phase separation. Washing the chloroform removes the emulsion and unwanted impurities from the sodium hydroxide phase.

15. Discard the chloroform washes. Transfer the sodium hydroxide extracts to a 250-milliliter beaker. Rinse each separatory fun-

nel with two 5-milliliter portions of water and add to the sodium hydroxide extract. Wash each funnel twice with tap water and twice with distilled water before next use.

16. Neutralize the washed sodium hydroxide extract to pH 8.0 by dropwise addition of 3*N* phosphoric acid using a pH meter for pH detection.

17. Transfer the pH 8.0 water extract to a 250-milliliter separatory funnel using 10 to 20 milliliters of water for a rinse.

18. Extract the solution with three separate 50-milliliter portions of carbon tetrachloride. The zeranol transfers to the lower carbon tetrachloride phase. Use the same 30-count phase-mixing technique as in step 9 and allow the mixture to stand 5 minutes for phase separation.

19. Composite the carbon tetrachloride extracts.

20. Extract the carbon tetrachloride composite with two 20-milliliter portions of 1*N* sodium hydroxide. Zeranol transfers from carbon tetrachloride to the upper sodium hydroxide phase. After phase mixing, allow the mixture to stand 5 minutes for phase separation.

21. Composite the sodium hydroxide extracts.

22. Wash the extract with two 50-milliliter portions of carbon tetrachloride. Allow the mixture to stand 5 minutes for phase separation. Discard the carbon tetrachloride washes.

23. Transfer the sodium hydroxide extract into a 250-milliliter beaker. Rinse the separatory funnel with two 5-milliliter portions of water and add to the sodium hydroxide extract. Wash each funnel twice with tap water and twice with distilled water before next use. Adjust the sodium hydroxide extract to a pH of 9.5 by dropwise addition of 3*N* phosphoric acid and transfer to a 250-milliliter separatory funnel using 10–20 milliliters of water for a rinse.

24. Extract the pH 9.5 water solution with three separate 30-milliliter portions of anhydrous ethyl ether. Allow the mixture to stand 5 minutes for phase separation. The zeranol transfers to the upper ether phase.

25. Composite the ether extracts in a 125-milliliter Erlenmeyer flask.

26. Reduce the volume of ether to about 1–2 milliliters by evaporation on a hot plate with low heat while removing vapor from top of flask by vacuum aspiration.

27. Transfer ether residue to a 1-dram glass vial. Rinse down flask side wall with 1–2 milliliters of fresh ether and transfer to the glass vial.

28. Continue evaporation of ether to 0.1 milliliter.

29. Place vial in a vacuum desiccator and evaporate residue at line vacuum and room temperature overnight to dryness.

30. Close vial with a plastic cap and submit ether residue for preparation of TMS derivative and gas chromatographic assay. *Stopping place.*

F. Gas liquid chromatography.

1. Start the gas chromatography and maintain the following operational conditions:

Carrier gas pressure: 50 p.s.i. at tank.

Carrier gas flow rate: Sufficient to give zeranol derivative peak a retention time of 4–8 minutes.

Electrometer range: 10^2 or 10^1.

Detector temperature: 325° C.

Injection port temperature: 325° C.

Column temperature: 250°–280° C., operate isothermally.

Recorder sensitivity: 1 millivolt.

Recorder chart speed: 1 inch per minute.

Sample size: 1 microliter to 5 microliters as necessary to give desired peak area for quantitative measurement.

Septums: Replace each evening and allow to condition overnight at operational temperature.

Flame assembly: Remove silica ash from the flame assembly each week. The flame assembly is removed; the anode, flame jet, and chimney are cleaned with a nylon bristle brush. Water and acetone are drawn through the jet capillary to remove any foreign material.

2. Add 0.2 milliliter of silating reagent to the sample or to the zeranol standard.

3. Stopper the vial and shake vigorously.

4. Warm the vial at 40°–50° C. for a few minutes, then roll the vial on a horizontal plane to insure that all of the interior surfaces of the vial have been in contact with the reagent.

5. Let vial stand for 4 hours or overnight in a warm area (40° C.) to allow reaction to reach completion.

6. Place vial in a small padded centrifuge tube and centrifuge to settle the precipitate and insure that all the liquid is at the bottom of the vial.

7. Inject 1.0–5.0 microliters of clear solution into the chromatograph. At the beginning of the day's run, make 3–5 injections of a standard to condition the column for that day before taking quantitative data.

8. Run known mixtures at the beginning, middle, and end of the day's run over the concentration range of samples to be analyzed to compensate for day-to-day sensitivity fluctuations and drift. If four or less samples are to be run, calibrating at the beginning and end of the run is sufficient.

VI. CALCULATIONS

Area values are obtained on known mixtures and samples by multiplying the net peak height by the peak width at half height or by counting squares. Area values obtained on knowns are plotted versus zeranol concentration. Calibration plots indicate a near linear function in the 0–10 microgram range. Area values obtained on samples are converted directly to microgram quantities using the curve. Control tests demonstrated a 70 percent recovery of zeranol from spiked wet beef liver and muscle necessitating a correction factor.

$$\text{Zeranol, parts per billion} = \frac{\text{Micrograms of zeranol found} \times 1{,}000}{W \times 0.7}$$

Where:

0.7=Correction factor for 70 percent recovery.

W=Grams of tissue examined.

VII. RECOVERY STUDY

A. Fortification of reagent blank.

1. For those using this method for the first time either for recovery study or tissue assay, a solvent blank and solvent fortified with zeranol should be processed through the entire procedure. This preliminary operation will establish whether or not the procedure is free from contamination arising from solvents and glassware and demonstrate the level of recovery of the standard zeranol. Level of recovery should be in the same range as the samples.

2. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2*N* HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate.

3. Transfer 600 milliliters of methanol to a 1-liter beaker. Add 50 milliliters of 2*N* HCl to the methanol and concentrate to 125 milliliters by boiling on a hot plate. Spike the concentrate with 1.0 milliliter of stock solution D.

4. Assay both samples as described in the procedure beginning extraction step V–E1.

B. Fortification of samples.

1. Transfer 100-gram portions of partially thawed tissues into 250-milliliter homogenizing flasks and set half of them aside to serve as tissue blanks.

2. Add to the remaining samples 1 milliliter of stock solution D to serve as fortified samples to which 20 parts per billion zearalanol have been added.

3. Assay both fortified and unfortified tissue as described in the procedure section beginning with V–C1.

§ 556.770 Zoalene.

Tolerances are established for residues of zoalene(3,5-dinitro-o-toluamide) and its metabolite 3-amino-5-nitro-o-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Subpart A—General Provisions

Sec.	
558.4	Approval of new animal drug applications for medicated feeds.
558.5	New animal drug requirements for liquid feed supplements.
558.15	Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.
558.19	Combination antibiotic drugs in animal feeds no longer sanctioned.

Subpart B—Specific New Animal Drugs For Use in Animal Feeds

558.25	2-Acetylamino-5-nitrothiazole.
558.35	Aklomide.
558.45	Ammonium chloride, feed grade.
558.55	Amprolium.
558.95	Bambermycins.
558.105	Buquinolate.
558.115	Carbadox.
558.145	Chlortetracycline, procaine penicillin, and sulfamethazine.
558.155	Chlortetracycline, procaine penicillin, and sulfathiazole.
558.173	Clopidol.
558.185	Coumaphos.
558.195	Decoquinate.
558.205	Dichlorvos.
558.225	Diethylstilbestrol.
558.305	Ipronidazole.
558.315	Levamisole hydrochloride (equivalent).
558.325	Lincomycin.
558.355	Monensin.
558.365	Nequinate.
558.415	Novobiocin.
558.435	Oleandomycin.
558.465	Poloxalene liquid feed supplement.
558.485	Pyrantel tartrate.
558.505	Reserpine.
558.515	Robenidine hydrochloride.
558.525	Ronnel.
558.565	Styrylpyridinium chloride, diethylcarbamazine (as base).

Sec.
558.575 Sulfadimethoxine, ormetoprim.
558.615 Thiabendazole.
558.625 Tylosin.
558.630 Tylosin and sulfamethazine.
558.635 Virginiamycin.

AUTHORITY: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); unless otherwise noted.

Subpart A—General Provisions

§ 558.4 Approval of new animal drug applications for medicated feeds.

(a) The Food and Drug Administration cannot approve an initial new animal drug application for a drug that is to be added to animal feed until a regulation providing for the safe use of the new animal drug substance as a food additive has been promulgated by publication in the FEDERAL REGISTER in accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act.

(b) In the past the Food and Drug Administration has received many medicated feed new animal drug applications from feed manufacturers prior to the promulgation of the required regulation, and these applications could not or cannot be reviewed until such promulgation. Frequently when such applications were finally reviewed after issuance of the regulation, they were found to contain information and labeling not in conformance with such regulation. This resulted in considerable unnecessary work on the part of the applicants and the Food and Drug Administration.

(c) Accordingly, effective on date of publication of this section in the FEDERAL REGISTER, the following is the policy of the Food and Drug Administration regarding the processing of medicated feed new animal drug applications:

(1) Only those applications for a new animal drug for which a regulation has been established in this part will be accepted and reviewed.

(2) Applications for new animal drugs for which no such regulation has been established will be returned to the applicant without review or comment.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b (i)).)

§ 558.5 New animal drug requirements for liquid feed supplements.

(a) Information available to the Commissioner of Food and Drugs shows that certain drugs are unstable when added to some liquid feed supplements. The demonstrated instability of these drugs gives rise to the question of the stability of other drugs when added to liquid feed supplements, except where specific approval has been granted for such use. Therefore, the labeling of a drug to provide for its use in a liquid feed supplement causes the drug to be a new animal drug for such use for which an approved new animal drug application is required pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act.

(b) The addition of a drug to a liquid feed supplement causes such supplement to become an animal feed bearing or containing a new animal drug for which an approved application is required pursuant to section 512(m) of the act.

(c) Each drug product, intended for oral administration to animals, which contains any of the drugs listed in paragraph (d) of this section and which bears labeling for its use in animal feed and/or drinking water shall also include in such labeling the following statement: "FOR USE IN _____ ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS," the blank being filled in with the words "DRY FEEDS," "DRINKING WATER," "DRY FEEDS AND DRINKING WATER" as applicable, unless:

(1) Such drug product is the subject of an approved new animal drug application providing for its use in liquid feed supplements, or;

(2) The labeling provisions of this paragraph have been waived on the basis of approval of a petition which includes a copy of the product label; a description of the formulation; and information which establishes that the physical, chemical, or other properties of the particular drug product are such that it cannot reasonably be expected to be diverted for use in liquid feed supplements. Such petitions shall be submitted to the Food and Drug Administration, Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, MD 20852.

(d) The labeling provisions of paragraph (c) of this section apply to all forms of bacitracin, oxytetracycline, and chlortetracycline.

(e) For any drug which is the subject of an approved new animal drug application, the labeling provisions of paragraph (c) of this section may be implemented without prior approval as provided for in § 514.8 (d) and (e) of this chapter.

§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofuran drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofuran drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofuran drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofuran, and sulfonamide drugs pursuant to section 512(1) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1973; and for the nitrofuran drugs by March 4, 1974. The Food and Drug Administration encourages sponsors to consult with the Bureau of Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofuran drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic, nitrofuran, or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal

feeds under section 512(1) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Bureau of Veterinary Medicine, 5600 Fishers Lane, Rockville, MD 20852.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Bureau of Veterinary Medicine, Office of the Assistant to the Director for Antibiotics in Animal Feeds, 5600 Fishers Lane, Rockville, MD 20852.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofuran, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

§ 558.19 Combination antibiotic drugs in animal feeds no longer sanctioned.

(a) The National Academy of Sciences-National Research Council, Drug Efficacy Study Group evaluated the effectiveness of various drugs intended for use in animals. In furtherance of the principles laid down by the National Academy of Sciences-National Research Council, and in response to the need for an integrated monitoring program of all animal drugs, the Commissioner of Food and Drugs has conducted a review of certain additional combination antibiotic drugs used in animal feeds that were not considered by the National Academy of Sciences-National Research Council. The Commissioner has concluded that available information fails to provide substantial evidence of effectiveness of the drugs listed in paragraph (c) of this section, and the manufacturers or distributors have informed the Commissioner that either the drugs are no longer marketed or that there is no interest in their continued marketing.

(b) Certain drug combinations listed in paragraph (c) of this section were in use or sanctioned in Subpart C of Part 121 and/or § 510.515 of this chapter, while other drug combinations should be the subject of an approved new animal drug application. The listing of certain combination antibiotic drugs that are no longer sanctioned for use in animal feed provides prompt public notice of this action and serves as an interim measure to withdraw approval of the drugs listed under paragraph (c) of this section until recodification and amendment to the applicable sections can be completed.

(c) The Commissioner finds that any further marketing of the following combination drugs constitutes a violation of the Federal Food, Drug, and Cosmetic Act in that they have not been shown to be effective for their intended use. This listing is subject to later additions resulting from continued evaluation of combination animal drug products.

IDENTIFICATION	DRUG	DOSAGE
	SPECIES: CHICKEN BREEDER	
83810	RESERPINE	.002 PERCENT
	BACITRACIN	10-200 GM/TON
	SPECIES: CHICKEN BROILER	
83021	AMPROLIUM	.004-.025 PERCENT
	STREPTOMYCIN	30-50 GM/TON
83023	AMPROLIUM	.004-.025 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
83027	AMPROLIUM	.004-.25 PERCENT
	DIENESTROL DIACETATE	.0023-.007 PERCENT
	PENICILLIN	2.4-50 GM/TON
83043	AMPROLIUM	.0125-.025 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	BACITRACIN	4-50 GM/TON
83052	AMPROLIUM	.0125-.025 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83056	AMPROLIUM	.0125-.025 PERCENT
	ROXARSONE	.025-.005 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
	ETHOPABATE	.0004 PERCENT
83100	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ETHOPABATE	.0004 PERCENT
83126	AMPROLIUM	.004-.0125 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83143	AMPROLIUM	.0125-.025 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
83145	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN	4-50 GM/TON
83146	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83159	AMPROLIUM	.0125-.025 PERCENT
	DIENESTROL DIACETATE	.0023 PERCENT
	PENICILLIN	2.4-50 GM/TON
83189	AMPROLIUM	.0125-.025 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	PENICILLIN	2.4-50 GM/TON
83190	AMPROLIUM	.0125-.025 PERCENT
	DIENESTROL DIACETATE	.0035 PERCENT
	PENICILLIN	2.4-50 GM/TON
83198	AMPROLIUM	.004-.0125 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83149	AMPROLIUM	.0125-.025 PERCENT
	ARSANILIC ACID	.01 PERCENT
	ETHOPABATE	.0004 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
83082	DIENESTROL DIACETATE	.0023-.007 PERCENT
	PENICILLIN	.0125 PERCENT
83138	HYGROMYCIN B	8 GM/TON
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83060	NIHYDRAZONE	100 GM/TON
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83049	RESERPINE	.0001 PERCENT
	BACITRACIN	4-50 GM/TON
83050	RESERPINE	.0001 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
83051	RESERPINE	.0001 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83122	RESERPINE	.0001 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
83123	RESERPINE	.0001 PERCENT
	ZINC BACITRACIN	200 GM/TON MAXIMUM
83066	ROXARSONE	.0025-.005 PERCENT
	ZOALENE	.0125 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83075	ROXARSONE	.005 PERCENT
	ZOALENE	.0125 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83076	ROXARSONE	.005 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	ZOALENE	.0125 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83032	ZOALENE	.0125 PERCENT
	HYGROMYCIN B	8-12 GM/TON
	PENICILLIN PLUS	
	TYLOSIN	3.2-50 GM/TON COMB.
83069	ZOALENE	.0125 PERCENT
	PENICILLIN PLUS	
	TYLOSIN	3.2-50 GM/TON COMB.
83133	ZOALENE	.0125 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83135	ZOALENE	.004-.0125 PERCENT
	ARSANILIC ACID	.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83205	ZOALENE	.004-.0125 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	SPECIES: CHICKEN LAYER	
83714	RESERPINE	.0002 PERCENT
	ZINC BACITRACIN	10-200 GM/TON
	SPECIES: CHICKEN REPLACEMENT	
83411	AMPROLIUM	.004-.025 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
83416	AMPROLIUM	.0125-.025 PERCENT
	ETHOPABATE	.0004 PERCENT
	STREPTOMYCIN	30-50 GM/TON
83417	AMPROLIUM	.0125-.025 PERCENT
	ETHOPABATE	.0004 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
83430	AMPROLIUM	.0125-.025 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	BACITRACIN	4-50 GM/TON
	ETHOPABATE	.0004 PERCENT
83431	AMPROLIUM	.0125-.025 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	BACITRACIN	4-50 GM/TON
83444	AMPROLIUM	.0125-.025 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
	ETHOPABATE	.0004 PERCENT
83551	AMPROLIUM	.004-.0125 PERCENT
	BACITRACIN	4-50 GM/TON
83506	NIHYDRAZONE	100 GM/TON
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83442	RESERPINE	.0001 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
83443	RESERPINE	.0001 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83463	ROXARSONE	.005 PERCENT
	ZOALENE	.0125 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6 GM/TON
83539	ROXARSONE	.0025-.005 PERCENT
	ZOALENE	.0083-.0125 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83453	ZOALENE	.004-.0125 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
83480	ZOALENE	.004-.0125 PERCENT
	HYGROMYCIN B	8-12 GM/TON
	PENICILLIN PLUS	
	TYLOSIN	3.2-50 GM/TON COMB.
83537	ZOALENE	.0083-.0125 PERCENT
	ARSANILIC ACID	.01 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	SPECIES: CHICKEN UNSPECIFIED	
	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN	4-50 GM/TON
82121	ETHOPABATE	.0004 PERCENT

IDENTIFICATION	DRUG	DOSAGE
82122	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ETHOPABATE	.0004 PERCENT
82753	AMPROLIUM	.0125-.025 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ETHOPABATE	.0004 PERCENT
82005	ARSANILIC ACID	.005-.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82057	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82069	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82378	ARSANILIC ACID	.005-.01 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82418	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB
82425	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82139	BACITRACIN	4-50 GM/TON
	NYSTATIN	50 GM/TON
82140	BACITRACIN	3.6-50 GM/TON
	NYSTATIN PLUS	
	PENICILLIN	50 GM/TON COMB.
82141	BACITRACIN	4-50 GM/TON
	NYSTATIN	100 GM/TON
82142	NYSTATIN	100 GM/TON
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82000	NYSTATIN	50 GM/TON
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82171	MANGANESE BACITRACIN	4-50 GM/TON
	NYSTATIN	50 GM/TON
82173	NYSTATIN	100 GM/TON
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82502	NYSTATIN	50 GM/TON
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82503	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	NYSTATIN	50 GM/TON
82504	NYSTATIN	100 GM/TON
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82505	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	NYSTATIN	100 GM/TON
82783	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	SODIUM FLUORIDE	.5-1 PERCENT
82754	NYSTATIN	50 GM/TON
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82756	NYSTATIN	100 GM/TON
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82484	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82496	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82739	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	PIPERAZINE SULFATE	.12 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82883	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82662	CHLORTETRACYCLINE	10-50 GM/TON
	NYSTATIN	50 GM/TON
82663	CHLORTETRACYCLINE	10-50 GM/TON
	NYSTATIN	100 GM/TON
82203	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82204	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82205	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	10-50 GM/TON
82206	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82547	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	BACITRACIN	4-50 GM/TON
82638	DIENESTROL DIACETATE	.0023-.007 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82639	DIENESTROL DIACETATE	.0023-.007 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
82493	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82944	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82945	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	PENICILLIN	10-50 GM/TON
82946	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82947	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	BACITRACIN	4-50 GM/TON
82948	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82949	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82950	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	PENICILLIN	10-50 GM/TON
82951	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82952	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	BACITRACIN	4-50 GM/TON
82953	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82954	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82955	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	PENICILLIN	2.4-50 GM/TON
82956	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82011	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	

IDENTIFICATION	DRUG	DOSAGE
	PENICILLIN	3.6-50 GM/TON COMB.
82012	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82060	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82066	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100-500 GM/TON
82072	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82176	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	2.4-50 GM/TON
82222	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
82353	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82414	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82428	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82435	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	50-100 GM/TON
82442	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON
82449	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100-200 GM/TON
82543	FURAZOLIDONE	.011 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82548	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015-.05 PERCENT
82549	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82550	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015-.05 PERCENT
82552	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015-.05 PERCENT
82553	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	100 GM/TON
82556	FURAZOLIDONE	.00083 PERCENT
	PROCAINE PENICILLIN	100 GM/TON
82559	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	200 GM/TON
82561	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	200 GM/TON COMB.
82567	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	50 GM/TON
82572	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	50 GM/TON
82574	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	50 GM/TON COMB.
82578	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100 GM/TON
82580	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	100 GM/TON COMB.
82934	FURAZOLIDONE	.022 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82939	FURAZOLIDONE	.0055 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82501	HYGROMYCIN B	8-12 GM/TON
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.

IDENTIFICATION	DRUG	DOSAGE
82123	NICARBAZIN	.01-.02 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82127	NICARBAZIN	.01-.02 PERCENT
	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82129	NICARBAZIN	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.010 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82131	NICARBAZIN	.01-.02 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82133	NICARBAZIN	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	100-500 GM/TON
	PENICILLIN	125 GM/TON MAXIMUM
82135	NICARBAZIN	.01-.02 PERCENT
	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82196	NICARBAZIN	.01-.02 PERCENT
	BACITRACIN	4-50 GM/TON
82562	NICARBAZIN	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	200 GM/TON
82569	NICARBAZIN	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	50 GM/TON
82510	NIHYDRAZONE	.011 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82019	NITHIAZIDE	.0125-.04 PERCENT
	OXYTETRACYCLINE	50 GM/TON MAXIMUM
82020	NITHIAZIDE	.0125-.04 PERCENT
	PENICILLIN	2.4-50 GM/TON
82021	NITHIAZIDE	.0125-.04 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82146	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN	4-50 GM/TON
82147	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6 GM/TON COMB.
82513	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82585	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
82586	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82587	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82588	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00082 PERCENT
	PENICILLIN	2.4-50 GM/TON
82589	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82660	NITHIAZIDE	.0125-.04 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82762	NITHIAZIDE	.0125-.04 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82013	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82016	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82018	NITROFURAZONE	.0056 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82048	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
82049	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
82055	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	50-100 GM/TON
82056	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	50-100 GM/TON
82061	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	50-100 GM/TON
	PENICILLIN	.00083 PERCENT
82062	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	50-100 GM/TON COMB.
82067	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100-500 GM/TON
82068	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100-500 GM/TON
82073	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
82074	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON
		125 GM/TON MAXIMUM
82092	NITROFURAZONE	.0112 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
82093	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
82094	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
82095	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
82096	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
82153	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 PERCENT
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.005 PERCENT
82155	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82161	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.

IDENTIFICATION	DRUG	DOSAGE
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82163	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.005 PERCENT
82180	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS STREPTOMYCIN	14.4-50 GM/TON COMB.
82181	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS STREPTOMYCIN	14.4-50 GM/TON COMB.
82223	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
82225	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
82258	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82265	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL-PYRIMIDINE	.003-.006 PERCENT
82272	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82279	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82286	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82322	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	50 GM/TON
82324	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS OXYTETRACYCLINE	50 GM/TON COMB.
82325	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100 GM/TON
82326	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	CHLORTETRACYCLINE	100 GM/TON
82327	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	100 GM/TON
82328	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	100 GM/TON COMB.
82329	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	90-180 GM/TON COMB.
82330	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	90-180 GM/TON COMB.
82332	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	200 GM/TON
82333	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82334	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	200 GM/TON COMB.
82335	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	100 GM/TON
82336	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	100 GM/TON
82337	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100 GM/TON
82338	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100 GM/TON
82339	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100 GM/TON
82340	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	100 GM/TON
82341	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	100 GM/TON
82342	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	100 GM/TON COMB
82343	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100 GM/TON COMB
82344	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100 GM/TON COMB
82356	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82368	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82370	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82394	NITROFURAZONE	.0056 PERCENT
	NITROPHENIDE	.05 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82415	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82417	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82422	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82424	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82429	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82431	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82443	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
82445	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
82450	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100-200 GM/TON
82452	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100-200 GM/TON
82461	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82462	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82468	NITROFURAZONE	.0056 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82469	NITROFURAZONE	.0112 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82471	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82472	NITROFURAZONE	.0056 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82678	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82680	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
82682	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82715	NITROFURAZONE	.0056 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82716	NITROFURAZONE	.0112 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82717	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82900	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82907	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82930	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82085	NITROPHENIDE	.0125-.025 PERCENT
	BACITRACIN	4-50 GM/TON
82087	NITROPHENIDE	.0125-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82174	NITROPHENIDE	.0125-.025 PERCENT
	PENICILLIN	2.4-50 GM/TON
82178	NITROPHENIDE	.0125-.025 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82207	NITROPHENIDE	.0125-.05 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82208	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	OXYTETRACYCLINE	10-50 GM/TON
82209	NITROPHENIDE	.0125-.05 PERCENT
	PENICILLIN	2.4-50 GM/TON
82210	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	PENICILLIN	2.4-50 GM/TON
82211	NITROPHENIDE	.0125-.05 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82212	NITROPHENIDE	.0125-.05 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82213	NITROPHENIDE	.0125-.05 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82298	NITROPHENIDE	.0125-.05 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82299	NITROPHENIDE	.0125-.05 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82300	NITROPHENIDE	.0125-.05 PERCENT
	BACITRACIN	4-50 GM/TON

IDENTIFICATION	DRUG	DOSAGE
82301	NITROPHENIDE	.0125-.05 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82302	NITROPHENIDE	.0125-.05 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82303	NITROPHENIDE	.0125-.05 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
82304	NITROPHENIDE	.0125-.05 PERCENT
	STREPTOMYCIN	30-50 GM/TON
82305	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	CHLORTETRACYCLINE	50-200 GM/TON
82306	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	STREPTOMYCIN	30-50 GM/TON
82307	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82308	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82309	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82310	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82311	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82312	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	BACITRACIN	4-50 GM/TON
82313	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82314	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
82315	NITROPHENIDE	.0125-.05 PERCENT
	DIENESTROL DIACETATE	.007 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82390	NITROPHENIDE	.05 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82391	NITROPHENIDE	.05 PERCENT
	ARSANILIC ACID	.0025-.01 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82392	NITROPHENIDE	.05 PERCENT
	SODIUM ARSANILATE	.0025-.01 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82393	NITROPHENIDE	.05 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
82695	NITROPHENIDE	.0125-.025 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
82696	NITROPHENIDE	.0125-.025 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
82713	NITROPHENIDE	.0125-.025 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82687	NITROPHENIDE	.0125-.025 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82294	NYSTATIN	50-100 GM/TON
	PENICILLIN	2.4-50 GM/TON
82295	NYSTATIN	50-100 GM/TON
	STREPTOMYCIN	30-50 GM/TON
82296	NYSTATIN	50-100 GM/TON
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
82097	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN	4-50 GM/TON
	NICOTINE	.03-.07 PERCENT
82093	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN	4-50 GM/TON
82107	PHENOTHIAZINE	.3-1 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NICOTINE	.03-.07 PERCENT
82108	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82698	PHENOTHIAZINE	.3-1 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82728	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NICOTINE	.003-.07 PERCENT
82729	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82765	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NICOTINE	.03-.07 PERCENT
82766	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON
82777	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	NICOTINE	.03-.07 PERCENT
82778	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82860	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	NICOTINE	.003-.07 PERCENT
82861	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82406	PIPERAZINE	.1-.4 PERCENT
	OXYTETRACYCLINE	10-50 GM/TON
82407	PIPERAZINE	.1-.4 PERCENT
	PENICILLIN	2.4-50 GM/TON
82104	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN	4-50 GM/TON
82114	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82480	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82492	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82699	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82735	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82867	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82483	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82495	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB
82738	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82870	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82105	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN	4-50 GM/TON
82115	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82493	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82700	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82736	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82773	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82868	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82106	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN	4-50 GM/TON
82116	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82482	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82494	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82701	PIPERAZINE SULFATE	.21-.85 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82737	PIPERAZINE SULFATE	.21-.85 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82859	PIPERAZINE SULFATE	.21-.85 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82664	RESERPINE	.0001 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
82665	RESERPINE	.0001 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
82666	RESERPINE	.0001 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
82015	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82050	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82076	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82151	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82159	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82162	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82255	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82257	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82262	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82264	ROXARSONE	.0125-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82269	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82271	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82276	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82278	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82283	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82285	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82292	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82366	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82369	ROXARSONE	.0056 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82423	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82430	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82444	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
82928	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82931	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82007	SODIUM ARSANILATE	.005-.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82058	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82070	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
82419	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82426	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
82440	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
82022	SULFAQUINOXALINE	.0075 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82023	SULFAQUINOXALINE	.0075 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82024	SULFAQUINOXALINE	.0075 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82025	SULFAQUINOXALINE	.0075 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82026	SULFAQUINOXALINE	.0075 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82027	SULFAQUINOXALINE	.0075 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82079	SULFAQUINOXALINE	.0125-.025 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	BACITRACIN	4-50 GM/TON
82080	SULFAQUINOXALINE	.0125-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82083	SULFAQUINOXALINE	.033-.1 PERCENT
	BACITRACIN	4-50 GM/TON
82084	SULFAQUINOXALINE	.033-.1 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
82143	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82149	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82150	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82152	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82156	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82157	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82158	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.005 PERCENT
82160	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82227	SULFAQUINOXALINE	.0075 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82251	SULFAQUINOXALINE	.0075 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82252	SULFAQUINOXALINE	.01-.02 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82253	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82254	SULFAQUINOXALINE	.01-.02 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	SODIUM ARSANILATE	.005-.01 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82256	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82259	SULFAQUINOXALINE	.01-.02 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.005 PERCENT
82260	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82261	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82263	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	STREPTOMYCIN	30-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82266	SULFAQUINOXALINE	.01-.02 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82267	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82268	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82270	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82273	SULFAQUINOXALINE	.01-.02 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82274	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82275	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82277	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82280	SULFAQUINOXALINE	.01-.02 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82281	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82282	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82287	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82288	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82289	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82291	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82364	SULFAQUINOXALINE	.0075 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82365	SULFAQUINOXALINE	.0075 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.0075 PERCENT
82367	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82455	SULFAQUINOXALINE	.033-.10 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
82465	SULFAQUINOXALINE	.033-.10 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON
82506	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82526	SULFAQUINOXALINE	.0125-.025 PERCENT
	PROCAINE PENICILLIN	2.4-50 GM/TON
82564	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	200 GM/TON

IDENTIFICATION	DRUG	DOSAGE
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82571	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82577	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82584	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82594	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS STREPTOMYCIN	14.4-50 GM/TON COMB.
82648	SULFAQUINOXALINE	.00075 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82884	SULFAQUINOXALINE	.0125-.025 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
82925	SULFAQUINOXALINE	.0075 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82927	SULFAQUINOXALINE	.0075 PERCENT
	SODIUM ARSANILATE	.005-.010 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82964	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82965	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82966	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82972	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS OXYTETRACYCLINE	200 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82991	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
82999	SULFAQUINOXALINE	.0075 PERCENT
	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
82499	ZOALENE	.0125-.0188 PERCENT
	ARSANILIC ACID	.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	SPECIES: RABBIT	
80059	FURAZOLIDONE	.0055 PERCENT
	OXYTETRACYCLINE	10 GM/TON
80058	OXYTETRACYCLINE	10 GM/TON
	SULFAQUINOXALINE	.1 PERCENT
80269	OXYTETRACYCLINE	10 GM/TON
	SULFAQUINOXALINE	.025 PERCENT
	SPECIES: SWINE	
80032	ARSANILIC ACID	.005-.01 PERCENT
	OXYTETRACYCLINE	150 GM/TON
	NITROFURAZONE	.0056 PERCENT
80045	ARSANILIC ACID	.005-.01 PERCENT
	OXYTETRACYCLINE	150 GM/TON
	PEPSIN	
80082	ARSANILIC ACID	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
	OXYTETRACYCLINE	500 GM/TON
80294	ARSANILIC ACID	.005-.01 PERCENT
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.011 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80018	BACITRACIN	50 GM/TON
	THYROPROTEIN	200 GM/TON
80019	BACITRACIN	25 GM/TON
	PENICILLIN	25 GM/TON
	THYROPROTEIN	200 GM/TON
80020	BACITRACIN	100 GM/TON
	THYROPROTEIN	200 GM/TON
80021	BACITRACIN	50 GM/TON
	PENICILLIN	50 GM/TON
	THYROPROTEIN	200 GM/TON
80113	BACITRACIN PLUS	
	PENICILLIN	100 GM/TON COMB.
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80133	BACITRACIN METHYLENE DISALICYLATE	10-50 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80154	BACITRACIN METHYLENE DISALICYLATE	50-100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80155	BACITRACIN METHYLENE DISALICYLATE	50-100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80158	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB
	ARSANILIC ACID	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
80161	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
	SODIUM ARSANILATE	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON

IDENTIFICATION	DRUG	DOSAGE
80168	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80232	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	10-50 GM/TON COMB.
	PIPERAZINE	.6 PERCENT
80233	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	10-50 GM/TON COMB.
	SODIUM FLUORIDE	.5-1 PERCENT
80266	BACITRACIN METHYLENE DISALICYLATE	10-50 GM/TON
	PIPERAZINE	.6 PERCENT
80267	BACITRACIN METHYLENE DISALICYLATE	10-50 GM/TON
	SODIUM FLUORIDE	.5-1 PERCENT
80273	BACITRACIN METHYLENE DISALICYLATE	50 GM/TON
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80277	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50 GM/TON COMB.
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80279	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100 GM/TON COMB.
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80281	BACITRACIN METHYLENE DISALICYLATE	10-50 GM/TON
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80152	ZINC BACITRACIN	50-100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80157	ZINC BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
	ARSANILIC ACID	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
80160	ZINC BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
	SODIUM ARSANILATE	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
80163	ZINC BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	HYGROMYCIN B	12 GM/TON
80166	ZINC BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80236	ZINC BACITRACIN PLUS	
	PENICILLIN	10-50 GM/TON COMB.
	NICOTINE	.003-.07 PERCENT
	PHENOTHIAZINE	.3-1.0 PERCENT
80238	ZINC BACITRACIN	10-50 GM/TON
	NICOTINE	.03-.07 PERCENT
	SODIUM FLUORIDE	.3 PERCENT
	SODIUM SULFATE	2 PERCENT
80241	ZINC BACITRACIN	10-50 GM/TON
	SODIUM FLUORIDE	.5-1.0 PERCENT
80242	ZINC BACITRACIN	10-50 GM/TON
	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
80243	ZINC BACITRACIN	10-50 GM/TON
	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
80244	ZINC BACITRACIN	10-50 GM/TON
	PIPERAZINE SULFATE	.21-.85 PERCENT
80245	ZINC BACITRACIN	10-50 GM/TON
	PIPERAZINE MONOHYDROCHLORIDE	.12-.52 PERCENT

IDENTIFICATION	DRUG	DOSAGE
80246	ZINC BACITRACIN	10-50 GM/TON
	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
80278	ZINC BACITRACIN PLUS	
	PENICILLIN	100 GM/TON COMB.
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80280	ZINC BACITRACIN	10-50 GM/TON
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80292	ZINC BACITRACIN	10-50 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80027	CHLORTETRACYCLINE	100 GM/TON
	OXYTETRACYCLINE	100 GM/TON
80028	CHLORTETRACYCLINE	100 GM/TON
	ARSANILIC ACID	.005-.01 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80029	CHLORTETRACYCLINE	100 GM/TON
	SODIUM ARSANILATE	.005-.01 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80030	CHLORTETRACYCLINE	100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80029	CHLORTETRACYCLINE	100 GM/TON
	SODIUM ARSANILATE	.005-.01 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80030	CHLORTETRACYCLINE	100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80127	CHLORTETRACYCLINE	10-50 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80190	CHLORTETRACYCLINE	10-50 GM/TON
	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
80191	CHLORTETRACYCLINE	10-50 GM/TON
	PIPERAZINE PHOSPHATE	.23-.92 PERCENT
80192	CHLORTETRACYCLINE	10-50 GM/TON
	PIPERAZINE PHOSPHATE	.21-.85 PERCENT
80202	CHLORTETRACYCLINE	10-50 GM/TON
	FURAZOLIDONE	.00083 PERCENT
80205	CHLORTETRACYCLINE	10-50 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	NITROFURAZONE	.0056 PERCENT
80206	CHLORTETRACYCLINE	50-100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	NITROFURAZONE	.0056 PERCENT
80207	CHLORTETRACYCLINE	100-200 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	NITROFURAZONE	.0056 PERCENT
80208	CHLORTETRACYCLINE	10-50 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
80209	CHLORTETRACYCLINE	50-100 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
80220	CHLORTETRACYCLINE	10-50 GM/TON
	PHENOTHIAZINE	.3-1.0 PERCENT
80104	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	STREPTOMYCIN	10-50 GM/TON
80179	FURAZOLIDONE	.011 PERCENT
	OXYTETRACYCLINE	50 GM/TON
80002	HYGROMYCIN B	12 GM/TON
	OXYTETRACYCLINE	50 GM/TON MAXIMUM
80035	OXYTETRACYCLINE	10-50 GM/TON
	PIPERAZINE	.6 PERCENT
80044	OXYTETRACYCLINE	150 GM/TON
	PEPSIN	
80036	PENICILLIN	10-50 GM/TON
	PIPERAZINE	.1-.4 PERCENT
80037	PENICILLIN PLUS	
	STREPTOMYCIN	10-50 GM/TON COMB.
	PIPERAZINE	.1-.4 PERCENT

IDENTIFICATION	DRUG	DOSAGE
80108	PENICILLIN PLUS	
	STREPTOMYCIN	45-90 GM/TON COMB.
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80109	PENICILLIN PLUS	
	STREPTOMYCIN	90-270 GM/TON COMB.
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80117	PENICILLIN	10-50 GM/TON
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80134	PENICILLIN PLUS	
	STREPTOMYCIN	45-90 GM/TON COMB.
	ARSANILIC ACID	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
80135	PENICILLIN PLUS	
	STREPTOMYCIN	45-90 GM/TON COMB.
	ROXARSONE	.0025-.0075 PERCENT
	HYGROMYCIN B	12 GM/TON
80137	PENICILLIN PLUS	
	STREPTOMYCIN	45-90 GM/TON COMB.
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80138	PENICILLIN PLUS	
	STREPTOMYCIN	90-270 GM/TON COMB.
	ARSANILIC ACID	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
80139	PENICILLIN PLUS	
	STREPTOMYCIN	90-270 GM/TON COMB.
	SODIUM ARSANILATE	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
80141	PENICILLIN PLUS	
	STREPTOMYCIN	90-270 GM/TON COMB.
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80142	PENICILLIN PLUS	
	STREPTOMYCIN	90-270 GM/TON COMB.
	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80005	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
80006	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
80047	ROXARSONE	.005-.01 PERCENT
	OXYTETRACYCLINE	150 GM/TON
	PEPSIN	
80077	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	OXYTETRACYCLINE	50 GM/TON MAXIMUM
	NITROFURAZONE	.0056 PERCENT
80096	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	OXYTETRACYCLINE	50-150 GM/TON
	NITROFURAZONE	.0056 PERCENT
80098	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	OXYTETRACYCLINE	500 GM/TON
	NITROFURAZONE	.0056 PERCENT
80123	ROXARSONE	.0025-.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	HYGROMYCIN B	12 GM/TON
	NITROFURAZONE	.0056 PERCENT
	STREPTOMYCIN	10-50 GM/TON
80318	ROXARSONE	.0025-.0075 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	FURAZOLIDONE	.011 PERCENT
	OXYTETRACYCLINE	100 GM/TON
80033	SODIUM ARSANILATE	.005-.01 PERCENT
	OXYTETRACYCLINE	150 GM/TON

IDENTIFICATION	DRUG	DOSAGE
	NITROFURAZONE	.0056 PERCENT
80046	SODIUM ARSANILATE	.005-.01 PERCENT
	OXYTETRACYCLINE	150 GM/TON
	PEPSIN	
80090	SODIUM ARSANILATE	.005-.01 PERCENT
	HYGROMYCIN B	12 GM/TON
	OXYTETRACYCLINE	500 GM/TON
	SPECIES: TURKEY UNSPECIFIED	
84185	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
	STREPTOMYCIN	30-50 GM/TON
84174	AMPROLIUM	.0125-.025 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84213	AMPROLIUM	.0125-.025 PERCENT
	STREPTOMYCIN	30-50 GM/TON
84214	AMPROLIUM	.0125-.025 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
84215	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN	4-50 GM/TON
84216	AMPROLIUM	.0125-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84003	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84039	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84090	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
84146	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84166	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84276	ARSANILIC ACID	.005-.01 PERCENT
	AMINO NITROTHIAZOLE	.05-10 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84343	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
84410	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84424	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84431	ARSANILIC ACID	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84581	ARSANILIC ACID	.005-.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84618	ARSANILIC ACID	.005-.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
85077	ARSANILIC ACID	.005-.010 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84038	BACITRACIN	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84069	BACITRACIN	4-50 GM/TON
	NYSTATIN	50 GM/TON
84070	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	50 GM/TON
84071	BACITRACIN	4-50 GM/TON
	NYSTATIN	100 GM/TON
84072	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	100 GM/TON
84193	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84175	MANGANESE BACITRACIN	4-50 GM/TON
	NYSTATIN	50 GM/TON
84176	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	50 GM/TON
84177	MANGANESE BACITRACIN	4-50 GM/TON
	NYSTATIN	100 GM/TON
84178	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	100 GM/TON
84406	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	50 GM/TON
84407	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	NYSTATIN	50 GM/TON
84408	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84409	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	NYSTATIN	100 GM/TON
85105	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
85107	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
85108	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84616	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	50 GM/TON
84617	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NYSTATIN	100 GM/TON
84744	ZINC BACITRACIN	4-50 GM/TON
	NYSTATIN	100 GM/TON
84746	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
85073	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84388	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84400	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84465	BUTYNORATE	.02 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	DINITRODIP ENYLSULFONYLETHYLENE DIAMINE	.02 PERCENT
	SULFANITRAN	.03 PERCENT
84782	BUTYNORATE	.07 PERCENT
	PHENOTHIAZINE	.29 PERCENT
	PIPERAZINE SULFATE	.12 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84191	CHLORTETRACYCLINE	10-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84534	CHLORTETRACYCLINE	10-50 GM/TON
	NYSTATIN	50 GM/TON

IDENTIFICATION	DRUG	DOSAGE
84535	CHLORTETRACYCLINE	10-50 GM/TON
	NYSTATIN	100 GM/TON
85139	CHLORTETRACYCLINE	10-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.10 PERCENT
84496	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00033 PERCENT
	BACITRACIN	4-50 GM/TON
84522	DIENESTROL DIACETATE	.0023-.007 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84523	DIENESTROL DIACETATE	.0023-.007 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
84524	DIENESTROL DIACETATE	.0023-.007 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
85134	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85135	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
85136	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.00033 PERCENT
	PENICILLIN	2.4-50 GM/TON
85203	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	BACITRACIN	4-50 GM/TON
85204	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85205	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
85206	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	PENICILLIN	4-50 GM/TON
85207	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.011 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
85208	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	BACITRACIN	4-50 GM/TON
85209	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85210	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
85211	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	PENICILLIN	2.4-50 GM/TON
85212	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.022 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
85213	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	BACITRACIN	4-50 GM/TON
85215	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
85216	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	PENICILLIN	2.4-50 GM/TON
85217	DIENESTROL DIACETATE	.0023-.007 PERCENT
	FURAZOLIDONE	.0055 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
84013	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	50-100 GM/TON
84042	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84087	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100-500 GM/TON
84169	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84204	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
84267	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84346	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
84353	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100-200 GM/TON
84413	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84451	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84458	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84499	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	50 GM/TON COMB.
84503	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100 GM/TON
84505	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	100 GM/TON COMB.
84510	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
84511	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84512	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84513	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	2.4-50 GM/TON
84584	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84621	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84759	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
85060	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
85140	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	100 GM/TON
85143	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	100 GM/TON
85156	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	200 GM/TON
85158	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	200 GM/TON COMB.
85194	FURAZOLIDONE	.022 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85199	FURAZOLIDONE	.0055 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85202	FURAZOLIDONE	.0055 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
85222	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015-.05 PERCENT
85224	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
84442	NIHYDRAZONE	.011 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84022	NITARSONE	.01875 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84049	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN	4-50 GM/TON
84050	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84257	NITHIAZIDE	.0125-.04 PERCENT
	OXYTETRACYCLINE	50 GM/TON
84258	NITHIAZIDE	.0125-.04 PERCENT
	PENICILLIN	2.4-50 GM/TON
84440	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84445	NITHIAZIDE	.0125-.04 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84514	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
84533	NITHIAZIDE	.0125-.04 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84628	NITHIAZIDE	.0125-.04 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84738	NITHIAZIDE	.0125-.04 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
85125	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85126	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
85127	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	10-50 GM/TON
85128	NITHIAZIDE	.0125-.04 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
84007	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84014	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	50-100 GM/TON
84[illegible]	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84058	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84064	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84066	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.

IDENTIFICATION	DRUG	DOSAGE
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84088	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100-500 GM/TON
84094	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
84112	NITROFURAZONE	.0056 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84113	NITROFURAZONE	.00112 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84114	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
84116	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84159	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
84164	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	50-100 GM/TON
84230	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	50 GM/TON
84232	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	50 GM/TON COMB.
84234	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100 GM/TON
84235	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	100 GM/TON
84236	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	100 GM/TON COMB.
84237	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	90-180 GM/TON COMB.
84241	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84242	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS	
	OXYTETRACYCLINE	200 GM/TON COMB.
84244	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	100 GM/TON
84246	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100 GM/TON
84247	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100 GM/TON
84249	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	100 GM/TON
84250	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	100 GM/TON COMB.
84252	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100 GM/TON COMB.
84280	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	AMINO NITROTHIAZOLE	.05-.1 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	OXYTETRACYCLINE	200 GM/TON
84296	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84298	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84322	NITROFURAZONE	.0056 PERCENT
	NITROPHENIDE	.05 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84347	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
84354	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100-200 GM/TON
84365	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84375	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84414	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84416	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84439	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
84551	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84552	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
84553	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
84593	NITROFURAZONE	.0112 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84594	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84623	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84640	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
	STREPTOMYCIN	30-50 GM/TON

IDENTIFICATION	DRUG	DOSAGE
84642	NITROFURAZONE	.0056 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
	STREPTOMYCIN	30-50 GM/TON
84678	NITROFURAZONE	.0056 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84679	NITROFURAZONE	.0112 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84691	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84761	NITROFURAZONE	.0056 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
85012	NITROFURAZONE	.0125-.025 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85013	NITROFURAZONE	.0112 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85071	NITROFURAZONE	.0056 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84106	NITROPHENIDE	.0125-.025 PERCENT
	BACITRACIN	4-50 GM/TON
84323	NITROPHENIDE	.0125-.05 PERCENT
	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84335	NITROPHENIDE	.0125-.025 PERCENT
	AMINO NITROTHIAZOLE	.05-.10 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84360	NITROPHENIDE	.0125-.025 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84370	NITROPHENIDE	.0125-.025 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84371	NITROPHENIDE	.05 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84484	NITROPHENIDE	.0125-.025 PERCENT
	PENICILLIN	2.4-50 GM/TON
84488	NITROPHENIDE	.0125-.025 PERCENT
	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
84590	NITROPHENIDE	.0125-.025 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84591	NITROPHENIDE	.05 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85019	NITROPHENIDE	.0125-.025 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
85020	NITROPHENIDE	.05 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84183	NYSTATIN	50-100 GM/TON
	PENICILLIN	2.4-50 GM/TON
84189	NYSTATIN	50-100 GM/TON
	STREPTOMYCIN	30-50 GM/TON
84118	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN	4-50 GM/TON
	NICOTINE	.03-.07 PERCENT
84119	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN	4-50 GM/TON
84123	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NICOTINE	.03-.07 PERCENT

IDENTIFICATION	DRUG	DOSAGE
84129	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84377	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
	NICOTINE	.03-.07 PERCENT
84378	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84389	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NICOTINE	.03-.07 PERCENT
84390	PHENOTHIAZINE	.3-1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84596	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	NICOTINE	.03-.07 PERCENT
84597	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84796	PHENOTHIAZINE	.3-1 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84127	PIPERAZINE	.21-.85 PERCENT
	BACITRACIN	4-50 GM/TON
84341	PIPERAZINE	.1-.4 PERCENT
	OXYTETRACYCLINE	10-50 GM/TON
84342	PIPERAZINE	.1-.4 PERCENT
	PENICILLIN	2.4-50 GM/TON
84125	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN	4-50 GM/TON
84135	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84334	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84396	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84568	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84603	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84790	PIPERAZINE DIHYDROCHLORIDE	.18-.72 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84138	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	BACITRACIN	4-50 GM/TON
84387	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84399	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84606	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84793	PIPERAZINE MONOHYDROCHLORIDE	.13-.52 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84126	PIPERAZINE PHOSPHATE MONOHYDRATE	.18-.72 PERCENT
	BACITRACIN	4-50 GM/TON
84136	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84397	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84569	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84604	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84669	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84791	PIPERAZINE PHOSPHATE MONOHYDRATE	.23-.92 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84137	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84386	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84398	PIPERAZINE SULFATE	.21-.85 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84570	PIPERAZINE SULFATE	.21-.85 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84605	PIPERAZINE SULFATE	.21-.85 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84792	PIPERAZINE SULFATE	.21-.85 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84183	PENICILLIN	2.4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84184	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84187	PENICILLIN PLUS	
	STREPTOMYCIN	14.4-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84058	RESERPINE	.0001 PERCENT
	BACITRACIN	4-50 GM/TON
84179	RESERPINE	.0001 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
84180	RESERPINE	.0001 PERCENT
	MANGANESE BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84181	RESERPINE	.0002 PERCENT
	MANGANESE BACITRACIN	4-50 GM/TON
84481	RESERPINE	.0001 PERCENT
	PENICILLIN	2.4-50 GM/TON
84535	RESERPINE	.00002-.0001 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84537	RESERPINE	.00002-.0001 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
84538	RESERPINE	.00002-.0001 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
84533	RESERPINE	.00002 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84534	RESERPINE	.0001 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
84008	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84044	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84054	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84152	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84281	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	AMINO NITROTHIAZOLE	.05-.1 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84294	ROXARSONE	.0025-.005 PERCENT

IDENTIFICATION	DRUG	DOSAGE
	SULFAQUINOXALINE	.0075 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84297	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84348	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
84412	ROXARSONE	.0025-.005 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84415	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84429	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84460	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84624	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84641	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
	STREPTOMYCIN	30-50 GM/TON
84750	ROXARSONE	.0025-.005 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
85040	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
85069	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85072	ROXARSONE	.0025-.005 PERCENT
	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85086	ROXARSONE	.0025-.005 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
85090	ROXARSONE	.0025-.005 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.05 PERCENT
84004	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84040	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN	4-50 GM/TON
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84091	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	100-500 GM/TON COMB.
84147	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84167	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	50-100 GM/TON COMB.
84344	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	100-200 GM/TON COMB.
84411	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84456	SODIUM ARSANILATE	.005-.01 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84582	SODIUM ARSANILATE	.005-.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84619	SODIUM ARSANILATE	.005-.01 PERCENT
	ZINC BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	ACETYLAMINO-NITROTHIAZOLE	.015 PERCENT
84045	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84046	SULFAQUINOXALINE	.01-.02 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84052	SULFAQUINOXALINE	.01-.02 PERCENT
	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84053	SULFAQUINOXALINE	.01-.02 PERCENT
	SODIUM ARSANILATE	.005-.010 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84055	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84100	SULFAQUINOXALINE	.0125-.025 PERCENT
	BACITRACIN	4-50 GM/TON
84101	SULFAQUINOXALINE	.0125-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84103	SULFAQUINOXALINE	.005-.025 PERCENT
	BACITRACIN PLUS	
	PENICILLIN	3.6-50 GM/TON COMB.
84292	SULFAQUINOXALINE	.0075 PERCENT
	ARSANILIC ACID	.005-.01 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84293	SULFAQUINOXALINE	.0075 PERCENT
	SODIUM ARSANILATE	.005-.01 PERCENT
	OXYTETRACYCLINE	50 GM/TON

IDENTIFICATION	DRUG	DOSAGE
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84295	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84334	SULFAQUINOXALINE	.0125-.025 PERCENT
	AMINO NITROTHIAZOLE	.05-.10 PERCENT
	OXYTETRACYCLINE	200 GM/TON
84357	SULFAQUINOXALINE	.0125-.025 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84358	SULFAQUINOXALINE	.005-.025 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84359	SULFAQUINOXALINE	.033-.1 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	4-50 GM/TON
84502	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84509	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84523	SULFAQUINOXALINE	.0075 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84529	SULFAQUINOXALINE	.0075 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84530	SULFAQUINOXALINE	.0075 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
84575	SULFAQUINOXALINE	.0125-.025 PERCENT
	CHLORTETRACYCLINE	10-50 GM/TON
84576	SULFAQUINOXALINE	.0125-.025 PERCENT
	CHLORTETRACYCLINE	50-100 GM/TON
84577	SULFAQUINOXALINE	.0125-.025 PERCENT
	CHLORTETRACYCLINE	100-200 GM/TON
84587	SULFAQUINOXALINE	.0125-.025 PERCENT
	ZINC BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
84588	SULFAQUINOXALINE	.005-.025 PERCENT
	ZINC BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
84589	SULFAQUINOXALINE	.033-.10 PERCENT
	ZINC BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
84629	SULFAQUINOXALINE	.01-.02 PERCENT
	ZINC BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
84674	SULFAQUINOXALINE	.005-.025 PERCENT
	BACITRACIN METHYLENE DISALICYLATE PLUS PENICILLIN	3.6-50 GM/TON COMB.
85017	SULFAQUINOXALINE	.005-.025 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
85018	SULFAQUINOXALINE	.033-.10 PERCENT
	ZINC BACITRACIN	4-50 GM/TON
85066	SULFAQUINOXALINE	.0075 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85067	SULFAQUINOXALINE	.0075 PERCENT
	ARSANILIC ACID	.005-.010 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85068	SULFAQUINOXALINE	.0075 PERCENT
	SODIUM ARSANILATE	.005-.010 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85070	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	100-500 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85113	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85114	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS OXYTETRACYCLINE	50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85122	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE PLUS OXYTETRACYCLINE	100 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85123	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS STREPTOMYCIN	90-180 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85131	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLIN	10-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
85132	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	2.4-50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
85133	SULFAQUINOXALINE	.01-.02 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN PLUS STREPTOMYCIN	14.4-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.003-.006 PERCENT
85152	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85153	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	100 GM/TON

IDENTIFICATION	DRUG	DOSAGE
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85154	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85155	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85165	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	CHLORTETRACYCLINE	200 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85166	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	OXYTETRACYCLINE	100 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85183	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	ZINC BACITRACIN	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85184	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN METHYLENE DISALICYLATE	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85185	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85186	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	PENICILLIN	50 GM/TON
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT
85187	SULFAQUINOXALINE	.0075 PERCENT
	FURAZOLIDONE	.00083 PERCENT
	BACITRACIN PLUS PENICILLIN	3.6-50 GM/TON COMB.
	2,4-DIAMINO-5-(PARA-CHLOROPHENYL)-6-ETHYL PYRIMIDINE	.00075 PERCENT

(Sec. 512(i), 82 Stat. 347; (21 U.S.C. 360b(i).)

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

AUTHORITY: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).

§ 558.25 2-Acetylamino-5-nitrothiazole.

(a) *Specifications.* Assay of not less than 96 percent by ultraviolet spectrophotometry.

(b) *Approvals.* (1) Premix 10 percent granted to Sponsor No. 010042 in § 510.600(c) of this chapter.

(c) *Related tolerances in edible products.* See § 556.20 of this chapter.

(d) *Conditions of use.* It is used in turkey feed as follows:

(1) *Amount per ton.* 136.2 grams (0.015 percent).

(i) *Indications for use.* Aid in prevention of blackhead (histomoniasis).

(ii) *Limitations.* Administer continuously starting 1 to 2 weeks before outbreaks usually occur; discontinue use 7 days before slaughter; use eggs from medicated birds for hatching purposes only.

(2) *Amount per ton.* 454 grams (0.05 percent).

(i) *Indications for use.* Aid in control of blackhead (histomoniasis).

(ii) *Limitations.* Administer for 2 weeks at first sign of outbreaks; discontinue use 7 days before slaughter; use eggs from medicated birds for hatching purposes only.

§ 558.35 Aklomide.

(a) *Chemical name.* 2-Chloro-4-nitrobenzamide.

(b) *Specifications.* (1) Minimum melting point 170° C.

(2) Moisture content not to exceed 1 percent.

(3) Purity not less than 98 percent on anhydrous basis.

(c) *Approvals.* The following premix levels have been granted; for sponsor No. 017210 in § 510.600(c) of this chapter.

(1) 50 percent aklomide.

(2) 20 percent sulfanitran and 25 percent aklomide.

(3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.

(4) 50 percent aklomide and 10 percent roxarsone.

(d) *Assay limits.* Finished feed must contain 85 to 120 percent of labeled amount of the drug.

(e) *Special considerations.* Maximum level permitted in medicated concentrate is 0.1 percent of aklomide.

(f) *Related tolerances.* See § 556.30 of this chapter.

(g) *Conditions of use.* It is used in feed for chickens as follows:

(1) *Amount per ton.* Aklomide, 227 grams (0.025 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix.*

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption.

(2) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter.

(3) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent) + roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(4) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella,* and *E. necatrix;* growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(5) *Amount per ton.* Aklomide, 227 grams (0.025 percent) plus sulfanitran, 181.6 grams (0.02 percent) combined with bacitracin, 4–50 grams.

(i) *Indications for use.* Growth promotion and feed efficiency; as an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as zinc bacitracin.

(6) *Amount per ton.* Aklomide, 227 grams (0.025 percent) plus sulfanitran, 181.6 grams (0.02 percent) combined with chlortetracycline (as chlortetracycline hydrochloride), 10–50 grams.

(i) *Indications for use.* Growth promotion and feed efficiency; as an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as chlortetracycline hydrochloride.

(7) *Amount per ton.* Aklomide, 227 grams (0.025 percent) plus sulfanitran, 181.6 grams (0.02 percent) plus penicillin-streptomycin, 14.4–50 grams (a combination containing 16.7 percent penicillin).

(i) *Indications for use.* Growth promotion and feed efficiency; as an aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as procaine penicillin; as streptomycin sulfate.

(8) *Amount per ton.* Aklomide, 227 grams (0.025 percent) plus sulfanitran, 181.6 grams (0.02 percent) plus oxytetracycline, 10–50 grams.

(i) *Indications for use.* Growth promotion and feed efficiency; as an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as monoalkyl (C_8–C_{18}) trimethylammonium oxytetracycline.

§ 558.45 Ammonium chloride, feed grade.

(a) *Chemical name.* Ammonium chloride.

(b) *Specifications.* The ammonium chloride conforms to the following:

(1) Assay after drying: 99 percent minimum.

(2) Sodium chloride: 0.6 percent maximum.

(3) Loss on drying: 0.5 percent maximum.

(4) Arsenic (as As): 3 parts per million maximum.

(5) Heavy metals (as Pb): 10 parts per million maximum.

(c) *Approvals.* Premix level of 99 percent has been granted; for sponsors see Nos. 011462 and 000018 in § 510.600(c) of this chapter.

(d) *Assay limits.* Finished feed must contain not less than 85 percent nor more than 115 percent of labeled amount.

(e) *Special considerations.* Maximum level permitted in medicated concentrate is 8 percent for administration to cattle and 6 percent for administration to sheep.

(f) *Conditions of use.* It is used in feed for cattle and sheep as follows:

(1) *Amount per day.* 21.3–35.5 grams (0.75–1.25 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For range cattle.

(2) *Amount per day.* 28.4–42.5 grams (1.0–1.5 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For fattening cattle.

(3) *Amount per day.* 7.1 grams (0.25 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For sheep.

§ 558.55 Amprolium.

(a) *Chemical name.* 1-(4-Amino-2-*n*-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride.

(b) *Approvals.* Premix level 25 percent granted to No. 000006 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed 80–120 percent of labeled amount.

(d) [Reserved].

(e) *Related tolerances.* See § 556.50 of this chapter.

(f) *Conditions of use.* It is used in feed for calves as follows:

(1) *Amount.* 227 milligrams per 100 lb. (5 milligrams per kilogram) body weight per day.

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Administer from a supplement containing from 0.05 to 0.5 percent amprolium with the usual amount of feed consumed in one day; feed for 21 days during periods of exposure or when experience indicates

that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium.

(2) *Amount.* 454 milligrams per 100 lb. (10 milligrams per kilogram) body weight per day.

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Administer from a supplement containing from 0.05 to 0.5 percent amprolium with the usual amount of feed consumed in one day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium.

§ 558.95 Bambermycins.

(a) *Specifications.* Bambermycins are the dried fermentation residues produced by the fermentation of *Streptomyces bambergiensis, Streptomyces ghanaensis, Streptomyces ederensis, Streptomyces geysiriensis,* and mutants and variants of these organisms.

(b) *Approvals.* Premix level of 2 grams of bambermycin activity per pound of premix has been granted; for sponsor see No. 000039 in § 510.600(c) of this chapter.

(c) *Assay limits.* Premix must contain not less than 90 percent nor more than 110 percent of labeled amount of bambermycin activity. Finished feed must contain not less than 70 percent nor more than 130 percent of the labeled amount of bambermycin activity.

(d) *Related tolerances.* See § 556.380 of this chapter.

(e) *Conditions of use.* It is used in feed for broiler chickens as follows:

(1) *Amount per ton.* 1 to 2 grams.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(3) *Limitations.* Feed continuously as the sole ration.

§ 558.105 Buquinolate.

(a) *Chemical name.* Ethyl 4-hydroxy-6,7-diisobutoxy-3-quinolinecarboxylate.

(b) *Approvals.* Premix levels of 16.5 and 22 percent have been granted; for sponsor see No. 000947 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 80 percent nor more than 120 percent of the labeled amount.

(d) *Special considerations.* Maximum level permitted in medicated feed: 0.011 percent (100 grams per ton). Do not use in feeds containing bentonite.

(e) *Related tolerances.* See § 556.90 of this chapter.

(f) *Conditions of use.* It is used in animal feed as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent).

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(b) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus arsanilic acid, 90 grams (0.01 percent).

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* Feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* Feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iv) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus penicillin, 2.4–50 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(b) *Limitations.* Feed continuously as the sole ration; as procaine penicillin.

(v) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus bacitracin, 4–50 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(b) *Limitations.* Feed continuously as the sole ration; as zinc bacitracin or bacitracin methylene disalicylate.

(vi) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus penicillin + bacitracin, 3.6–50 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(b) *Limitations.* Feed continuously as the sole ration; not less than 0.6 gram of penicillin nor less than 3 grams of bacitracin; as procaine penicillin plus zinc bacitracin or bacitracin methylene disalicylate.

(vii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus chlortetracycline, 200 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific enteritis) prevention of synovitis.

(b) *Limitations.* In low calcium feed containing 0.8 percent dietary calcium and 1 percent to 1.5 percent sodium sulfate; to be fed continuously for not more than the first 21 days of life.

(viii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus lincomycin, 2–4 grams.

(a) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused *E. tenella, E. maxima, E. necatrix, E. brunetti, E. acervulina.*

(b) *Limitations.* For floor raised broiler and fryer chickens; feed continuously as the sole ration.

(ix) *Amount per ton.* Buquinolate, 75–100 grams (0.00825–0.011 percent) plus roxarsone, 22.7–34.0 grams (0.0025–0.00375 percent).

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* Feed continuously as the sole ration; withdrawn 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by sponsor No. 017210, see § 510.600(c) of this chapter.

(x) *Amount per ton.* Buquinolate, 100 grams (0.011 percent) plus bacitracin, 4–15 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* increased rate of weight gain.

(b) *Limitations.* Feed continuously as the sole ration; as bacitracin methylene disalicylate provided by sponsor No. 000794, in § 510.600(c) of this chapter.

(xi) *Amount per ton.* Buquinolate, 100 grams (0.011 percent) combined with bacitracin, 19–35 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* For floor raised broiler or fryer chickens, feed continuously as the sole ration; as zinc bacitracin provided by sponsor No. 012769 in § 510.600 (c) of this chapter.

(2) *Broiler, fryer, roaster or replacement chickens*—(i) *Amount per ton.* 75–100 grams (0.00825–0.011 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(iii) *Limitations.* Feed continuously as the sole ration; do not administer over 75 grams per ton (0.00825 percent) to replacement chickens over 20 weeks of age.

(3) *Laying or breeding chickens*—(i) *Amount per ton.* 75 grams (0.00825 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(iii) *Limitations.* Feed to caged layers for 2 weeks following caging; feed continuously to layers and breeders kept on floors while in production or until marketed.

§ 558.115 Carbadox.

(a) *Chemical name.* Methyl 3-(2-quinoxalinylmethylene) carbazate-N^1, N^4-dioxide.

(b) *Approvals.* Premix level containing 2.2 percent (10 grams per pound) of carbadox has been granted; for sponsor, see No. 000069 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 75 percent nor more than 125 percent of labeled amount.

(d) *Related tolerances.* See § 556.100 of this chapter.

(e) *Special considerations.* (1) Finished feeds processed from feed supplements that contain up to 0.055 percent of carbadox and that comply with the provisions of both this paragraph and paragraph (f) of this section are exempted from the requirements of section 512(m) of the act.

(2) Do not use in feeds containing bentonite.

(f) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in complete feeds containing less than 15 percent crude protein.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increase rate of weight gain and improve feed efficiency.

(ii) *Limitations.* Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in complete feeds containing less than 15 percent crude protein.

§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

(a) *Specifications.* (1) Chlortetracycline is the antibiotic substance produced by growth of *Streptomyces aureofaciens* or the same antibiotic substance produced by any other means and, for the purpose of this section, refers to chlortetracycline or feed grade chlortetracycline as the specified salt.

(2) Procaine penicillin is the procaine salt of the antibiotic substance produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum* or the same antibiotic substance produced by any other means and, for the purposes of this section, refers to procaine penicillin or feed grade procaine penicillin.

(3) Sulfamethazine is the chemical N'-(4,6-Dimethyl-2-pyrimidinyl) sulfanilamide.

(4) The antibiotic activities authorized are expressed in this section in terms of the weight of the appropriate antibiotic standards.

(5) Finished feed contains in each ton, 100 grams of chlortetracycline, 50 grams of penicillin as procaine penicillin, and 100 grams of sulfamethazine.

(b) *Approvals.* Premix level of 20 grams of chlortetracycline per pound, 4.4 percent of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound has been granted; for sponsor see Nos. 000196 and 010042 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed must contain not less than 70 percent nor more than 130 percent of labeled amount of chlortetracycline and procaine penicillin and not less than 80 percent nor more than 120 percent of labeled amount of sulfamethazine.

(d) *Special considerations.* Finished feeds conforming to the requirements of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See §§ 556.150, 556.510, and 556.670 of this chapter.

(f) *Conditions of use.* (1) It is administered to swine in a complete feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 7 days prior to slaughter.

§ 558.155 Chlortetracycline, procaine penicillin, and sulfathiazole.

(a) *Specifications.* (1) Chlortetracycline is the antibiotic substance produced by growth of *Streptomyces aureofaciens* or the same antibiotic substance produced by any other means and, for the purpose of this section, refers to chlortetracycline or feed grade chlortetracycline as the specified salt.

(2) Procaine penicillin is the procaine salt of the antibiotic substance produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum* or the same antibiotic substance produced by any other means and, for the purposes of this section, refers to procaine penicillin or feed-grade procaine penicillin.

(3) Sulfathiazole is the chemical *N'*-2-thiazolyl-sulfanilamide.

(4) The antibiotic activities authorized are expressed in this section in terms of the weight of the appropriate antibiotic standards.

(b) *Approvals.* (1) Premix level of 20 grams of chlortetracycline hydrochloride per pound, 20 grams of sulfathiazole per pound, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound has been granted; for sponsor see No. 025001 in § 510.600(c) of this chapter.

(2) Premix level of 40 grams of chlortetracycline hydrochloride, 40 grams of sulfathiazole, and procaine penicillin equivalent to 20 grams of penicillin per pound has been granted to No. 025001 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed must contain not less than 70 percent nor more than 130 percent of labeled amount of chlortetracycline and procaine penicillin and not less than 80 percent nor more than 120 percent of labeled amount of sulfathiazole.

(d) *Special considerations.* Finished feeds conforming to the requirements of this section are exempt from the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See §§ 556.150, 556.510, and 556.690 of this chapter.

(f) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Chlortetracycline, 100 grams plus penicillin, 50 grams plus sulfathiazole, 100 grams.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency in animals up to 6 weeks postweaning. For increased rate of weight gain in animals from 6 to 16 weeks postweaning. Maintenance of weight gains in the presence of atrophic rhinitis; reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery).

(3) *Limitations.* For swine raised in confinement (dry-lot) or on limited pasture; withdraw 7 days prior to slaughter; as procaine penicillin and chlortetracycline hydrochloride, as follows:

Type of feed	Approximate body weight in pounds	Minimum daily feed but not more than pounds
Prestarter (up to 6 weeks postweaning)	20	1
Starter (up to 6 weeks postweaning)	40	2
Grower (6–16 weeks postweaning)	80	4
Finisher (6 to 16 weeks postweaning)	160	8

§ 558.175 Clopidol.

(a) *Chemical name.* 3,5-Dichloro-2,6-dimethyl-4-pyridinol.

(b) *Approvals.* (1) Premix level of clopidol 25 percent granted to No. 025700 in § 510.600(c) of this chapter.

(2) Premix level 0.0345 percent clopidol with or without 0.0138 percent roxarsone granted to No. 012286 as identified in § 510.600(c) of this chapter.

(3) Premix levels, combinations of clopidol 25 percent, roxarsone 10 percent,

and bacitracin methylene disalicylate, 4, 10, 15 or 25 grams per pound, granted to No. 025700 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 80 percent nor more than 120 percent of the labeled amount of clopidol.

(d) *Related tolerances.* See § 556.160 of this chapter.

(e) *Conditions of use.* It is used in complete feed for animals as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Clopidol 113.5 grams (0.0125 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* Do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus 3-nitro-4-hydroxyphenylarsonic acid, 45.4 grams (0.005 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improved pigmentation.

(b) *Limitations.* Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus 3-nitro-4-hydroxyphenylarsonic acid, 45.4 grams (0.005 percent) plus bacitracin, 4–25 grams.

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improved pigmentation; increased rate of weight gain.

(b) *Limitations.* Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate, provided by No. 000794 in § 510.600(c) of this chapter; or as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter.

(2) *Broiler chickens and replacement chickens*—(i) *Amount per ton.* Clopidol, 113.5 or 227 grams (0.125 or 0.025 percent).

(ii) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(iii) *Limitations.* Feed up to 16 weeks of age if intended for use as caged layers; feed continuously as the sole ration; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.

(3) *Floor-raised broiler chickens*—(i) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus lincomycin, 2–4 grams.

(ii) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* increase in rate of weight gain and improved feed efficiency.

(iii) *Limitations.* As lincomycin hydrochloride monohydrate; do not feed to chickens over 16 weeks of age.

(4) *Replacement chickens*—(i) *Amount per ton.* Clopidol 113.5 grams (0.0125 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol 113.5 grams (0.0125 percent) plus 3-nitro-4-hydroxyphenylarsonic acid 45.4 grams (0.005 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(5) *Turkeys*—(i) *Amount per ton.* Clopidol 113.5 or 227 grams (0.0125 or 0.025 percent).

(ii) *Indications for use.* Aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi.*

(iii) *Limitations.* For turkeys grown for meat purposes only; to be administered continuously in feed at 0.0125 or 0.025 percent clopidol as the sole ration depending upon management practices, degree of exposure, and amount of feed eaten; withdraw medication 5 days before slaughter.

§ 558.185 Coumaphos.

(a) *Chemical name.* *O,O*-Diethyl *O*-3-chloro - 4 - methyl - 2 - oxo - 2H - 1 - benzopyran-7-yl-phosphorothioate.

(b) *Approvals.* (1) Premix levels 1.12, 2.0, 11.2, and 50 percent have been granted; for sponsor see No. 000859 in § 510.600(c) of this chapter.

(2) Premix levels 1.12 and 11.2 percent have been granted for use in accordance with item 2 of the table; for sponsor see No. 017800 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed must contain not less than 80 percent nor more than 120 percent of the labeled amount of the drug.

(d) *Special considerations.* Adequate directions and warnings for use must be given and shall include a statement that coumaphos is a cholinesterase inhibitor and that animals being treated with coumaphos should not be exposed during or within a few days before or after treatment to any other cholinesterase inhibiting drugs, insecticides, pesticides, or chemicals.

(e) *Related tolerances.* See 40 CFR 180.189.

(f) *Conditions of use.* It is used in animal feeds as follows:

(1) *Beef and dairy cattle*—(i) *Amount.* Coumaphos 0.00012 lb. (0.054 gram) per 100 lb. body weight per day.

(a) *Indications for use.* As an aid in the reduction of fecal breeding flies through control of fly larvae.

(b) *Limitations.* Feed for the duration of fly season in a complete feed containing 0.0033 percent or in a feed supplement containing not over 0.0066 percent coumaphos; do not feed to animals less than 3 months old; not for use in pelleted feeds.

(ii) *Amount.* Coumaphos, 0.002 lb. (0.091 gram) per 100 lb. body weight per day.

(a) *Indications for use.* Control of gastrointestinal roundworms (*Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Trichostrongylus spp.*).

(b) *Limitations.* Feed 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days in the normal grain ration to which the animals are accustomed but not in rations containing more than 0.1 percent coumaphos; do not feed to animals less than 3 months old; do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks; do not feed in conjunction with oral drenches or with feeds containing phenothiazine. Should conditions warrant, repeat treatment at 30-day intervals.

(2) *Laying chickens*—(i) *Amount.* Coumaphos 27.2 grams per ton (0.003 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common round worm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In complete feed; administer continuously as the total feed ration for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) *Replacement pullets*—(i) *Amount.* Coumaphos 36.3 grams per ton (0.004 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In complete feed; administer before the onset of production; diagnosis by competent personnel is essential; administer continuously as total feed ration for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if

birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

§ 558.195 Decoquinate.

(a) *Chemical name.* Ethyl 6-(decyloxy)-7-ethoxy- 4 -hydroxy- 3 -quinoline-carboxylate ($C_{24}H_{35}NO_5$).

(b) *Specifications.* Assay—not less than 98 percent by ultraviolet spectrophotometry; melting-point range—242°–245° C.

(c) *Approvals.* (1) Premix level 6 percent granted to No. 011801 in § 510.600 (c) of this chapter.

(2) Premix level 0.00828 percent granted to No. 012286 in § 510.600(c) of this chapter.

(d) *Assay limits.* Finished feed not less than 80 percent nor more than 120 percent of labeled amount.

(e) *Related tolerances in edible products.* See § 556.170 of this chapter.

(f) *Special considerations.* Bentonite should not be used in decoquinate feeds.

(g) *Conditions of use.* It is used in feed for broiler chickens as follows:

(1) *Amount per ton.* Decoquinate, 27.2 grams (0.003 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti.*

(ii) *Limitations.* Do not feed to laying chickens.

(2) *Amount per ton.* Decoquinate, 27.2 grams (0.003 percent) plus 3-nitro-4-hydroxyphenlyarsonic acid, 45.4 grams (0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* growth promotion and feed efficiency: improving pigmentation.

(ii) *Limitations.* Do not feed to laying chickens; withdraw 5 days before slaughter, as sole source of organic arsenic.

(3) *Amount per ton.* Decoquinate, 27.2 grams (0.003 percent) plus bacitracin, 10–50 grams.

(i) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti.*

(ii) *Limitations.* Do not feed to laying chickens; feed as sole ration; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter.

(4) *Amount per ton.* Decoquinate, 27.2 grams (0.003 percent) plus chlortetracycline, 200 grams.

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* for the treatment of chronic respiratory disease (air sac infection), prevention of synovitis.

(ii) *Limitations.* Do not feed to laying chickens; in low calcium feed containing 0.8 percent of calcium; not to be fed continuously for more than 8 weeks; as chlortetracycline hydrochloride provided by No. 010042 in § 510.600(c) of this chapter.

(5) *Amount per ton.* Decoquinate, 27.2 grams (0.003 percent) combined with lincomycin, 2 grams.

(i) *Indications for use.* For increase in rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti.*

(ii) *Limitations.* For floor raised broiler chickens; do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009 in § 510.600(c) of this chapter.

(6) *Amount per ton.* Decoquinate, 27.2 grams (0.003 percent) plus 3-nitro-4-hydroxyphenylarsonic acid, 11–45 grams (0.0012–0.005 percent) plus bacitracin, 12–50 grams.

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Do not feed to laying chickens; withdraw 5 days before slaughter, as sole source of organic arsenic; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter; as 3 - nitro - 4 - hydroxyphenylarsonic acid as provided by No. 017210, § 510.600(c) of this chapter.

§ 558.205 Dichlorvos.

(a) *Chemical name.* 2,2-Dichlorovinyl dimethyl phosphate.

(b) *Approvals.* Premix level 9.6 percent granted to No. 011461 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed must contain 80 to 130 percent of the labeled amount of dichlorvos.

(d) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feeds to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Feed must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing this preparation or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. If human or animal poisoning should occur, immediately consult a physician or a veterinarian. Atropine is antidotal.

(3) Labeling for feed supplements must include a statement that containers or materials used in packaging such supplements are not to be reused and all such packaging materials must be destroyed after the product has been used.

(4) Finished feeds conforming to the requirements of this section processed from feed supplements containing up to 0.768 percent of dichlorvos are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See § 556.180 of this chapter.

(f) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount.* Dichlorvos, 0.0384 percent.

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*) and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For swine up to 70 pounds body weight, feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the medicated feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.

(2) *Amount.* Dichlorvos, 0.0528 percent.

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For boars, open or bred gilts, and sows, feed as sole ration at the rate of 6 pounds per head for one feeding.

§ 558.225 Diethylstilbestrol.

(a) *Chemical name.* 3,4-Bis(*p*-hydroxyphenyl)-3-hexene.

(b) *Specifications.* Complies with U.S.P. XVII.

(c) *Approvals.* (1) In dry premix, levels of 2 grams (0.44 percent) and 10 grams (2.2 percent) of diethylstilbestrol per pound have been granted, and, in liquid premix, levels of 20 grams (4.4 percent) and 40 grams (8.8 percent) of diethylstilbestrol per pound have been granted for use in manufacturing finished feeds within the currently approved use levels of 5–20 milligrams per head per day; for sponsor see No. 000986 in § 510.600(c) of this chapter.

(2) In dry premix, levels of 2 grams (0.44 percent), 4 grams (0.88 percent), and 10 grams (2.2 percent) of diethylstilbestrol per pound has been granted for use in manufacturing finished feeds within currently approved use levels of 5–20 milligrams per head per day; for sponsor see No. 024264 in § 510.600(c) of this chapter.

(d) *Assay limits.* Finished feed containing below 0.00022 percent diethylstilbestrol must have not less than 80 percent nor more than 120 percent of labeled amount. Finished feed containing over 0.00022 percent diethylstilbes-

trol must have not less than 85 percent nor more than 115 percent of labeled amount.

(e) *Special considerations.* Maximum level of diethylstilbestrol permitted in concentrate for cattle is 0.0044 percent.

(f) *Related tolerances.* See § 556.190 of this chapter.

(g) *Conditions of use.* It is used in dry feed for beef cattle as follows:

(1) *Amount.* 5 to 20 milligrams per head per day.

(2) *Indications for use.* Fattening of beef cattle.

(3) *Limitations.* Use at 5 to 20 milligrams per head in not less than 1 pound of feed; withdraw 7 days before slaughter; do not feed to breeding or dairy animals; feed not more than 10 milligrams per head per day to animals under 750 pounds body weight.

§ 558.305 Ipronidazole.

(a) *Chemical name.* 2-Isopropyl-1-methyl-5-nitroimidazole.

(b) *Approvals.* Premix level containing 12.5 percent of the drug had been granted; for sponsor see No. 000004 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed containing 0.00625 percent ipronidazole not less than 75 percent nor more than 125 percent of labeled amount. Finished feed containing 0.025 percent ipronidazole not less than 80 percent nor more than 120 percent of labeled amount. Premix not less than 98 percent nor more than 115 percent of labeled amount.

(d) *Related tolerances.* See § 556.340 of this chapter.

(e) *Special considerations.* Finished feed processed from feed supplements that contain up to 0.0625 percent ipronidazole and that comply with the provisions of both this paragraph and paragraph (f) of this section is not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(f) *Conditions of use.* It is used in feed for turkeys as follows:

(1) *Amount per ton.* Ipronidazole, 56.75 grams (0.00625 percent).

(i) *Indication for use.* As an aid in the prevention of blackhead (histomoniasis). For increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food.

(2) *Amount per ton.* Ipronidazole, 56.75 grams (0.00625 percent) plus sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(i) *Indications for use.* As an aid in the prevention of blackhead (histomoniasis) and coccidiosis caused by all Eimeria species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis;* bacterial infections due to *P. multocida* (fowl cholera).

(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food.

(3) *Amount per ton.* Ipronidazole, 227 grams (0.025 percent).

(i) *Indications for use.* For the treatment of blackhead (histomoniasis) in turkeys.

(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food. Feed for 7 days at the 0.025 percent level. Follow treatment with the preventive level (0.00625 percent) of ipronidazole.

§ 558.315 Levamisole hydrochloride (equivalent).

(a) *Chemical name.* (−)-2,3,5,6-Tetrahydro-6-phenylimidazo [2,1-*b*] thiazole monohydrochloride.

(b) *Specifications.* Assay of not less than 98 percent of nonaqueous titration with 0.1*N* potassium isoproproxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Approvals.* Premix level 227 grams per pound granted to No. 010042 in § 510.600(c) of this chapter.

(d) *Assay limits.* Finished feed 85–125 percent of labeled amount.

(e) *Related tolerances.* See § 556.350 of this chapter.

(f) *Conditions of use.* It is used in animal feed as follows:

(1) *Cattle*—(i) *Amount per ton.* 0.36–3.6 grams (0.08–0.8 percent).

(ii) *Indications for use.* Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus Cooperia, Nematodirus, Bunostomum, Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Administer medicated feed mixed thoroughly in one half the usual amount of morning feed; the medicated feed mix should be consumed within 6 hours; when medicated feed is consumed resume normal feeding; medicated feed is to be fed at the rate of 0.36 gram of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal feeds only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully."

(2) *Swine*—(i) *Amount per ton.* 0.36 grams (0.8 percent).

(ii) *Indications for use.* Treatment of the following nematode infections; large round worms (*Ascaris suum*), nodular worms (*Oesophagostomum spp.*), lungworms (*Metastrongylus spp.*), intestinal threadworms (*Strongyloides ransomi*).

(iii) *Limitations.* It is recommended that regular feed be withheld overnight and worming feed administered the following morning; feed 1 lb. of worming feed per 100 lb. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when medicated feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require re-treatment within 4 to 5 weeks after the first treatment due to reinfection; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

§ 558.325 Lincomycin.

(a) *Specifications.* Meets the specifications prescribed by § 453.30(a) (1) of this chapter.

(b) *Approvals.* Premix level of 4 grams per pound has been granted; for sponsor see No. 000009 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 80 percent nor more than 130 percent of labeled amount. Premix not less than 90 percent nor more than 115 percent of labeled amount.

(d) *Related tolerances in edible products.* See § 556.360 of this chapter.

(e) *Conditions of use.* (1) It is used in feed for floor-raised broilers as follows:

(i) *Amount per ton.* 2 to 4 grams.

(ii) *Indications for use.* For increase in rate of weight gain and improved feed efficiency.

(iii) *Limitations.* As lincomycin hydrochloride monohydrate.

(2) Lincomycin may also be used in combination with:

(i) Amprolium, ethopabate, and 3-nitro-4-hydroxyphenylarsonic acid in accordance with §§ 121.210 and 121.262 of this chapter.

(ii) Amprolium and ethopabate in accordance with § 121.210 of this chapter.

(iii) Clopidol in accordance with § 558.175.

(iv) Buquinolate in accordance with § 558.105.

(v) Decoquinate in accordance with § 558.195.

(vi) Zoalene in accordance with § 121.207 of this chapter.

(vii) Monensin in accordance with § 558.355.

(viii) Robenidine hydrochloride in accordance with § 558.515.

(ix) 3 - Nitro - 4 - hydroxyphenylarsonic acid, monensin sodium in accordance with § 121.262 of this chapter and § 558.355.

§ 558.355 Monensin.

(a) *Specifications.* Monensin is the substance produced by the fermentation of *Streptomyces cinnamonensis* or the same substance produced by any other means. It is present as monensin or the sodium salt. A minimum of 90 percent of monensin activity is derived from monensin A.

(b) *Approvals.* Approvals for premixes containing the specified levels of monensin activity granted to firms identified by

sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 44 or 45 grams per lb., paragraph (f) (1) (i).

(2) To 000986: 110 grams per lb., paragraph (f) (1) (i), (iii), (iv) and (v) and (2) (i) and (ii).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of 3-nitro-4-hydroxyphenylarsonic acid, 110 grams per lb. with 45 grams per lb. of 3-nitro-4-hydroxyphenylarsonic acid, paragraph (f) (1) (ii).

(4) To 012286: 303.5 grams per ton, as monensin sodium, with .0138 percent 3-nitro - 4 - hydroxyphenylarsonic acid, paragraph (f) (1) (ii).

(5) To 011904: 14.67 grams per lb., as monensin sodium, paragraph (f) (1) (i).

(6) To 011904: 11.786 grams per lb., as monensin sodium, with 1.063 percent 3-nitro-4-hydroxyphenylarsonic acid, 22 grams per lb., as monensin sodium, with 1.98 percent 3-nitro-4-hydroxyphenylarsonic acid, paragraph (f) (1) (ii).

(c) *Assay limits.* Finished feed not less than 75 percent nor more than 125 percent of labeled amount of monensin activity.

(d) *Special considerations.* Finished feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(e) *Related tolerances.* See § 556.420 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Monensin, 90–110 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 72 hours before slaughter; as monensin or monensin sodium.

(ii) *Amount per ton.* Monensin, 90–110 grams, plus 3-nitro-4-hydroxyphenylarsonic acid 45.4 grams (0.005 percent).

(*a*) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(iii) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 5–10 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as bacitracin methylene disalicylate provided by No. 000794 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter; as monensin sodium.

(2) *Floor raised broiler chickens*—(i) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; to be fed as a sole ration, withdraw 72 hours before slaughter; as monensin sodium.

(ii) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams and 3-nitro-4-hydroxyphenylarsonic acid, 15–45 grams.

(*a*) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as 3-nitro-4-hydroxyphenylarsonic acid provided by No. 017210, § 510.600(c) of this chapter; as monensin sodium provided by No. 000986, § 510.600(c) of this chapter; as lincomycin provided by No. 000009, § 510.600(c) of this chapter; as a combination provided by No. 000009, § 510.600(c) of this chapter.

§ 558.365 Nequinate.

(a) *Chemical name.* Methyl 7-(benzyloxy) - 6 - butyl - 1,4 dihydro - 4 - oxo-3-quinoline carboxylate.

(b) *Approvals.* (1) Premix level containing 4 percent nequinate granted to No. 000046 in § 510.600(c) of this chapter.

(2) Premix level containing 4 percent nequinate granted to No. 017800 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed must contain not less than 80 percent nor more than 120 percent of nequinate.

(d) *Related tolerances.* See § 556.440 of this chapter.

(e) *Special considerations.* Do not use in feeds containing bentonite.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Nequinate, 18.16 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent) plus 3-nitro-4-hydroxyphenylarsonic acid, 45.4 grams (0.005 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; for improving pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration throughout the starting period; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent) plus oxytetracycline, 200 grams.

(*a*) *Indications for use.* For control of complicated chronic respiratory disease (air-sac infection), infectious synovitis, and treatment of blue comb (nonspecific infectious enteritis).

(*b*) *Limitations* As monoalkyl (C_8—C_{18}) trimethylammonium oxytetracycline as provided by No. 000069 in § 510.600(c) of this chapter.

(2) *Roaster chickens or replacement chickens for caged layers*—(i) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati.*

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

§ 558.415 Novobiocin.

(a) *Specifications.* Novobiocin is the antibiotic substance produced by growth of *Streptomyces niveus* or the same antibiotic substance produced by any other means.

(b) *Approvals.* Premix level 25 grams of novobiocin activity per pound granted to No. 000009 as listed in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 80 percent nor more than 120 percent of labeled amount.

(d) *Special considerations.* Finished feeds conforming to the requirements of this section are exempt from the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See § 556.460 of this chapter.

(f) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton

of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount.* Novobiocin, 4–5 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 5–8 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by stains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound body weight per day.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount.* 20 mgs. per lb. body weight per day.

(ii) *Indications for use.* For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed for 7 days.

§ 558.435 Oleandomycin.

(a) *Specifications.* It is the antibiotic substance produced by the growth of *Streptomyces antibioticus* or the same antibiotic substance produced by any other means, and for the purpose of this section refers to oleandomycin or feed grade oleandomycin.

(b) *Approvals.* Premix level of 5 grams of oleandomycin activity per pound granted to No. 000069 in § 510.600(c) of this chapter.

(c) *Assay limits.* (1) Feeds containing up to 11.25 grams of oleandomycin per ton to contain 70 to 130 percent of the labeled amount of product.

(2) Feed concentrates containing more than 11.25 grams of oleandomycin per ton to contain 75 to 125 percent of the labeled amount of product.

(d) *Related tolerances.* See § 556.480 of this chapter.

(e) *Special considerations.* (1) Bentonite should not be used in feeds containing oleandomycin.

(2) Finished swine feeds processed from concentrates that contain up to 225 grams of oleandomycin per ton and conforming to the requirements of paragraph (f)(1)(ii) of this section are not required to comply with the provisions of section 512(m) of the act.

(f) *Conditions of use.* (1) It is used in animal feed as follows:

(i) *Chickens and turkeys*—(a) *Amount per ton.* Oleandomycin, 1–2 grams.

(b) *Indications for use.* For increased rate of weight gain and improved feed efficiency for floor raised broiler chickens and growing turkeys.

(c) *Limitations.* Not to be used for laying hens.

(ii) *Swine*—(a) *Amount per ton.* Oleandomycin, 5–11.25 grams.

(b) *Indications for use.* For increased rate of weight gain and improved feed efficiency for confined and pasture raised swine.

(c) *Limitations.* Not to be used for breeding swine.

(2) Oleandomycin may also be used in combination with amprolium in accordance with § 121.210 of this chapter.

§ 558.465 Poloxalene liquid feed supplement.

(a) *Specifications.* Poloxalene liquid feed supplement contains poloxalene meeting the specifications given in § 520.1840 of this chapter.

(b) *Approvals.* Premix level 99.5 percent granted to No. 000007 in § 510.600 (c) of this chapter.

(c) *Assay limits.* Medicated liquid feed supplement must contain not less than 85 percent nor more than 115 percent of labeled amount of poloxalene.

(d) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) bloat in cattle.

(2) Poloxalene liquid premix must be thoroughly blended and evenly distributed into a liquid feed supplement and offered to cattle in a covered liquid feed supplement feeder with lick wheels. The formula for the liquid feed supplement, on a weight/weight basis, is as follows: Ammonium polyphosphate 2.660 percent, phosphoric acid (75 percent) 3.370 percent, sulfuric acid 1.000 percent, water 10.000 percent, and molasses sufficient to make 100.000 percent, vitamins A&D and/or trace minerals may be added. Poloxalene liquid premix (99.5 percent) is to be added to the liquid feed supplement at a level of 7.5 grams (1.65 percent w/w) per pound of the liquid feed supplement. One free-turning lick wheel per 25 head of cattle must be provided and each animal must consume the medicated liquid feed supplement at the rate of 0.2 pound per 100 pounds of body weight per day for adequate protection. The medicated liquid feed supplement must be introduced at least 2–5 days before legume consumption to accustom the cattle to the medicated liquid feed supplement and to lick wheel feedings. If the medicated liquid feed supplement feeding is interrupted, this 2–5 day introductory feeding should be repeated.

§ 558.485 Pyrantel tartrate.

(a) *Approvals.* Premix level 10.6 percent (48 grams per pound) granted to Nos. 000069 and 017800 in § 510.600(c) of this chapter.

(b) *Assay limits.* Finished feed 88–118 percent of labeled amount.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Special considerations.* (1) Consult veterinarian before using in severely debilitated animals.

(2) Finished feeds processed from feed supplements that contain up to 0.0881 percent of pyrantel tartrate and that comply with the provisions of paragraph (e) (1) and (2) of this section, are exempted from the requirements of section 512(m) of the act.

(3) Do not mix in feeds containing bentonite.

(e) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* 96 grams (0.0106 percent).

(i) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Feed continuously as the sole ration in a complete feed; withdraw 24 hours prior to slaughter.

(2) *Amount per ton.* 96 grams (0.0106 percent).

(i) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(ii) *Limitations.* Feed for 3 days as the sole ration in a complete feed; withdraw 24 hours prior to slaughter.

(3) *Amount per ton.* 800 grams (0.0881 percent).

(i) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* As a single therapeutic treatment in complete feed; feed at the rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over; withdraw 24 hours prior to slaughter.

§ 558.505 Reserpine.

(a) *Chemical name.* 3,4,5-Trimethoxybenzoyl methyl reserpate.

(b) *Specifications.* For the purpose of this section, the term reserpine refers to reserpine or feed grade reserpine; assay 94–102 percent (anhydrous basis).

(c) *Approvals.* Premix level of reserpine 0.08 percent has been granted to No. 000003 in § 510.600(c) of this chapter.

(d) *Assay limits.* Finished feed 80–120 percent of labeled amount.

(e) [Reserved]

(f) *Related tolerances.* See § 556.570 of this chapter.

(g) *Conditions of use.* It is used in feed for turkeys as follows:

(1) *Amount per ton.* Reserpine, 0.182 gram (0.00002 percent).

(i) *Indications for use.* To aid in the prevention of aortic rupture.

(ii) *Limitations.* For turkeys over 4 weeks of age.

(2) *Amount per ton.* Reserpine, 0.182 grams (0.00002 percent) plus penicillin, 2.4–50 grams.

(i) *Indications for use.* Growth promotion and feed efficiency; to aid in the prevention of aortic rupture.

(ii) *Limitations.* As procaine penicillin; for turkeys over 4 weeks of age.

(3) *Amount per ton.* Reserpine, 0.182 gram (0.00002 percent) plus penicillin-bacitracin, 3.6–50 grams.

(i) *Indications for use.* Growth promotion and feed efficiency; to aid in the prevention of aortic rupture.

(ii) *Limitations.* As procaine penicillin plus manganese bacitracin; for turkeys over 4 weeks of age.

(4) *Amount per ton.* Reserpine, 0.182 gram (0.00002 percent) plus bacitracin, 4–50 grams.

(i) *Indications for use.* Growth promotion and feed efficiency; to aid in the prevention of aortic rupture.

(ii) *Limitations.* As bacitracin; for turkeys over 4 weeks of age.

(5) *Amount per ton.* Reserpine, 0.908 gram (0.0001 percent).

(i) *Indications for use.* To lessen the incidence of aortic rupture.

(ii) *Limitations.* For turkeys over 4 weeks of age; feed not to exceed 5 days.

§ 558.515 Robenidine hydrochloride.

(a) *Chemical name.* 1,3-Bis(para-chloro-benzylideneamino)-guanidine hydrochloride.

(b) *Approvals.* Premix level of 30 grams per pound has been granted to No. 010042 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 80 percent nor more than 120 percent of labeled amount. Premix not less than 95 percent or more than 115 percent of labeled amount.

(d) *Special considerations.* Finished feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Do not use in feeds containing bentonite.

(e) *Related tolerances in edible products.* See § 556.580 of this chapter.

(f) *Conditions of use.* It is used in feed for chickens as follows:

(1) *For broiler and fryer chickens*—(i) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*

(b) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter.

(ii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus roxarsone (3-nitro-4-hydroxyphenylarsonic acid), 22.5–45.4 grams (.005 percent).

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix* and increased rate of weight gain.

(b) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter; as sole source of organic arsenic. Roxarsone provided by No. 017210, § 510.600(c) of this chapter.

(iii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 100 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline; as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(b) *Limitations.* For broiler or fryer chickens only; withdraw 5 days prior to slaughter; do not feed to layers, feed continuously as sole ration; as chlortetracycline hydrochloride provided by No. 010042, § 510.600(c) of this chapter.

(iv) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the treatment of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline; as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline.

(b) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to layers; feed continuously as sole ration; as chlortetracycline hydrochloride provided by No. 010042, § 510.600(c) of this chapter.

(v) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 500 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.

(b) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to layers; not to be fed continuously for more than 5 days; as chlortetracycline hydrochloride provided by sponsor No. 010042, § 510.600(c) of this chapter.

(2) *For floor-raised broiler and fryer chickens*—(i) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus lincomycin, 2 grams.

(ii) *Indications for use.* For increase in rate of weight gain and improved feed efficiency and as an aid in prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*

(iii) *Limitations.* Do not feed to laying hens; feed continuously as the sole ration; withdraw 5 days before slaughter; lincomycin as provided by No. 000009, § 510.600(c) of this chapter; approval for this combination granted to No. 000009 as identified in § 510.600(c) of this chapter.

§ 558.525 Ronnel.

(a) *Chemical name.* *O,O*-Dimethyl *O*-(2,4,5-trichlorophenyl) phosphorothioate.

(b) *Approvals.* (1) Premix levels 18 and 40 percent have been granted to No. 025700 in § 510.600(c) of this chapter.

(2) Premix level 5.5 percent in mineral premix has been granted to No. 021930 in § 510.600(c) of this chapter.

(c) *Assay limits.* Feed supplement 80 to 120 percent of labeled amount.

(d) *Special considerations.* (1) Maximum level permitted in a medicated concentrate 6 percent.

(2) The label shall bear adequate directions and warnings for use, which shall also include:

(i) A statement in the case of feed additive supplements containing ronnel that such supplements shall be thoroughly mixed with ground grain for top dressing or with complete ration.

(ii) A statement that ronnel-medicated feed concentrate is to be used as the sole source of ronnel medication.

(iii) "Warning-Ronnel is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after exposure to cholinesterase inhibiting drugs, pesticides, or chemicals."

(e) *Related tolerances.* See 40 CFR 180.177.

(f) *Conditions of use.* It is used in the feed of beef cattle and nonlactating dairy animals as follows:

(1) *Amount.* 0.00078 lb. (0.35 gram) per 100 lb. body weight per day for 14 days.

(i) *Indications for use.* Control of grubs.

(ii) *Limitations.* Feed 0.00078 lb. (0.35 gram) per 100 lb. of animal weight per day for 14 days in a feed supplement containing not over 0.26 percent ronnel; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during medication, or if medication has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(2) *Amount.* 0.0018 lb. (0.82 gram) per 100 lb. body weight per day for 7 days.

(i) *Indications for use.* Control of grubs; aid in the reduction of cattle lice, when the drug is used for cattle grub control.

(ii) *Limitations.* Feed 0.0018 lb. (0.82 gram) per 100 lb. animal weight per day for 7 days in a feed supplement containing not over 6 percent ronnel; withdraw from dairy animals 10 days; if dairy cows or heifers freshen during medication, or if medication has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last

treatment; withdraw 10 days prior to slaughter.

(3) *Amount.* 0.01375 lb. (6.24 gram) per 100 lb. body weight per month for not less than 75 days.

(i) *Indications for use.* Control of grubs and hornflies.

(ii) *Limitations.* Feed 0.25 lb. of a mineral supplement in granular form containing 5.5 percent ronnel per 100 lb. of animal weight per month for not less than 75 days; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during medication, or if medication has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(4) *Amount.* 0.0009 lb. (0.41 gram) per 100 lb. body weight per day for 14 days.

(i) *Indications for use.* Control of grubs.

(ii) *Limitations.* Feed 0.0009 lb. (0.41 gm.) per 100 lb. of animal weight per day for 14 days in a feed supplement containing 0.3 percent ronnel; withdraw from dairy animals 10 days before calving, if dairy cows or heifers freshen during medication, or if medication has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(5) *Amount.* 0.012 lb. (5.5 gram) per 100 lb. body weight per month for not less than 75 days.

(i) *Indications for use.* Control of grubs and hornflies.

(ii) *Limitations.* Feed 0.2 lb. of mineral supplement containing 6 percent ronnel per 100 lb. of animal weight per month for not less than 75 days; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during medication, or if medication has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

§ 558.565 Styrylpyridinium chloride, diethylcarbamazine (as base).

(a) *Chemical name.* (1) Styrylpyridinium chloride: 2-(*p*-Chlorostyryl)-1-methylpyridinium chloride.

(2) Diethylcarbamazine: *N,N*-Diethyl-4-methyl-1-piperazine-carboxamide.

(b) *Approvals.* Finished feed containing 0.035 percent styrylpyridinium chloride, and 0.021 percent diethylcarbamazine (as base) has been granted to No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the control of hookworms (*Ancylostoma caninum*) and roundworms (*Toxocara canis*) and for the prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(2) Finished feed containing 0.035 percent styrylpyridinium chloride and 0.021 percent diethylcarbamazine (as the base) is administered to dogs as follows: Maximum stressed dogs are fed an amount of the finished feed in ounces equal to the dogs body weight in pounds divided by 4. Medium stressed dogs are fed an amount of the finished feed in ounces equal to the dogs body weight in pounds divided by 4.5. Low stressed dogs are fed an amount of the finished feed in ounces equal to the dogs body weight in pounds divided by 5. Underweight dogs are fed 10 percent more than the amounts specified in this paragraph. Overweight dogs are fed 10 percent less than the amounts specified in this paragraph, with adjustments made every 7 days until the desired body weight is obtained.

(3) Dogs with established heartworm infections should not be treated with the drug until they have been converted to a negative status. For the prevention of heartworm infestation, the drug should be administered before the mosquito season and as soon as young puppies are born. The drug should be administered continuously during periods of exposure to hookworm, roundworm, and heartworm infestations to control recurring burdens of hookworms and roundworms and prevent the maturation of immature heartworms (third stage infective larvae) into adults.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 558.575 Sulfadimethoxine, ormetoprim.

(a) *Chemical names.* (1) Sulfadimethoxine: *N'*(2,6-Dimethoxy-4-pyrimidinyl)-sulfanilamide.

(2) Ormetoprim: 2,4-Diamino-5(6-methylveratryl) pyrimidine.

(b) *Approvals.* Premix levels containing 25 percent of sulfadimethoxine and 15 percent of ormetoprim granted to No. 000004 in § 510.600(c) of this chapter.

(c) *Assay limits.* (1) Finished feed containing 0.01 percent of combined drug must contain not less than 75 percent nor more than 125 percent of either ormetoprim or sulfadimethoxine.

(2) Finished feed containing 0.02 percent of combined drug must contain not less than 85 percent nor more than 115 percent of either ormetoprim or sulfadimethoxine.

(d) *Related tolerances.* See § 556.490 of this chapter.

(e) *Conditions of use.* It is used in feeds for animals as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5, grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(*b*) *Limitations.* Feed as sole ration; withdraw 2 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent) plus 3 - nitro - 4 - hydroxyphenlyarsonic acid, 22.7 grams (0.0025 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namedy *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli,* (colibacillosis); and *P. multocida* (fowl cholera); growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) *Replacement chickens* — (i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. galmaxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 2 days before slaughter.

(3) *Turkeys*—(i) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. allopavonis,* and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).

(*b*) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 2 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent) plus ipronidazole, 56.75 grams (0.00625 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis;* bacterial infections due to *P. multocida* (fowl cholera); and blackhead (histomoniasis).

(*b*) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 4 days before slaughter.

§ 558.615 Thiabendazole.

(a) *Chemical name.* 2-(4'-Thiazolyl)-benzimidazole.

(b) *Specifications.* Conforms to N.F. XII specifications.

(c) *Approvals.* In dry premix, levels of 22, 44.1, 66.1 percent. The 66.1 percent level is solely for the manufacture of cane molasses liquid supplement which is mixed in dry feeds; for sponsor see No. 000006 in § 510.600(c) of this chapter.

(d) *Assay limits.* Finished feed containing less than 7 percent thiabendazole: 85–115 percent of labeled amount. Finished feed containing 7 percent or

more of thiabendazole: 90–110 percent of labeled amount.

(e) *Special considerations.* Maximum level permitted in a medicated supplement: 9.9 percent. Not to be used in feeds containing bentonite.

(f) *Related tolerances.* See § 556.730 of this chapter.

(g) *Conditions of use.* It is used in feed for animals as follows:

(1) *Cattle*—(i) *Amount.* 3 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum rddiatum*).

(*b*) *Limitations.* Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(*b*) *Limitations.* 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats*—(i) *Amount.* 3 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.*, and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.*, and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.*; less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine*—(i) *Amount.* 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (genus *Ascaris*).

(iii) *Limitations.* Administer continuously feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

§ 558.625 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means.

(b) *Approvals.* Premix levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section:

(1) To 000986: 10, 40 and 100 grams per pound, paragraphs (f) (1) (ii) through (f) (1) (vi) of this section; 40 grams per pound, paragraph (f) (1) (i) of this section.

(2) To 017255: 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(3) To 043733: 4 and 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(4) To 011490: 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(5) To 017800: 0.4 and 0.8 gram per pound, paragraph (f) (1) (vi) (*a*); 10 grams per pound, paragraphs (f) (1) (i) and (f) (1) (vi) (*a*) of this section; 40 grams per pound, paragraphs (f) (1) (i), (f) (1) (vi) (*a*), (*b*), (*c*), and (*d*) of this section.

(6) To 018356: 0.66, 1.33, 6.66 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(7) To 017162: 0.4 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(8) To 035369: 4 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(9) To 043727: 4 and 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(10) To 012286: 0.4 and 0.8 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(11) To 017274: 8 or 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(12) To 021930: 2 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(13) To 035393: 0.4 and 2 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(14) To 016968: 4 and 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(15) To 026186: 4, 10, and 20 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(16) To 024817: 5 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(17) To 021780; 0.8 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(18) To 017434: 0.4 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(19) To 033999: 0.8 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(20) To 033071: 0.4 and 0.8 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(21) To 043426: 2.0 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(22) To 026282: 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(23) To 030804: 0.8 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(24) To 025796: 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(25) To 043743: 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(26) To 034418: 10 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(27) To 020275: 40 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(28) To 034139: 4 grams per pound; paragraph (f) (1) (vi) (*a*) of this section.

(29) To 043744: 0.4 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(30)–(31) [Reserved]

(32) To 018597: 0.4 gram per pound; paragraph (f) (1) (vi) (*a*) of this section.

(c) *Assay limits.* Finished feed not less than 75 percent nor more than 125 percent of labeled amount.

(d) *Special considerations.* The manufacture of finished feeds containing tylosin phosphate does not require compliance with the provisions of section 512 (m) of the Federal Food, Drug, and Cosmetic Act if:

(1) Processed from feed supplements or concentrates for:

(i) Chickens at not more than 200 grams per ton.

(ii) Swine at not more than 500 grams per ton.

(iii) Cattle at not more than 360 grams per ton and complying with paragraph (f) (1) (i) of this section.

(2) Processed from premixes which contain not more than 10 grams of tylosin per pound and conforming to the provisions of paragraph (f) (1) (vi) (*a*) of this section.

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in animal feeds as follows:

(i) *For beef cattle*—(*a*) *Amount per ton.* 8–10 grams.

(*b*) *Indications for use.* For reduction of incidence of liver abscesses caused by *Sphaerophorus necrophorus* and *Corynebacterius pyogenes.*

(*c*) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens*—(*a*) *Amount per ton.* Tylosin, 800–1000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24–48 hours at 3 to 5 weeks of age.

(iii) *Chickens*—(*a*) *Amount per ton.* Tylosin, 4–50 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate.

(b) *Amount per ton.* Tylosin, 3.2–50 grams combined with penicillin.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* Use 1.2 parts of penicillin to 2.0 parts of tylosin; as tylosin phosphate and procaine penicillin.

(iv) *Laying chickens*—(a) *Amount per ton.* Tylosin, 20–50 grams.

(b) *Indications for use.* For improved feed efficiency.

(c) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens*—(a) *Amount per ton.* Tylosin, 1,000 grams.

(b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine*—(a) *Amount per ton.* Tylosin, 10–100 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(b) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Prevention of swine dysentery (vibrionic).

(2) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(c) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Treatment and control of swine dysentery (vibrionic).

(2) *Limitations.* Administer in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3–10 days, 40–100 grams per ton in feed for 2–6 weeks.

(d) *Amount per ton.* Tylosin, 100 grams.

(1) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(2) *Limitations.* As tylosin phosphate.

(2) Tylosin may also be used with:

(i) Zoalene as in § 121.207 of this chapter.

(ii) Hygromycin B as in § 121.213 of this chapter.

(iii) Amprolium as in § 121.210 of this chapter.

§ 558.630 Tylosin and sulfamethazine.

(a) *Specifications.* (1) Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means.

(2) Sulfamethazine is the chemical N'-(4,6-dimethyl-2-pyrimidinyl) sulfanilamide.

(b) *Approvals.* Premix levels, a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section:

(1) To 000986: 40 grams per pound each, paragraph (f) (2) (i).

(2) To 000986, 012190: 10 grams per pound each, paragraph (f) (2) (i).

(3) To 017255, 016968, 025796, 034500: 10 grams per pound each, paragraph (f) (2) (ii).

(c) *Assay limits.* Finished feed must contain not less than 75 percent nor more than 125 percent of tylosin and not less than 80 percent nor more than 120 percent of sulfamethazine.

(d) [Reserved].

(e) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(f) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) *Indications for use.* (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella Bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*P. multocida* and/or *C. pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(3) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter.

§ 558.635 Virginiamycin.

(a) *Specifications.* Virginiamycin is the antibiotic substance produced by the growth of *Streptomyces virginiae* or the same antibiotic substance produced by any other means.

(b) *Approvals.* Premix levels of 2.2 percent virginiamycin activity (10 grams per pound) and 50 percent virginiamycin activity (227 grams per pound) granted to No. 000007 in § 510.600(c) of this chapter.

(c) *Assay limits.* Finished feed must contain not less than 70 percent nor more than 130 percent of the labeled amount of the drug.

(d) *Related tolerances.* See § 556.750 of this chapter.

(e) *Special considerations.* (1) Not for use in breeding swine over 120 pounds.

(2) Dilute premix with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of complete feed.

(f) *Conditions of use.* It is used in complete swine feeds as follows:

(1) *Amount per ton.* 100 grams (for 2 weeks).

(i) *Indications for use.* Treatment of swine dysentery in nonbreeding swine.

(ii) *Animal weight.* Over 120 pounds.

(2) *Amount per ton.* 100 grams for 2 weeks, 50 grams thereafter.

(i) *Indications for use.* Treatment and control of swine dysentery.

(ii) *Animal weight.* Over 120 pounds.

(3) *Amount per ton.* 25 grams.

(i) *Indications for use.* Aid in control of swine dysentery. For use in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.

(ii) *Animal weight.* Over 120 pounds.

(4) *Amount per ton.* 10 grams.

(i) *Indications for use.* Increased rate of weight gain and improved feed efficiency (starter and grower feeds only).

(ii) *Animal weight.* Weaning to 120 pounds.

NOTE: Incorporation by reference provisions approved by the Director of the Federal Register March 25, 1975.

[FR Doc.75-7951 Filed 3-26-75;8:45 am]

federal register

THURSDAY, MARCH 27, 1975
WASHINGTON, D.C.
Volume 40 ■ Number 60

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

DRUGS: GENERAL

Reorganization and Republication

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 9]

SUBCHAPTER C—DRUGS: GENERAL

Reorganization and Republication

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the ninth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

This recodification document represents a reorganization of material remaining in Subchapter C—Drugs that has general applicability, rather than strictly human or animal use. In addition certain related sections under Parts 1 and 3 have been redesignated as part of the revised Subchapter C—Drugs: General.

The following table shows the relationship of the CFR section numbers under the former Subchapters A and C to their redesignation reflected in the new Parts 200 through 299:

Old Section	New Section	Old Section	New Section
1.100	299.5	3.21	250.102
1.101	201.6	3.22	200.101
1.101a	201.60	3.27	250.203
1.102	201.50	3.28	200.50
1.102a	201.61	3.29	201.307
1.102b	201.1	3.30	201.308
1.102c	201.51	3.35	201.303
1.102d	201.62	3.36	250.103
1.103	201.15	3.37	201.309
1.104	201.10	3.40	250.201
1.105	202.1	3.43	201.310
1.106(a)	201.5	3.44	201.311
1.106(b)	201.100	3.45	200.30
1.106(c)	201.105	3.48	250.106
1.106(d)	201.109	3.50	250.104
1.106(f)	201.110	3.52	250.107
1.106(g)	201.115	3.53	250.10
1.106(h)	201.116	3.56	201.405
1.106(i)	201.117	3.61	200.18
1.106(j)	201.119	3.62	299.4
1.106(k)	201.120	3.63	250.11
1.106(l)	201.122	3.64	250.12
1.106(m)	201.125	3.67	201.305
1.106(n)	201.127	3.71	250.100
1.106(o)	201.128	3.74	201.56
1.107	201.150	3.76	200.10
1.108(a) & (b)	201.16	3.77	290.35
		3.81	201.200
1.108(c)	290.6	3.84	201.410
1.109	290.5	3.90	250.300
1.110	290.10	3.91	250.250
1.115	200.15	3.94	250.109
3.3	201.300	3.95	250.110
3.4	201.302	3.501	200.5
3.7	250.108	3.502	201.19
3.8	250.101	3.503	201.312
3.11	201.301	3.505	201.313
3.12	201.304	3.506	200.11
3.15	201.306	3.507	201.17
3.16	200.100	3.508	201.18
3.509	201.314	133.11	211.58
3.510	201.315	133.12	211.110
3.512	200.31	133.13	211.60
3.513	200.7	133.14	211.62
3.514	201.55	133.15	211.115
3.515	201.160	133.100	225.1
3.516	250.105	133.101	225.20
3.518	201.161	133.102	225.30
132.1	207.3	133.103	225.10
132.2	207.20	133.104	225.42
132.3	207.21	133.105	225.102
132.4	207.22	133.106	225.40
132.5	207.25	133.107	225.60
132.6	207.30	133.108	225.58
132.7	207.31	133.109	225.110
132.8	207.35	133.110	225.115
132.9	207.37	133.200	226.1
132.10	207.26	133.201	226.20
132.11	207.39	133.202	226.30
132.31	207.40	133.203	226.10
132.51	207.65	133.204	226.42
133.1	210.3	133.205	226.102
133.2	211.1	133.206	226.40
133.3	211.20	133.207	226.80
133.4	211.30	133.208	226.58
133.5	211.10	133.209	226.110
133.6	211.42	133.210	226.115
133.7	211.101	133.300	229.25
133.8	211.40	138.1	299.3
133.9	211.55	138.2	299.20
133.10	211.80		

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 200, 201, 202, 207, 210, 211, 225, 226, 229, 250, 290, and 299 of Subchapter C is set forth below.

Dated: March 21, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

Therefore, 21 CFR is amended by redesignating portions of Parts 1 and 3 of Subchapter A and Parts 132, 133, and 138 of Subchapter C as Parts 200, 201, 202, 207, 210, 211, 225, 226, 229, 250, 290, and 299 of Subchapter C—Drugs: General, and republished to read as follows:

SUBCHAPTER C—DRUGS: GENERAL

Part

200—General

201—Labeling

202—Prescription Drug Advertising

207—Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

210—Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding of Drugs: General

211—Current Good Manufacturing Practice for Finished Pharmaceuticals

225—Current Good Manufacturing Practice for Medicated Feeds

226—Current Good Manufacturing Practice for Medicated Premixes

229—Current Good Manufacturing Practice for Certain Other Drug Products

250—Special Requirements for Specific Human Drugs

290—Controlled Drugs

299—Drugs; Official Names and Established Names

PART 200—GENERAL

Subpart A—General Provisions

Sec.

200.5 Mailing of important information about drugs.

200.7 Supplying pharmacists with indications and dosage information.

200.10 Contract facilities (including consulting laboratories) utilized as extramural facilities by pharmaceutical manufacturers.

200.11 Use of octadecylamine in steam lines of drug establishments.

200.15 Definition of term "insulin."

200.18 Use of secondhand containers for the shipment or storage of food and animal feed.

Subpart B—Manufacturing Procedures Affecting New Drug Status

200.30 Sterilization of drugs by irradiation.

200.31 Timed release dosage forms.

Subpart C—Requirements for Specific Classes of Drugs

200.50 Ophthalmic preparations and dispensers.

Subpart D—Suitability of Specific Drug Components

200.100 Use of ox bile from condemned livers from slaughtered animals in the manufacture of drugs.

200.101 Suprarenal glands from hog carcasses prior to final inspection.

AUTHORITY: Sec. 701, 52 Stat. 1055; 21 U.S.C. 371, unless otherwise noted.

Subpart A—General Provisions

§ 200.5 Mailing of important information about drugs.

Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail should be distinctive in appearance so that it will be promptly recognized and read. The Food and Drug Administration will make such mailings in accordance with the specifications set forth in this section. Manufacturers and distributors of drugs are asked to make such mailings as prescribed by this section and not to use the distinctive envelopes for ordinary mail.

(a) Use first class mail and No. 10 white envelopes.

(b) The name and address of the agency or the drug manufacturer or distributor is to appear in the upper left corner of the envelope.

(c) The following statements are to appear in the far left third of the envelope front, in the type and size indicated, centered in a rectangular space approximately 3 inches wide and 2¼ inches high with an approximately ⅜-inch-wide border in the color indicated:

(1) When the information concerns a significant hazard to health, the statement:

IMPORTANT
DRUG
WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36 point Gothic Bold type. "Drug" and "Warning" shall be in 36 point Gothic Condensed type. The rectangle's

border and the statement therein shall be red.

(2) When the information concerns important changes in drug package labeling, the statement:

IMPORTANT
PRESCRIBING
INFORMATION

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36 point Gothic Bold type. "Prescribing" and "Information" shall be in 36 point Gothic Condensed type. The rectangle's border and the statement therein shall be blue.

(3) When the information concerns a correction of prescription drug advertising or labeling, the statement:

IMPORTANT
CORRECTION
OF DRUG
INFORMATION

The statement shall be in four lines, all capitals, and centered. "Important" shall be in 36 point Gothic Bold type. "Correction," "Of Drug," and "Information" shall be in 36 point Gothic Condensed type. The rectangle's border and the statement therein shall be brown.

(Sec. 705(b), 52 Stat. 1058; 21 U.S.C. 375(b))

§ 200.7 Supplying pharmacists with indications and dosage information.

There are presently no regulations under the Federal Food, Drug, and Cosmetic Act that prevent a manufacturer of prescription drugs from sending the pharmacist data he needs on indications and dosage in exercising his important professional function of checking against possible mistakes in a prescription. The Food and Drug Administration believes manufacturers should be encouraged to supply such printed matter to the pharmacist for his professional information. Obviously, such printed matter should not be displayed to prospective purchasers to promote over-the-counter sale of prescription drugs.

(Secs. 502(f)(1), 503(b)(1)(B), 52 Stat. 1051, 52 Stat. 1052, as amended 65 Stat. 648, 649; 21 U.S.C. 352(f)(1), 353(b)(1)(B))

§ 200.10 Contract facilities (including consulting laboratories) utilized as extramural facilities by pharmaceutical manufacturers.

(a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act specifically authorizes inspection of consulting laboratories as well as any factory, warehouse, or establishment in which prescription drugs are manufactured, processed, packed, or held.

(b) The Food and Drug Administration is aware that many manufacturers of pharmaceutical products utilize extramural independent contract facilities, such as testing laboratories, contract packers or labelers, and custom grinders, and regards extramural facilities as an extension of the manufacturer's own facility.

(c) The Food and Drug Administration reserves the right to disclose to the pharmaceutical manufacturer, or to the applicant of a new drug application (NDA) or to the sponsor of a Notice of Claimed Exemption for Investigational New Drug (IND), any information obtained during the inspection of an extramural facility having a specific bearing on the compliance of the manufacturer's, applicant's, or sponsor's product with the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration's position is that by the acceptance of such contract work, the extramural facility authorizes such disclosures.

(d) The Food and Drug Administration does not consider results of validation studies of analytical and assay methods and control procedures to be trade secrets that may be withheld from the drug manufacturer by the contracted extramural facility.

(Secs. 501, 505, 704(a), 52 Stat. 1049–50, as amended, 1052–53, as amended, 67 Stat. 477, as amended, 76 Stat. 792; 21 U.S.C. 351, 355, 374(a))

§ 200.11 Use of octadecylamine in steam lines of drug establishments.

The Food and Drug Administration will not object to the use of octadecylamine in steam lines where the steam may be used for autoclaving surgical instruments and gauze if the octadecylamine in the steam is not more than 2.4 parts per million.

(Sec. 502, 52 Stat. 1051; 21 U.S.C. 352)

§ 200.15 Definition of term "insulin."

For the purposes of sections 502(k) and 506 of the act:

(a) The term "insulin" as used therein means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(b) The following substances, when they are intended for use in the manufacture of insulin-containing drugs that will subsequently be submitted for certification, shall not be considered to be subject to certification as "drugs composed wholly or partly of insulin":

(1) Pancreas glands; and

(2) Materials prepared from pancreas glands, such as "salt cake" and "isoelectric precipitate," which materials must be subjected to further purification in order to meet the standards of purity established by Part 429 of this chapter.

(Sec. 506, 55 Stat. 851; 21 U.S.C. 356)

§ 200.18 Use of secondhand containers for the shipment or storage of food and animal feed.

(a) Investigations by the Food and Drug Administration, the National Communicable Disease Center of the U.S. Public Health Service, the Consumer and Marketing Service of the U.S. Department of Agriculture, and by various State public health agencies have revealed practices whereby food and animal feed stored or shipped in secondhand containers have been rendered dangerous to health. Such contamination has been the result of the original use of these containers for the storage and shipment of articles containing or bearing disease organisms or poisonous or deleterious substances.

(b) The Commissioner concludes that such dangerous or potentially dangerous practices include, but are not limited to, the following:

(1) Some vegetable growers and packers employ used poultry crates for shipment of fresh vegetables, including cabbage and celery. Salmonella organisms are commonly present on dressed poultry and in excreta and fluid exudates from dressed birds. Thus wooden crates in which dressed poultry has been iced and packed are potential sources of Salmonella or other enteropathogenic microorganisms that may contaminate fresh vegetables which are frequently consumed without heat treatment.

(2) Some potato growers and producers of animal feeds use secondhand bags for shipment of these articles. Such bags may have originally been used for shipping or storing pesticide-treated seed or other articles bearing or containing poisonous substances. Thus these secondhand bags are potential sources of contamination of the food or animal feed stored or shipped therein.

(c) In a policy statement issued April 11, 1968, the Food and Drug Administration declared adulterated within the meaning of section 402(a) of the Federal Food, Drug, and Cosmetic Act shipments of vegetables or other edible food in used crates or containers that may render the contents injurious to health. This policy statement is extended so that the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of vegetables, other edible food, or animal feed in used crates, bags, or other containers that may render the contents injurious to health.

(Secs. 402(a), 52 Stat. 1046, as amended; 21 U.S.C. 342(a))

Subpart B—Manufacturing Procedures Affecting New Drug Status

§ 200.30 Sterilization of drugs by irradiation.

There is a current interest in the utilization of newly developed sources of radiation for the sterilization of drugs. Prior to the marketing of a drug sterilized by such means, it is necessary in the interest of protecting the public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. Accordingly, all drug products, including injections, ophthalmic solutions, surgical sutures, and surgical dressings sterilized by means of irradiation are regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An effective new-drug application pursuant to section 505 of the act is therefore a prerequisite to interstate shipment of such articles, except as provided by section 505(i).

(Secs. 201, 505, 52 Stat. 1040, as amended, 1052, as amended; 21 U.S.C. 321, 355)

§ 200.31 Timed release dosage forms.

(a) Many drugs are now being offered in dosage forms that are designed to re-

lease the active ingredients over a prolonged period. There is a possibility of unsafe overdosage if such products are improperly made and the active ingredients are released at one time or over too short a time interval. Any such dosage form that contains per dosage unit (for example, capsule or tablet), a quantity of active drug ingredients which is not generally recognized as safe for administration as a single dose under the conditions suggested in its labeling, is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(b) The fact that the labeling of this type of drug may claim delayed or prolonged release of all or some of the active ingredients does not affect the new-drug status of such articles. A new-drug application is required in any such case to demonstrate that the drug is in fact safe because it is properly made and controlled to release the total dose at a safe rate. It should be noted particularly that such dosage forms are regarded as new drugs even when the total daily dosage recommended in the labeling is generally recognized as safe. For example, a capsule containing 50 milligrams of pyrilamine maleate and 15 milligrams of phenylephrine hydrochloride, offered for sale without prescription, is regarded as a new drug for which the distributor should have an effective new-drug application, even though the directions call for taking no more than two capsules daily. While the daily intake under such directions is within the range regarded as safe for use in self-medication, the single dose is too high for such use unless the release of the drug is sufficiently prolonged. It is obvious that, in filing a new-drug application for such an article, particular attention should be given to data which establish that the active ingredients are released over a period of time, as represented in the labeling.

(Sec. 201(p), 52 Stat. 1042; 21 U.S.C. 321(p))

Subpart C—Requirements for Special Classes of Drugs

§ 200.50 Ophthalmic preparations and dispensers.

(a) (1) Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use, including contact lens solutions and preparations for cleansing the eyes, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye.

(2) The Food and Drug Administration concludes that all such preparations, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe. In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act, and, further, may be deemed misbranded within the meaning of section 502(j) of the act. This ruling is extended to affect all preparations for ophthalmic use.

(3) The containers of ophthalmic preparations shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. To provide time for validation of sterility tests and changes to sterile production procedures, this ruling will be effective for nonantitbiotic ophthalmic ointment preparations recognized in the official compendia (U.S.P. and N.F.) on the dates specified in such official compendia. For all other ophthalmic ointments, this ruling will be effective 12 months after the date of publication in the FEDERAL REGISTER (10-28-72).

(b) Liquid ophthalmic preparations packed in multiple-dose containers should:

(1) Contain one or more suitable and harmless substances that will inhibit the growth of microorganisms; or

(2) Be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings as to afford adequate protection and minimize the hazard of injury resulting from contamination during use.

(c) Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. They should be so packaged as to maintain sterility until the package is opened and be so labeled, on or within the retail package, as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

Subpart D—Suitability of Specific Drug Components

§ 200.100 Use of ox bile from condemned livers from slaughtered animals in the manufacture of drugs.

(a) Conferences have recently been held between members of the Department of Health, Education, and Welfare and representatives of the Agricultural Research Service, Department of Agriculture, concerning requests made to that agency for the release of ox bile from condemned livers of slaughtered animals for use in the manufacture of certain drugs.

(b) The Secretary of Health, Education, and Welfare has given careful consideration to this problem and has reached the conclusion that no hazard to public health will be involved in the release of such ox bile, after the addition to it of sufficient sodium hydroxide to give the mixture a sodium hydroxide content of not less than 5 percent, the mixture then being allowed to stand at least 24 hours. This Department will not regard as in violation of the provisions of the Federal Food, Drug, and Cosmetic Act such alkalized and aged ox bile, if labeled "Ox Bile and Sodium Hydroxide (or Ox Bile and Sodium Hydroxide Solution). Sodium hydroxide not less than 5 percent by weight. For manufacturing use only," together with a statement of the quantity of contents in the container (for example, "50 gallons") and the name and address of the manufacturer, packer, or shipper.

(c) Bile from the condemned livers of sheep and goats also may be released, under the same conditions as outlined in the preceding paragraph, except that the words "Sheep Bile" or "Goat Bile," as the case may be, shall be substituted for the words "Ox Bile" upon the label. In the case of mixtures of bile from any two or all three of the sources mentioned, the label shall indicate the sources of such bile.

§ 200.101 Suprarenal glands from hog carcasses prior to final inspection.

(a) The Agricultural Research Service of the U.S. Department of Agriculture has informed the Food and Drug Administration of the Department of Health, Education, and Welfare that, under appropriate conditions, it will permit the removal of suprarenal glands from hogs that have not been finally inspected by Federal Inspectors. The glands to be so obtained are intended for use in manufacturing extracts containing one or more of the therapeutically useful constituents of suparenal glands.

(b) Under the conditions specified in this section, the Secretary of Health, Education, and Welfare has determined that the public health will be adequately protected from any danger from the use of drugs, made in whole or in part from suprarenal glands of hogs that may be condemned by Federal inspectors of the Department of Agriculture after removal of such glands from the carcasses, arising from any abnormality of such carcasses if such glands are subjected to the following prescribed treatment, which will destroy or eliminate any microorganisms or toxins that might be present in the glands:

(c) The glands are subjected to quick freezing promptly upon removal from the carcasses and maintained in a frozen state until they are ground and immersed in 95 percent to 100 percent acetone. The ground tissues remain in the acetone for a period of not less than 6 days, the mixture is filtered, and the residue is burned.

PART 201—LABELING

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AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended; 21 U.S.C. 371, unless otherwise noted.

Subpart A—General Labeling Provisions

§ 201.1 Drugs and devices; name and place of business of manufacturer, packer or distributor.

(a) The label of a drug or device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such drug or device; such as, "Manufactured for ------", "Distributed by ------", or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and ZIP Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including the invoice).

(e) If a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such drug or device was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 201.5 Drugs and devices; adequate directions for use.

"Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended (Section 201.128 defines "intended use.") Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(f) Route or method of administration or application.

(g) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

§ 201.6 Drugs and devices; misleading statements.

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(Sec. 502, 52 Stat. 1050, as amended; 21 U.S.C. 352)

§ 201.10 Drugs; statement of ingredients.

(a) The ingredient information required by section 502(e) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names, and such statements as "Warning—May be habit forming" that are specifically required for certain ingredients by the act or regulations in this chapter.

(b) The term "ingredient" applies to any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances.

(c) The labeling of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of the ingredients present in the drug appear in the labeling, or the relative prominence otherwise given such names.

(2) Failure to reveal the proportion of, or other fact with respect to, an ingredient present in such drug, when such proportion or other fact is material in the light of the representation that such ingredient is present in such drug.

(3) The employment of a fanciful proprietary name for a drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The featuring in the labeling of inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(d) (1) If the drug is in tablet or capsule form or other unit dosage form, any statement of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit. If the drug is not in unit dosage form, any statement of the quantity of an ingredient contained therein shall express the amount of such ingredient in a specified unit of weight or measure of the drug, or the percentage of such ingredient in such drug. Such statements shall be in terms that are informative to licensed practitioners, in the case of a prescription drug, and to the layman, in the case of a nonprescription drug.

(2) A statement of the percentage of an ingredient in a drug shall, if the term "percent" is used without qualification, mean percent weight-in-weight, if the ingredient and the drug are both solids, or if the ingredient is a liquid and the drug is a solid; percent weight in volume at 68° F. (20° C.), if the ingredient is a solid and the drug is a liquid; and percent volume in volume at 68° F. (20° C.), if both the ingredient and the drug are liquids, except that alcohol shall be stated in terms of percent volume of absolute alcohol at 60° F. (15.56° C.).

(e) A derivative or preparation of a substance named in section 502(e) of the act is an article derived or prepared from such substance by any method, including actual or theoretical chemical action

(f) If an ingredient is a derivative or preparation of a substance specifically named in section 502(e) of the act and the established name of such ingredient does not indicate that it is a derivative or preparation of the parent substance named in section 502(e) of the act, the labeling shall, in conjunction with the listing of the established name of such ingredient, declare that such article is a derivative or preparation of such parent substance.

(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured on the label or in the labeling for the drug; but, except as provided in this subparagraph, the established name need not be used with the proprietary name or designation in the running text of the label or labeling. On any label or page of labeling in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text in association with such proprietary name or designation and in the same type size used in such running text: *Provided, however,* That if the proprietary name or designation is used in the running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such running text. If any labeling includes a column with running text containing detailed information as to composition, prescribing, side effects, or contraindications and the proprietary name or designation is used in such column but is not featured above or below the column, the established name shall be used at least once in such column of running text in association with such proprietary name or designation and in the same type size used in such column of running text: *Provided, however,* That if the proprietary name or designation is used in such column of running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such column of running text. Where the established name is required to accompany or to be used in association with the proprietary name or designation, the established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of" preceding the established name, by brackets surrounding the established name, or by other suitable means.

(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(h) (1) In the case of a prescription drug containing two or more active ingredients, if the label bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required on the label by section 502(e) of the act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

(2) If the drug is packaged in a container too small to bear the quantitative ingredient information on the main display panel, the quantitative ingredient information required by section 502(e) of the act may appear elsewhere on the label, even though the proprietary name or designation appears on the main display panel of the label; but side- or back-panel placement shall in this case be so arranged and printed as to provide size and prominence of display reasonably related to the size and prominence of the front-panel display.

(i) A drug packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with section 502(e)(1)(A)(ii) and (B) of the act shall be exempt from compliance with those clauses: *Provided,* That:

(1) The label bears:

(i) The proprietary name of the drug;

(ii) The established name, if such there be, of the drug;

(iii) An identifying lot or control number; and

(iv) The name of the manufacturer, packer, or distributor of the drug; and

(2) All the information required to appear on the label by the act and the regulations in this chapter appears on the carton or other outer container or wrapper if such carton, outer container, or wrapper has sufficient space to bear such information, or such complete label information appears on a leaflet with the package.

§ 201.15 Drugs and devices; prominence of required label statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502(c) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502 (b) or (e) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502 (c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Sec. 502, 52 Stat. 1050, as amended; 21 U.S.C. 352)

§ 201.16 Drugs and devices; Spanish-language version of certain required statements.

An increasing number of medications restricted to prescription use only are being labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language. Such labeling is authorized under § 201.15(c). Two required warnings, the wording of which is fixed by law in the English language, are presently being translated in various ways, from literal translation to loose interpretation. The statutory nature of these two statements requires that the translation must convey the meaning properly, in order to avoid confusion and dilution of the purposes of the warnings. The Commissioner of Food and Drugs hereby adopts the following Spanish-language versions as the accepted equivalents of the English wording of the following:

(a) Section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act requires the statement "Caution: Federal law prohibits dispensing without prescription." The Spanish version of this shall be: "Precaucion: La ley Federal prohibe su despacho sin prescripcion facultativa."

(b) Section 502(d) of the Federal Food, Drug, and Cosmetic Act requires the statement "Warning—May be habit forming" on habit-forming drugs. The Spanish version of this shall be: "Aviso—Puede formar habito o vicio."

§ 201.17 Drugs; location of expiration date.

Drugs which require an expiration date should show the expiration date on the immediate container. When the immediate container is packaged in an individual carton, the expiration date should also be placed on the carton. When single-dose containers are packed in individual cartons, the expiration date may properly appear on the carton only.

(Secs. 505, 506, 507, 52 Stat. 1052, as amended, 55 Stat. 851, 59 Stat. 463, 61 Stat. 12, 63 Stat. 409; 21 U.S.C. 355, 356, 357)

§ 201.18 Drugs; significance of control numbers.

The lot number on the label of a drug should be capable of yielding the complete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded.

(Sec. 502, 52 Stat. 1050; 21 U.S.C. 352)

§ 201.19 Drugs; use of term "infant".

The regulations affecting special dietary foods (§ 125.1(d) of this chapter) define an infant as a child not more than 12 months old. Apart from this, the Food and Drug Administration has not established any definition of the term "infant." Some question has arisen whether, for the purposes of drug labeling, an infant means a child up to 1 year of age or a child up to 2 years of age. Until the term is more precisely defined by legislation or formal regulation, where the exact meaning of the term is significant, manufacturers should qualify any reference to "infant" to indicate whether it refers to a child who is not more than 1 year of age, or a child not more than 2 years of age.

(Sec. 502, 52 Stat. 1051; 21 U.S.C. 352)

Subpart B—Labeling Requirements for Prescription Drugs and/or Insulin

§ 201.50 Statement of identity.

(a) The label of prescription and insulin-containing drugs in package form shall bear as one of its principal features a statement of the identity of the drug.

(b) Such statement of identity shall be in terms of the established name of the drug. An insulin-containing drug shall be further identified by placement on the outside container or wrapper of the package, and on the label of the immediate container, of the distinguishing color(s) required by § 429.12 of this chapter. In the case of a prescription drug that is a mixture and that has no established name, the requirement for statement of identity shall be deemed to be satisfied by a listing of the quantitative ingredient information as prescribed by § 201.10.

(c) The statement of identity of a prescription drug shall also comply with the placement, size and prominence requirements of § 201.10.

§ 201.51 Declaration of net quantity of contents.

(a) The label of a prescription or insulin-containing drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement of quantity of drugs in tablet, capsule, ampule, or other unit dosage form shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, or in terms of fluid measure if the drug is liquid. When the drug quantity statement is in terms of the numerical count of the drug units, it shall be augmented to give the weight or measure of the drug units or the quantity of each active ingredient in each drug unit or, when quantity does not accurately reflect drug potency, a statement of the drug potency.

(b) Statements of weight of the contents shall in the case of prescription drugs be expressed in terms of avoirdupois pound, ounce, and grain or of kilogram, gram, and subdivisions thereof. A statement of liquid measure of the contents shall in the case of prescription drugs be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, fluid-ounce, and fluid-dram subdivisions thereof, or of the liter and milliliter, or cubic centimeter, and shall express the volume at 68° F. (20° C.). A statement of the liquid measure of the contents in the case of insulin-containing drugs shall be expressed in terms of the liter and milliliter, or cubic centimeter, and shall express the volume at 68° F. (20° C.).

(c) The declaration shall contain only such fractions as are generally used in expressing the quantity of the drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(d) The declaration shall appear as a distinct item on the label and, in the case of large volume parenterals, may be embossed on the glass.

(e) The declaration shall accurately reveal the quantity of drug in the package exclusive of wrappers and other material packed therewith.

(f) A statement of the quantity of a prescription or insulin-containing drug in terms of weight or measure applicable to such drug, under the provisions of paragraph (a) of this section, shall express with prominence and conspicuousness the number of the largest whole unit, as specified in paragraph (b) of this section, that are contained in the package. Any remainder shall be expressed in terms of common or decimal fractions of such unit or in terms of the next smaller whole unit and common or decimal fractions thereof.

(g) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large. In the case of a liquid drug in ampules or vials, intended for injection, the declaration shall be considered to express the minimum quantity and the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary or the U.S. Pharmacopeia for filling of ampules. In the case of a solid drug in ampules or vials, the declaration shall be considered to express the accurate net weight. Variations shall comply with the limitations provided in the U.S. Pharmacopeia or the National Formulary.

(h) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled "sample", "physician's sample", or a substantially similar statement and the contents of the package do not exceed 8 grams.

§ 201.55 Statement of dosage.

Section 201.100(b)(2) requires that labels for prescription drugs bear a statement of the recommended or usual dosage. Since the dosage for some prescription drugs varies within extremely wide limits, depending upon the conditions being treated, it may not be possible in all cases to present an informative or useful statement of the recommended or usual dosage in the space available on the label or carton of the package. It is the view of the Food and Drug Administration that when such a situation prevails, compliance with this requirement would be met by a statement such as "See package insert for dosage information", where the detailed information is contained in such insert. However, if an informative, realistic, recommended or usual dosage can readily be set forth on the label, it should appear thereon.

§ 201.56 Content and format of labeling.

(a) To be most useful to practitioners, labeling information for prescription drugs should be orderly and uniform in the sequence and kinds of information presented. For this reason, the Food and Drug Administration recommends that prescription drug labeling purporting to furnish adequate information for the safe and effective use of a drug, as required under § 201.100, should ordinarily contain information in substantially the format and order and with the section headings as follows:

DESCRIPTION
ACTIONS
INDICATIONS
CONTRAINDICATIONS
WARNINGS
PRECAUTIONS
ADVERSE REACTIONS
DOSAGE AND ADMINISTRATION
OVERDOSAGE (WHERE APPLICABLE)
HOW SUPPLIED

(b) The following sections are optional. If used, they should be placed after the information described above.

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(c) Although ordinarily prescription drug labeling should employ the format, order, and section headings described in paragraphs (a) and (b) of this section, in the case of some drugs special warnings may be required to appear conspicuously in the beginning of the labeling for special attention by physicians for the safety of patients. In the case of a drug for which there is no information applicable to a section heading described in paragraph (a) of this section, such heading and section may be omitted.

(Secs. 502, 503, 52 Stat. 1050–52, as amended; 21 U.S.C. 352, 353)

Subpart C—Labeling Requirements for Over-the-Counter Drugs and Devices

§ 201.60 Principal display panel.

The term "principal display panel," as it applies to over-the-counter drugs and devices in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 201.61 Statement of identity.

(a) The principal display panel of an over-the-counter drug or device in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the established name of the drug, if any there be, or common name of the device followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug or device. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s) in terms that are meaningful to the layman. Such statements shall be placed in direct conjunction with the most prominent display of the proprietary name or designation and shall employ terms descriptive of general pharmacological category(ies) or principal intended action(s); for example, "antacid," "analgesic," "decongestant," "antihistaminic," etc. The indications for use shall be included in the directions for use of the drug, as required by section 502(f)(1) of the act and by the regulations in this part.

(c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§ 201.62 Declaration of net quantity of contents.

(a) The label of an over-the-counter drug or device in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination or numerical count and weight, measure, or size. The statement of quantity of drugs in tablet, capsule, ampule, or other unit form and the quantity of devices shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of fluid measure if the drug

is liquid. The drug quantity statement shall be augmented when necessary to give accurate information as to the strength of such drug in the package; for example, to differentiate between several strengths of the same drug "100 tablets, 5 grains each" or "100 capsules, 125 milligrams each" or "100 capsules, 250 milligrams each": *Provided,* That:

(1) In the case of a firmly established, general consumer usage and trade custom of declaring the quantity of a drug or device in terms of linear measure or measure of area, such respective term may be used. Such term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire drug or device; for example, the net quantity of adhesive tape in package form shall be expressed in terms of linear measure augmented by a statement of its width.

(2) If the declaration of contents for a device by numerical count does not give accurate information as to the quantity of the device in the package, it shall be augmented by such statement of weight, measure, or size of the individual units or of the total weight, measure, or size of the device as will give such information; for example, "100 tongue depressors, adult size," "1 rectal syringe, adult size," etc. Whenever the Commissioner determines for a specific packaged drug or device that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisons by consumers, he shall by regulation designate the appropriate term or terms to be used for such article.

(b) Statements of weight of the contents shall be expressed in terms of avoirdupois pound and ounce. A statement of liquid measure of the contents shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof, and shall express the volume at 68° F. (20° C.) (see also paragraph (p) of this section).

(c) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established, general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(d) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(e) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as "giant pint" and "full quart") that tends to exaggerate the amount of the drug in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided,* That:

(1) On packages having a principal display panel of 5 square inches or less the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part; and

(2) In the case of a drug that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner container is waived.

(3) The principal display panel of a drug marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of contents statement is governed by the dimensions of the display card.

(f) The declaration shall accurately reveal the quantity of drug or device in the package exclusive of wrappers and other material packed therewith: *Provided,* That in the case of drugs packed in containers designed to deliver the drug under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(g) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width (of the letter) shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide)

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(h) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than five but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display 100 square inches, except not less than one-half inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (h) (1) through (4) of this section shall be increased by one-sixteenth of an inch

(i) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraph (k) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples set forth in paragraph (k) (3) and (4) of this section). If the net weight of the package is less panel of which has an area of more than than 1 ounce avoirdupois or the net fluid measure is less than 1 fluid ounce, the declaration shall be in terms of common or decimal fractions of the respective ounce and not in terms of drams.

(2) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz." or "6 oz. net wt.," and "6 fl. oz." or "net contents 6 fl. oz."

(j) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for

weight units with any remainder in terms of ounces or common or decimal fractions of the pound; in the case of fluid measure, it shall be expressed in the largest whole unit (gallons, followed by common or decimal fractions of a gallon or by the next smaller whole unit or units (quarts or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see paragraph (k) (5) of this section).

(k) Examples:

(1) A declaration of 1½ pounds weight shall be expressed as "Net wt. 24 oz. (1 lb. 8 oz.)," "Net wt. 24 oz. (1½ lb.)" or "Net wt. 24 oz. (1.5 lb.)."

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as "Net wt. 12 oz."

(3) A declaration of 1 quart liquid measure shall be expressed as "Net contents 32 fl. oz. (1 qt.)" or "32 fl. oz. (1 qt.)."

(4) A declaration of 1¾ quarts liquid measure shall be expressed as "Net contents 56 fl. oz. (1 qt. 1 pt. 8 oz.)" or "Net contents 56 fl. oz. (1 qt. 1.5 pt.)," but not in terms of quart and ounce such as "Net 56 fl. oz. (1 qt. 24 oz.)."

(5) A declaration of 2½ gallons liquid measure shall be expressed as "Net contents 2 gal. 2 qt.," "Net contents 2.5 gallons," or "Net contents 2½ gal." but not as "2 gal. 4 pt."

(l) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

gallon gal.	milliliter ml.
quart qt.	cubic centimeter cc.
pint pt.	yard yd.
ounce oz.	feet or foot ft.
pound lb.	inch in.
grain gr.	meter m.
kilogram kg.	centimeter cm.
gram g.	millimeter mm.
milligram mg.	fluid fl.
microgram mcg.	square sq.
liter l.	weight wt.

(m) On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (1 foot or more), the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or yard; if applicable (as in the case of adhesive tape), the initial declaration in linear inches shall be preceded by a statement of the width. Examples of linear measure are "86 inches (2 yd. 1 ft. 2 in.)," "90 inches (2½ yd.)," "30 inches (2.5 ft.)," "¾ inch by 36 in. (1 yd.)," etc.

(n) On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, "158 sq. inches (1 sq. ft. 14 sq. in.)."

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the drug or device contained in the package; for example, "giant pint" and "full quart." Dual or combination declarations of net quantity of contents as provided for in paragraphs (a) and (i) of this section are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

(p) A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(r) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled "sample," "physician's sample," or a substantially similar statement and the contents of the package do not exceed 8 grams.

Subpart D—Exemptions From Adequate Directions for Use

§ 201.100 Prescription drugs for human use.

A drug subject to the requirements of section 503 (b) (1) of the act shall be exempt from section 502 (f) (1) if all the following conditions are met:

(a) The drug is:

(1) (i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs: or

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs: and

(2) It is to be dispensed in accordance with section 503(b).

(b) The label of the drug bears:

(1) The statement "Caution: Federal law prohibits dispensing without prescription"; and

(2) The recommended or usual dosage, and

(3) The route of administration, if it is not for oral use; and

(4) The quantity or proportion of each active ingredient, as well as the information required by section 502 (d) and (e); and

(5) If it is for other than oral use, the names of all inactive ingredients, except that:

(i) Flavorings and perfumes may be designated as such without naming their components.

(ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in Part 8 of this chapter.

(iii) Trace amounts of harmless substances added solely for individual product identification need not be named. If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection it need not be named.

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

Provided, however, That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraph (b) (2), (3) and (5) of this section may be contained in other labeling on or within the package from which it is to be dispensed, and the information referred to in paragraph (b) (1) of this section may be placed on such outer container only, and the information required by paragraph (b) (6) of this section may be on the crimp of the dispensing tube.

(c) (1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and

(2) If the article is subject to section 505, 506, or 507 of the act, the labeling bearing such information is the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs: *Provided, however,* That the information required by paragraph (c) (1) of this section may be omitted from the dispensing package if, but only if, the article is a drug for which directions,

hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for the use of the drug (other than dose information required by paragraph (b)(2) of this section and § 201.105(b)(2)) contains:

(1) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to section 505 or 507 of the act, the parts of the labeling providing such information are the same in language and emphasis as labeling approved or permitted under the provisions of section 505 or 507, respectively, and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling; and

(2) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed: *Provided, however,* That the information required by paragraph (d)(1) and (2) of this section is not required on the so-called reminder-piece labeling which calls attention to the name of the drug but does not include indications or dosage recommendations for use of the drug: *And provided, however,* That reminder-piece labeling is not permitted for a drug for which an announcement has been published by the Food and Drug Administration pursuant to a review of the labeling claims for the drug by the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, and for which no claim has been evaluated as higher than "possibly effective." If the Commissioner finds the circumstances are such that reminder-piece labeling may be misleading to prescribers of drugs subject to NAS–NRC evaluation, such reminder labeling will not be allowed and the manufacturer, packer, or distributor will be notified either in the publication of the conclusions on the effectiveness of the drug or by letter.

(e) All labeling, except labels and cartons, bearing information for use of the drug also bears the date of the issuance or the date of the latest revision of such labeling.

§ 201.105 Veterinary drugs.

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The drug is:

(1) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

(2) In the possession of a licensed veterinarian for use in the course of his professional practice.

(b) The label of the drug bears:

(1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and

(2) The recommended or usual dosage; and

(3) The route of administration, if it is not for oral use; and

(4) The quantity or proportion of each active ingredient as well as the information required by section 502(e) of the act; and

(5) If it is for other than oral use, the names of all inactive ingredients, except that:

(i) Flavorings and perfumes may be designated as such without naming their components.

(ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in Part 8 of this chapter.

(iii) Trace amounts of harmless substances added solely for individual product identification need not be named.

If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection, it need not be named.

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug:

Provided, however, That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraph (b)(2), (3), and (5) of this section may be contained in other labeling on or within the package from which it is to be so dispensed, and the information referred to in paragraph (b)(1) of this section may be placed on such outer container only, and the information required by paragraph (b)(6) of this section may be on the crimp of the dispensing tube.

(c)(1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and

(2) If the article is subject to section 512 of the act, the labeling bearing such information is the labeling authorized by the approved new animal drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of antibiotic drugs: *Provided, however,* That the information required by paragraph (c)(1) of this section may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to veterinarians licensed by law to administer the drug. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for the use of the drug (other than dose information required by paragraph (b)(2) of this section and § 201.100(b)(2)) contains:

(1) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant warnings, hazards, contraindications, side effects, and precautions, and including information relevant to compliance with the new animal drug provisions of the act, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to section 512 of the act, the parts of the labeling providing such information are the same in language and emphasis as labeling approved or permitted under the provisions of section 512, and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling; and

(2) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed;

Provided, however, That the information required by paragraph (d)(1) and (2) of this section is not required on the so-called reminder-piece labeling which calls attention to the name of the drug but does not include indications or dosage recommendations for use of the drug.

(e) All labeling, except labels and cartons, bearing information for use of the drug also bears the date of the issuance or the date of the latest revision of such labeling.

(f) A prescription drug intended for both human and veterinary use shall comply with paragraphs (e) and (f) of this section and § 201.100.

§ 201.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device (other than surgical instruments) bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

§ 201.110 Retail exemption for veterinary drugs and prescription devices.

A drug or device subject to §§ 201.105 or 201.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

§ 201.115 News drugs or new animal drugs.

A new drug shall be exempt from section 502(f)(1) of the act:

(a) To the extent to which such exemption is claimed in an approved application with respect to such drug under section 505 or 512 of the act; or

(b) If no application under section 505 of the act is approved with respect to such drug but it complies with section 505 (i) or 512 of the act and regulations thereunder.

No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended uses.

§ 201.116 Drugs and devices having commonly known directions.

A drug or device shall be exempt from section 502(f)(1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

§ 201.117 Inactive ingredients.

A harmless drug that is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, in the preparation of other drugs shall be exempt from section 502(f)(1) of the act. This exemption shall not apply to any substance intended for a use which results in the preparation of a new drug, unless an approved new-drug application provides for such use.

§ 201.119 In vitro diagnostic products.

A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product as defined in § 328.3(a) of this chapter shall be deemed to be in compliance with the requirements of this section and section 502(f)(1) of the act if it meets the requirements of Part 328 of this chapter.

§ 201.120 Prescription chemicals and other prescription components.

A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(b) The label of the drug bears:

(1) The statement "For prescription compounding"; and

(2) If in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1) of the act, the statement "Caution: Federal law prohibits dispensing without prescription"; or

(3) If it is not subject to section 503 (b) (1) of the act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, "adequate directions for use" in the conditions for which it is so sold.

Provided, however, That the information referred to in paragraph (b)(3) of this section may be contained in the labeling on or within the package from which it is to be dispensed.

(c) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an approved new-drug application covers such use of the drug in compounding prescriptions.

§ 201.122 Drugs and devices for processing, repacking, or manufacturing.

A drug in a bulk package (except tablets, capsules, or other dosage unit forms) or a device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; and, if in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1), the statement "Caution: Federal law prohibits dispensing without prescription". This exemption and the exemption under § 201.120 may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes

the finished article to be a new drug, unless:

(a) An approved new-drug application or new animal drug application held by the person preparing the dosage form or drug for dispensing covers the production and delivery to him of such substance; or

(b) If no application is approved with respect to such new drug or new animal drug, the label statement "Caution: For manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug or new animal drug limited by Federal law to investigational use", and the delivery is made for use only in the manufacture of such new drug or new animal drug limited to investigational use as provided in § 312.1 or § 511.1 of this chapter.

§ 201.125 Drugs and devices for use in teaching, law enforcement, research, and analysis.

A drug or device subject to §§ 201.100, 201.105, or 201.109 shall be exempt from section 502(f)(1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

§ 201.127 Drugs and devices; expiration of exemptions.

(a) If a shipment or delivery, or any part thereof, of a drug or device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(b) The exemptions conferred by §§ 201.117, 201.119, 201.120, 201.122, and 201.125 shall continue until the drugs or devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502 (f) (1) of the act. If, however, the drug is converted, compounded, or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dosage form is labeled as required by section 503(b) and §§ 201.100, 201.105, or 201.109.

§ 201.128 Meaning of "Intended uses".

The words "intended uses" or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

(Secs. 201(n), 502, 505, 507, 701, 52 Stat. 1041, 1050–53 as amended, 1055–56 as amended by 70 Stat. 919 and 72 Stat. 948, 59 Stat. 463 as amended; 21 U.S.C. 321(n), 352, 355, 357, 701)

Subpart E—Other Exemptions

§ 201.150 Drugs and devices; processing, labeling, or repacking.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502 (b), (d), (e), (f), and (g) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such drug or device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such subparagraph.

(d) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) Except as provided in paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the act and which is, in accordance with the practice of the trade, to be processed or repacked in a substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (f) of the act during the time such drug is also exempt from the requirements of section 502 (l) of the act or, in the case of a new animal drug, is exempt from certification under section 512(n) of the act under the provisions of § 433.15 or § 433.16 of this chapter.

(f) Except as provided by paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the act and which is, in accordance with the practice of the trade, to be labeled in substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (b), (e) and (f) of the act during the time such drug is also exempt from the requirements of section 502 (l) of the act or, in the case of a new animal drug, is exempt from certification under section 512(n) of the act under § 433.12 of this chapter, if the words, statements, and other information required by section 502 (b) and (e) of the act appear on each shipping container of such drug.

(g) In case the person who introduced such shipment or other delivery

into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of such shipment or delivery under paragraph (e) or (f) of this section shall become void at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(h) In case the person who introduced such shipment or delivery into interstate commerce is not the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of a shipment or other delivery of such drug under paragraph (e) or (f) of this section shall expire at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(i) As it is a common industry practice to manufacture and/or assemble, package, and fully label a device as sterile at one establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization, the Food and Drug Administration will initiate no regulatory action against the device as misbranded or adulterated when the nonsterile device is labeled sterile, provided all the following conditions are met:

(1) There is in effect a written agreement which:

(i) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization.

(ii) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to insure that the number of units shipped is the same as the number received and sterilized.

(iii) Acknowledges that the device is nonsterile and is being shipped for further processing, and

(iv) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance with the Federal Food, Drug, and Cosmetic Act.

(2) Each pallet, carton, or other designated unit is conspicuously marked to show its nonsterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine, e.g. "sterilized-awaiting test results" or an equivalent designation.

(Secs. 501(c), 502(a), 503, 701(a), 52 Stat. 1049, 1050, 1051, 1055; 21 U.S.C. 351(c), 352(a), 371(a))

§ 201.160 Drugs; information commonly known.

(a) Section 201.100(c) of this chapter provides that in the case of certain drugs for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law, such information may be omitted from the dispensing package. Under this proviso, the Commissioner of Food and Drugs will offer an opinion, upon written request, stating reasonable grounds therefor, on a proposal to omit such information from the dispensing package.

(b) The Commissioner of Food and Drugs has considered submitted material covering a number of drug products and has offered the opinion that the following drugs, when intended for those human uses for which they are now generally employed by the medical profession, should be exempt from the requirements of § 201.100(c) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

Aminophylline. For oral use, not in excess of 200 milligrams per dosage unit, with or without not in excess of 33 milligrams of phenobarbital.

Atropine methyl nitrate. For oral use, not in excess of 1.0 milligram per dosage unit.

Atropine sulfate. For oral use, not in excess of 0.54 milligram per dosage unit; for injection, not in excess of 0.54 milligram (1/120-grain) per dosage unit.

Barbiturates. For oral use, not in excess of 100 milligrams per dosage unit; for use as suppositories, not in excess of 130 milligrams per suppository.

Chloral hydrate. For oral use, not in excess of 500 milligrams per dosage unit; for use as suppositories, not in excess of 1.0 gram per suppository.

Codeine phosphate. For oral use, not in excess of 65 milligrams per dosage unit; for injection, not in excess of 65 milligrams per dosage unit.

Codeine sulfate. For oral use, not in excess of 65 milligrams per dosage unit; for injection, not in excess of 65 milligrams per dosage unit.

Digitalis. Preparations of whole leaf digitalis including forms such as digitalis tincture. For oral use, containing the equivalent of not more than 1 U.S.P. digitalis unit per dosage unit.

Dihydrocodeinone bitartrate. For oral use, not in excess of 10 milligrams per dosage unit.

Dihydromorphinone hydrochloride. For oral use, not in excess of 4 milligrams per dosage unit.

Epinephrine injection, 1: 1,000.

Erythrityl tetranitrate. For oral use, not in excess of 30 milligrams per dosage unit.

Homatropine methylbromide. For oral use, not in excess of 5 milligrams per dosage unit.

Hyoscyamine hydrobromide. For oral use, not in excess of 1 milligram per dosage unit.

Hyoscyamine sulfate. For oral use, not in excess of 1 milligram per dosage unit.

Hyoscyamus tincture. For oral use, not in excess of 2 milliliters per dosage unit.

Mannitol hexanitrate. For oral use, not in excess of 32 milligrams per dosage unit.

Methenamine. For oral use, not in excess of 1 gram per dosage unit.

Morphine phosphate. For oral use, not in excess of 33 milligrams per dosage unit; for injection, not in excess of 33 milligrams per dosage unit.

Morphine sulfate. For oral use, not in excess of 33 milligrams per dosage unit; for injection, not in excess of 33 milligrams per dosage unit.

Nitroglycerin. For oral use, not in excess of 0.65 milligram per dosage unit.

Pentaerythritol tetranitrate. For oral use, not in excess of 20 milligrams per dosage unit.

Pentaerythritol tetranitrate with phenobarbital. For oral use, not in excess of 20 milligrams of pentaerythritol tetranitrate and 35 milligrams of phenobarbital.

Quinidine sulfate. For oral use, not in excess of 325 milligrams per dosage unit.

Scopolamine methylbromide. For oral use, not in excess of 2.5 milligrams per dosage unit.

Sodium chloride injection.

Sodium nitrite. For oral use, not in excess of 60 milligrams per dosage unit.

Theobromine. For oral use, not in excess of 325 milligrams per dosage unit.

Thyroid. For oral use, not in excess of 220 milligrams per dosage unit.

Water for injection, sterile.

§ 201.161 Carbon dioxide and certain other gases.

(a) Carbon dioxide, cyclopropane, ethylene, helium, and nitrous oxide gases intended for drug use are exempted from the requirements of § 201.100(b)(2), (3), and (c)(1) provided the labeling bears, in addition to any other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The warning statement "Warning—Administration of (name of gas) may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of (name of gas) and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications, and side effects and the precautions to be taken"; and

(2) Any needed directions concerning the conditions for storage and warnings against the inherent dangers in the handling of the specific compressed gas.

(b) This labeling exemption does not apply to mixtures of any one or more of these gases with oxygen or with each other.

(c) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the Act contrary to the provisions of this section after 60 days following publication of this section in the FEDERAL REGISTER.

(Sec. 502(f), 52 Stat. 1051; 21 U.S.C. 352(f))

Subpart F—Labeling Claims for Drugs in Drug Efficacy Study

§ 201.200 Disclosure of drug efficacy study evaluations in labeling and advertising.

(a) (1) The National Academy of Sciences-National Research Council, Drug Efficacy Study Group, has completed an exhaustive review of labeling claims made for drugs marketed under new-drug and antibiotic drug procedures between 1938 and 1962. The results are compiled in "Drug Efficacy Study, A Report to the Commissioner of Food and Drugs from the National Academy of Sciences (1969)." As the report notes, this review has made "an audit of the state of the art of drug usage that has been uniquely extensive in scope and uniquely intensive in time" and is applicable to more than 80 percent of the currently marketed drugs. The report further notes that the quality of the evidence of efficacy, as well as the quality of the labeling claims, is poor. Labeling and other promotional claims have been evaluated as "effective," "probably effective," "possibly effective," "ineffective," "ineffective as a fixed combination," and "effective but," and a report for each drug in the study has been submitted to the Commissioner.

(2) The Food and Drug Administration is processing the reports, seeking voluntary action on the part of the drug manufacturers and distributors in the elimination or modification of unsupported promotional claims, and initiating administrative actions as necessary to require product and labeling changes.

(3) Delays have been encountered in bringing to the attention of the prescribers of prescription items the conclusions of the expert panels that reviewed the promotional claims.

(b) The Commissioner of Food and Drugs concludes that:

(1) The failure to disclose in the labeling of a drug and in other promotional material the conclusions of the Academy experts that a claim is "ineffective," "possibly effective," "probably effective," or "ineffective as a fixed combination," while labeling and promotional material bearing any such claim are being used, is a failure to disclose facts that are material in light of the representations made and causes the drug to be misbranded.

(2) The Academy classification of a drug as other than "effective" for a claim for which such drug is recommended establishes that there is a material weight of opinion among qualified experts contrary to the representation made or suggested in the labeling, and failure to reveal this fact causes such labeling to be misleading.

(c) Therefore, after publication in the FEDERAL REGISTER of a Drug Efficacy Study Implementation notice on a prescription drug, unless exempted or otherwise provided for in the notice, all package labeling (other than the immediate container or carton label, unless such labeling contains information required by § 201.100(c)(1) in lieu of a package insert), promotional labeling, and advertisements shall include, as part of the information for practitioners under which the drug can be safely and effectively used, an appropriate qualification of all claims evaluated as other than "effective" by a panel of the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, if such claims continue to be included in either the labeling or advertisements. However, this qualifying information will be required in advertisements only if promotional material is included therein for claims evaluated as less than "effective" or if such claims are included in the indications section of the portion of the advertisement containing the information required in brief summary by § 202.1(e)(1) of this chapter. When, however, the Food and Drug Administration classification of such claim is "effective" (for example, on the basis of revision of the language of the claim or submission or existence of adequate data), such qualification is not necessary. When the Food and Drug Administration classification of the claim, as stated in the implementation notice, differs from that of the Academy but is other than "effective," the qualifying statement shall refer to this classification in lieu of the Academy's classification.

(d) For new drugs and antibiotics, supplements to provide for revised labeling in accord with paragraph (c) of this section shall be submitted under the provisions of § 314.8 (d) and (e) and § 514.50 of this chapter within 90 days after publication of the implementation notice in the FEDERAL REGISTER or by May 15, 1972, for those drugs for which notices have been published and such labeling shall be put into use as soon as possible but not later than the end of the time period allowed for submitting supplements to provide for revised labeling.

(e) Qualifying information required in drug labeling by paragraph (c) of this section in order to advise prescribers of a drug of the findings made by a panel of the Academy in evaluating a claim as other than "effective" shall be at least of the same size and color and degree of prominence as other printing in the labeling and shall be presented in a prominent box using one of the following formats and procedures:

(1) In drug labeling the box statement may entirely replace the indications section and be in the following format:

> INDICATIONS
>
> Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indication(s) as follows:
>
> Effective: (list or state in paragraph form).
>
> "Probably" effective: (list or state in paragraph form).
>
> "Possibly" effective: (list or state in paragraph form).
>
> Final classification of the less-than-effective indications requires further investigation.

(2) Or the indication(s) for which the drug has been found effective may appear outside the boxed statement and be followed immediately by the following boxed statement:

> Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the other indication(s) as follows:
>
> "Probably" effective: (list or state in paragraph form).
>
> "Possibly" effective: (list or state in paragraph form).
>
> Final classification of the less-than-effective indications requires further investigation.

(3) In drug labeling (other than that which is required by § 201.100(c)(1) which may contain a promotional message, the promotional message shall be keyed to the boxed statement by the same means as those provided for advertisements in paragraph (f)(2) of this section.

(f) Qualifying information required in prescription drug advertising by paragraph (c) of this section shall contain a prominent boxed statement of the advertised indication(s) and of the limitations of effectiveness using the same format, language, and emphasis as that required in labeling by paragraph (e) of this section.

(1) The boxed statement shall appear in (or next to) the information required in brief summary by § 202.1(e)(1) of this chapter and shall have prominence at least equal to that provided for other information presented in the brief summary and shall have type size, captions, color, and other physical characteristics comparable to the information required in the brief summary.

(2) Less-than-effective indication(s) in the promotional message of an advertisement which is a single page or less shall be keyed to the boxed statement by asterisk, by an appropriate statement, or by other suitable means providing adequate emphasis on the boxed statement. On each page where less-than-effective indication(s) appear in a mutiple page advertisement, an asterisk shall be placed after the most prominent mention of the indication(s); if the degree of prominence does not vary, an asterisk shall be

placed after the first mention of the indication. The asterisk shall refer to a notation at the bottom of the page which shall state "This drug has been evaluated as probably effective (or possibly effective whichever is appropriate) for this indication" and "See Brief Summary" or "See Prescribing Information," the latter legend to be used only if the advertisement carries the required information for professional use as set forth in § 201.100 (c) (1).

(3) For less-than-effective indications which are included in the advertisement only as a part of the information required in brief summary, the disclosure information shall appear in this portion of the advertisement in the same manner as is specified for labeling in paragraph (e) of this section.

(g) The Commissioner may find circumstances are such that, while the elimination of claims evaluated as other than effective will generally eliminate the need for disclosure about such claims, there will be instances in which the change in the prescribing or promotional profile of the drug is so substantial as to require a disclosure of the reason for the change so that the purchaser or prescriber is not misled by being left unaware through the sponsor's silence that a basic change has taken place. The Food and Drug Administration will identify these situations in direct correspondence with the drug promoters, after which the failure to make the disclosure will be regarded as misleading and appropriate action will be taken.

(Secs. 201(n), 502, 505, 507, 52 Stat. 1041, 1050–53 as amended, 1056, as amended by 70 Stat. 919 and 72 Stat. 948, 59 Stat. 463 as amended; 21 U.S.C. 321(n), 352, 355, 357, 701)

Subpart G—Specific Labeling Requirements for Specific Drug Products

§ 201.300 Notice to manufacturers, packers, and distributors of glandular preparations.

(a) Under date of December 4, 1941, in a notice to manufacturers of glandular preparations, the Food and Drug Administration expressed the opinion that preparations of inert glandular materials intended for medicinal use should, in view of the requirement of section 201(n) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1041; 21 U.S.C. 321(n)), be labeled with a statement of the material fact that there is no scientific evidence that the articles contain any therapeutic or physiologically active constituents. Numerous preparations of such inert glandular materials were subsequently marketed with disclaimers of the type suggested. The term "inert glandular materials" means preparations incapable of exerting an action or effect of some significant or measurable benefit in one way or another, i.e., in the diagnosis, cure, mitigation, treatment, or prevention of disease, or in affecting the structure or any function of the body.

(b) Manufacturers have heretofore taken advantage of § 201.100 permitting omission of directions for use when the label bears the prescription legend. Section 201.100(c) requires that the labeling of the drug, which may include brochures readily available to licensed practitioners, bear information as to the use of the drug by practitioners licensed by law to administer it. Obviously, information adequate for the use of an inert glandular preparation is not available to practitioners licensed by law.

(c) The Department of Health, Education, and Welfare is of the opinion that inert glandular materials may not be exempted from the requirements of section 502 (f) (1) of the act that they bear adequate directions for use; and, accordingly, that their labeling must include among other things, representations as to the conditions for which such articles are intended to be used or as to the structure or function of the human body that they are intended to affect. Since any such representations offering these articles for use as drugs would be false or misleading, such articles will be considered to be misbranded if they are distributed for use as drugs.

(d) The amended regulations provide also that in the case of drugs intended for parenteral administration there shall be no exemption from the requirement that their labelings bear adequate directions for use. Such inert glandular materials for parenteral use are therefore subject to the same comment as applies to those intended for oral administration.

§ 201.301 Notice to manufacturers, packers, and distributors of estrogenic hormone preparations.

Some drug preparations fabricated wholly or in part from estradiol and labeled as to potency in terms of international units or in terms of international units of estrone activity have been marketed. The international unit of the estrus-producing hormone was established by the International Conference on the Standardization of Sex Hormones at London, England, on August 1, 1932. This unit was defined as "the specific estrus-producing activity contained in 0.1 gamma (=0.0001 mg.) of the standard" hydroxyketonic hormone found in urine (estrone). The International Conference declared that it did not recommend the determination of the activity of nonhydroxyketonic forms of estrogenic hormones in units of estrone because of the varying ratios between the activity of such nonhydroxyketonic estrogenic hormones and estrone, when measured by different methods on test animals. There is no international unit for measuring the activity of estradiol and no accepted relationship between its activity and that of estrone, either in test animals or in humans. The declaration of potency of estradiol in terms of international units or in terms of international units of estrone activity is therefore considered misleading, within the meaning of 21 U.S.C. 352(a). The declaration of the estradiol content of an estrogenic hormone preparation in terms of weight is considered appropriate.

§ 201.302 Notice to manufacturers, packers, and distributors of drugs for internal use which contain mineral oil.

(a) In the past few years research studies have altered medical opinion as to the usefulness and harmfulness of mineral oil in the human body. These studies have indicated that when mineral oil is used orally near mealtime it interferes with absorption from the digestive tract of provitamin A and the fat-soluble vitamins A, D, and K, and consequently interferes with the utilization of calcium and phosphorus, with the result that the user is left liable to deficiency diseases. When so used in pregnancy it predisposes to hemorrhagic disease of the newborn.

(b) There is accumulated evidence that the indiscriminate administration of mineral oil to infants may be followed by aspiration of the mineral oil and subsequent "lipoid pneumonia."

(c) In view of these facts, the Department of Health, Education, and Welfare will regard as misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act a drug for oral administration consisting in whole or in part of mineral oil, the labeling of which encourages its use in pregnancy or indicates or implies that such drug is for administration to infants.

(d) It is also this Department's view that the act requires the labelings of such drugs to bear a warning against consumption other than at bedtime and against administration to infants. The following form of warning is suggested: "Caution: To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician."

(e) This statement of interpretation does not in any way exempt mineral oil or preparations containing mineral oil from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

§ 201.303 Labeling of drug preparations containing significant proportions of wintergreen oil.

(a) Because methyl salicylate (wintergreen oil) manifests no toxicity in the minute amounts in which it is used as a flavoring, it is mistakenly regarded by the public as harmless even when taken in substantially larger amounts. Actually, it is quite toxic when taken in quantities of a teaspoonful or more. Wintergreen oil and preparations containing it have caused a number of deaths through accidental misuse by both adults and children. Children are particularly attracted by the odor and are likely to swallow these products when left within reach.

(b) To safeguard against fatalities from this cause, the Department of Health, Education, and Welfare will regard as misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act any drug containing more than 5 percent methyl salicylate (wintergreen

oil), the labeling of which fails to warn that use otherwise than as directed therein may be dangerous and that the article should be kept out of reach of children to prevent accidential poisoning.

(c) This statement of interpretation in no way exempts methyl salicylate (wintergreen oil) or its preparations from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

(Sec. 502, 52 Stat. 1050, as amended; 21 U.S.C. 352)

§ 201.304 Tannic acid and barium enema preparations.

(a) It has become a widespread practice for tannic acid to be added to barium enemas to improve X-ray pictures. Tannic acid is capable of causing diminished liver function and severe liver necrosis when absorbed in sufficient amounts. The medical literature reports a number of deaths associated with the addition of tannic acid to barium enemas. There is a lack of scientific evidence to establish the conditions, if any, under which tannic acid is safe and effective for use in enemas. Tannic acid for rectal use to enhance X-ray visualization is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(b) In view of the hazards involved when tannic acid is used in barium enemas, any shipments of tannic acid labeled to come within the exemptions under 502(f) of the Act containing such phrases as: "Caution: For manufacturing, processing, or repackaging," "For prescription compounding," or "Diagnostic reagent—For professional use only" will be regarded by the Commissioner of Food and Drugs as misbranded within the meaning of section 502(f) of the Federal Food, Drug, and Cosmetic Act unless the label and the labeling bear conspicuously a warning to the effect: "Warning—Not for use in enemas."

(c) Any tannic acid intended for use by man and found within the jurisdiction of the Federal Food, Drug, and Cosmetic Act labeled contrary to this section after 60 days from the date of its publication in the FEDERAL REGISTER may be made the subject of regulatory proceedings.

(Sec. 502, 52 Stat. 1050, as amended; 21 U.S.C. 352)

§ 201.305 Isoproterenol inhalation preparations (pressurized aerosols, nebulizers, powders) for human use; warnings.

(a) Accumulating reports have been received by the Food and Drug Administration and have appeared in the medical literature of severe paradoxical bronchoconstriction associated with repeated, excessive use of isoproterenol inhalation preparations in the treatment of bronchial asthma and other chronic bronchopulmonary disorders. The cause of this paradoxical reaction is unknown; it has been observed, however, that patients have not responded completely to other forms of therapy until use of the isoproterenol inhalation preparation was discontinued. In addition, sudden unexpected deaths have been associated with the excessive use of isoproterenol inhalation preparations. The mechanism of these deaths and their relationship, if any, to the cases of severe paradoxical bronchospasm are not clear. Cardiac arrest was noted in several of these cases of sudden death.

(b) On the basis of the above information and after discussion with and concurrence of the Respiratory and Anesthetic Drugs Advisory Committee for Food and Drug Administration, the Commissioner of Food and Drugs concludes that in order for the labeling of such drugs to bear adequate information for their safe use, as required by § 201.100, such labeling must include the following:

Warning: Occasional patients have been reported to develop severe paradoxical airway resistance with repeated, excessive use of isoproterenol inhalation preparations. The cause of this refractory state is unknown. It is advisable that in such instances the use of this preparation be discontinued immediately and alternative therapy instituted, since in the reported cases the patients did not respond to other forms of therapy until the drug was withdrawn.

Deaths have been reported following excessive use of isoproterenol inhalation preparations and the exact cause is unknown. Cardiac arrest was noted in several instances.

(c) (1) The Commissioner also concludes that in view of the manner in which these preparations are self-administered for relief of attacks of bronchial asthma and other chronic bronchopulmonary disorders, it is necessary for the protection of users that warning information to patients be included as a part of the label and as part of any instructions to patients included in the package dispensed to the patient as follows:

Warning: Do not exceed the dose prescribed by your physician. If difficulty in breathing persists, contact your physician immediately.

(2) The warning on the label may be accomplished (i) by including it on the immediate container label with a statement directed to pharmacists not to remove the label or (ii) by including in the package a printed warning with instructions to pharmacists to place the warning on the container prior to dispensing.

(d) The marketing of isoproterenol inhalation preparations may be continued if all the following conditions are met:

(1) Within 30 days following the date of publication of this section in the FEDERAL REGISTER:

(i) The label and labeling of such preparations shipped within the jurisdiction of the act are in accordance with paragraphs (b) and (c) of this section.

(ii) The holder of an approved new-drug application for such preparation submits a supplement to his new-drug application to provide for appropriate labeling changes as described in paragraphs (b) and (c) of this section.

(2) Within 90 days following the date of publication of this section in the FEDERAL REGISTER, the manufacturer, packer, or distributor of any drug containing isoproterenol intended for inhalation for which a new-drug approval is not in effect submits a new-drug application containing satisfactory information of the kinds required by items 4, 5, 6, 7, 8, and 9 of the new-drug application form (form FD-356H set forth in § 314.1(c)(2) of this chapter), including appropriate labeling as described in paragraphs (b) and (c) of this section.

(3) The applicant submits additional information required for the approval of the application as may be specified in a written communication from the Food and Drug Administration.

(e) After 270 days following expiration of said 90 days, regulatory proceedings based on section 505(a) of the Federal Food, Drug, and Cosmetic Act may be initiated with regard to any such drug shipped within the jurisdiction of the act for which an approved new-drug application is not in effect.

(Secs. 502 (f), (j), 505, 52 Stat. 1051-53, as amended; 21 U.S.C. 352 (f), (j), 355)

§ 201.306 Potassium salt preparations intended for oral ingestion by man.

(a) The Food and Drug Administration will initiate no regulatory action with respect to the continued marketing of coated tablets containing potassium chloride or other potassium salts which supply 100 milligrams or more of potassium per tablet provided all the following conditions are met:

(1) Within 30 days from the date of publication of this statement of policy in the FEDERAL REGISTER:

(i) The labeling of the drug bears the prescription caution statement quoted in section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act;

(ii) The labeling on or within the package from which the drug is to be dispensed bears adequate information for its use by practitioners in accord with the "full disclosure" labeling requirements of § 201.100 of this chapter, including the following warning statement: "Warning—There have been several reports, published and unpublished, concerning nonspecific small-bowel lesions consisting of stenosis, with or without ulceration, associated with the administration of enteric-coated thiazides with potassium salts. These lesions may occur with enteric-coated potassium tablets alone or when they are used with nonenteric-coated thiazides, or certain other oral diuretics. These small-bowel lesions have caused obstruction, hemorrhage, and perforation. Surgery was frequently required and deaths have occurred. Based on a large survey of physicians and hospitals, both United States and foreign, the incidence of these lesions is low, and a causal relationship in man has not been definitely established. Available information tends to implicate enteric-coated potassium salts, although lesions of this type also occur spontaneously. Therefore, coated potassium-containing formulations should be administered only when indicated, and should be discontinued immediately if abdominal pain, distention, nausea, vomiting, or gastrointestinal bleeding occur. Coated potassium tablets should be used only when adequate dietary supplementation is not practicable."

(Although the warning statement includes references to enteric-coated potassium salt preparations, it applies to any capsule or coated tablet of a potassium salt intended for oral ingestion without prior dilution with an adequate volume of liquid to preclude gastrointestinal injury.)

(iii) Any other labeling or additional advertising for the drug conforms to the labeling described in paragraph (a)(1)(ii) of this section, in accordance with §§ 202.1 and 201.100 of this chapter.

(2) Within 90 days from the date of publication of this statement of policy in the FEDERAL REGISTER, the manufacturer, packer, or distributor of the drug shall submit a new-drug application containing satisfactory information of the kind required by Items 2, 3, 4, 6, 7, and 9 of the new-drug application form contained in § 314.1(c) of this chapter, with appropriate labeling as described in this paragraph.

(b) The Food and Drug Administration may initiate regulatory proceedings after 30 days from the date of publication of this section, with respect to the marketing of uncoated tablets containing potassium chloride or other potassium salts which supply 100 milligrams or more of potassium per tablet or with respect to liquid preparations containing potassium chloride or other potassium salts which supply 20 milligrams or more of potassium per milliliter, labeled or intended for human use, unless all the following conditions are met:

(1) The labeling of the drug bears the prescription caution statement quoted in section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act; and

(2) The labeling on or within the package from which the drug is to be dispensed bears adequate information for its use by practitioners in accord with the "full disclosure" labeling requirements of § 201.100 of this chapter, including a recommendation that patients be directed to disslove any such tablets in an appropriate amount of liquid and to dilute any such liquid preparations adequately to assure against gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations.

(Secs. 502(f), 503(b)(4), 505; 52 Stat. 1051, 1052; 21 U.S.C. 352(f), 353(b), 355)

§ 201.307 Chlorcyclizine, cyclizine, meclizine; warnings; labeling requirements.

(a) The Food and Drug Administration, pursuant to its responsibility for the safety and effectiveness of drugs, has conducted active investigations of reports of available animal data which reveal that chlorcyclizine hydrochloride, cyclizine hydrochloride and lactate, and meclizine hydrochloride exert a teratogenic response in animals such as the rat, mouse, rabbit, pig, and dog. While clinical studies to date are inconclusive, scientific experts are of the opinion that these drugs may possess a potential for adverse effects on the human fetus. Investigations have led to the conclusion that there exists sufficient evidence of teratogenicity in animals administered these drugs to justify warnings against their use in pregnancy except on advice of a physician. An Ad Hoc Advisory Committee on the Teratogenic Effect of Certain Drugs, comprised of scientists in various branches of medicine concerned with the problem, has submitted its findings and conclusions to the Commissioner of Food and Drugs and has recommended that all over-the-counter preparations containing chlorcyclizine, cyclizine, or meclizine or their salts bear a warning.

(b) On the basis of studies made by the Food and Drug Administration and on the recommendations of the Advisory Committee, the Commissioner of Food and Drugs has concluded that it is necessary for the protection of users that the label and labeling of all over-the-counter preparations containing chlorcyclizine, cyclizine, or meclizine or their salts bear a statement to the following effect: *"Warning*—Not for use by women who are pregnant or who may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child."

(c) The marketing of oral and parenteral drugs containing chlorcyclizine, cyclizine, or meclizine or their salts may be continued provided that all the following conditions are met:

(1) Within 30 days from the date of publication of this statement in the FEDERAL REGISTER.

(i) The label and applicable labeling of drugs containing chlorcyclizine, cyclizine, or meclizine or their salts at acceptable levels for over-the-counter distribution, shall prominently and conspicuously display the statement: *"Warning*—Not for use by women who are pregnant or who may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child."

(ii) The package labeling and other labeling providing professional use information concerning prescription drugs containing chlorcyclizine, cyclizine, or meclizine or their salts and not contraindicated for use in pregnancy because of some other ingredient, shall bear, in accordance with § 201.100* of this chapter, a section under "Adverse Reactions" headed "Use in Pregnancy," as follows:

The following information should be taken into account in determining whether the potential benefits of [chlorcyclizine, cyclizine, meclizine, or their salts] outweigh the risks of their use in women of childbearing age and particularly during pregnancy. A review of available animal data reveals that this drug exerts a teratogenic response in the [rat, mouse, rabbit, pig, dog]. While available clinical data are inconclusive, scientific experts are of the opinion that this drug may possess a potential for adverse effects on the human fetus. Consequently, consideration should be given to initial use of a nonphenothiazine agent that is not suspected of having a teratogenic potential. In any case, the dosage and duration of treatment should be kept to a minimum.

This statement shall be followed with an appropriate summary of the pertinent animal studies and adverse clinical experiences, with adequate references to the scientific literature. Also, the labeling shall contain, in juxtaposition with any representation for use in the treatment of nausea and vomiting in pregnancy, the following statement:

The effectiveness of ------ for the prevention and treatment of nausea and vomiting of pregnancy has not been established, and the decision to use ------ should be based on the seriousness of the situation, remembering that while this drug has been used clinically for a decade, there are yet no controlled studies to demonstrate its usefulness in an objective fashion. In most cases, nausea and vomiting of pregnancy may be unpleasant but do not present a serious threat to the health of the patient or to the progress of her pregnancy. In view of the desirability of keeping the administration of all drugs to a minimum during pregnancy, management by physiologic means such as proper nutrition and by psychologic support is preferable to antiemetic therapy.

(2) Within 30 days from the date of publication of this statement of policy in the FEDERAL REGISTER, the applicant under an approved new-drug application for a drug containing chlorcyclizine, cyclizine, or meclizine or their salts shall submit a supplement to his new-drug application, providing for appropriate labeling changes as described in paragraph (c)(1)(i) or (ii) of this section.

(3) Within 90 days from the date of publication of this statement of policy in the FEDERAL REGISTER, the manufacturer, packer, or distributor of any drug containing chlorcyclizine, cyclizine, or meclizine or their salts for which a new-drug approval is not in effect shall submit a new-drug application containing satisfactory information of the kinds required in the new-drug application form contained in § 314.1(c) of this chapter, including appropriate labeling as described in paragraph (c)(1)(i) or (ii) of this section.

(d) In view of the fact that no substantial evidence has been offered for the effectiveness of chlorcyclizine, cyclizine, and meclizine or their salts in the prevention and treatment of nausea and vomiting of pregnancy, but mindful of the fact that some practicing physicians believe that these drugs exert a beneficial effect upon this condition, the Food and Drug Administration will permit a modified claim in indications for this use for a period not exceeding 2 years. However, this modified indication for use of these drugs in the prevention and treatment of nausea and vomiting of pregnancy will be deleted from the labeling unless substantial evidence is offered before the expiration of this period of time. The Food and Drug Administration will also continue to follow the large-scale surveys of clinical experience and any reports of adverse reaction that may be due to the use of these drugs under the revised labeling.

*Section 202.1 will require that prescription drug advertising contain this warning.

§ 201.308 Ipecac syrup; warnings and directions for use for over-the-counter sale.

(a) It is estimated that each year about 500,000 accidental poisonings occur in the United States and result in approximately 1,500 deaths, of which over 400 are children. In the emergency treatment of these poisonings, ipecac syrup is considered the emetic of choice. The immediate availability of this drug for use in such situations is critical, since rapid treatment may be the difference between life and death. The restriction of this drug to prescription sale limits its availability in emergencies. On the other hand, it is the consensus of informed medical opinion that ipecac syrup should be used only under medical supervision in the emergency treatment of poisonings. In view of these facts, the question of whether ipecac syrup labeled as an emergency treatment for use in poisonings should be available over the counter has been controversial.

(b) In connection with its study of this problem, the Food and Drug Administration has obtained the views of medical authorities. It is the unanimous recommendation of the American Academy of Pediatrics, the American Association of Poison Control Centers, the American Medical Association, and the Medical Advisory Board of the Food and Drug Administration that ipecac syrup in 1 fluid ounce containers be permitted to be sold without prescription so that it will be readily available in the household for emergency treatment of poisonings, under medical supervision, and that the drug be appropriately packaged and labeled for this purpose.

(c) In view of the above recommendations, the Commissioner of Food and Drugs has determined that it is in the interest of the public health for ipecac syrup to be available for sale without prescription, provided that it is packaged in a quantity of 1 fluid ounce (30 milliliters), and its label bears, in addition to other required label information, the following, in a prominent and conspicuous manner:

(1) A statement conspicuously boxed and in red letters, to the effect: "For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice."

(2) A warning to the effect: "Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested."

(3) Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age.

§ 201.309 Acetophenetidin (phenacetin)-containing preparations; necessary warning statement.

(a) In 1961, the Food and Drug Administration, pursuant to its statutory responsibility for the safety and effectiveness of drugs shipped in interstate commerce, began an active investigation of reports of possible toxic effects and renal damage due to misuse of the drug acetophenetidin. This study led to the decision that there was probable cause to conclude that misuse and prolonged use of the drug were in fact responsible for kidney lesions and disease. The Commissioner of Food and Drugs, in December 1963, appointed an ad hoc Advisory Committee of Inquiry on Possible Nephrotoxicity Associated With the Abuse of Acetophenetidin (Phenacetin)-Containing Preparations. This committee, composed of scientists in the fields of pharmacology and medicine, on April 23, 1964, submitted its findings and conclusions in the matter and recommended that all acetophenetidin (phenacetin)-containing preparations bear a warning as provided in section 502(f)(2) of the Federal Food, Drug, and Cosmetic Act.

(b) On the basis of the studies made by the Food and Drug Administration and the report of the Advisory Committee, the Commissioner of Food and Drugs has concluded that it is necessary for the protection of users that the label and labeling of all acetophenetidin (phenacetin)-containing preparations bear a warning statement to the following effect: "Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician."

§ 201.310 Phenindione; labeling of drug preparations intended for use by man.

(a) Reports in the medical literature and data accumulated by the Food and Drug Administration indicate that phenindione, a synthetic anticoagulant drug, has caused a number of cases of agranulocytosis (with two fatalities). There are also reports implicating the drug in cases of hepatitis and hypersensitivity reactions. In view of the potentially serious effects found to be associated with preparations of this drug intended for use by man, the Commissioner of Food and Drugs will regard such preparations as misbranded within the meaning of section 502(f)(1) and (2) of the Federal Food, Drug, and Cosmetic Act, unless the label and labeling on or within the package from which the drug is to be dispensed, and any other labeling furnishing or purporting to furnish information for use of the drug, bear a conspicuous warning statement to the following effect: "Warning: Agranulocytosis and hepatitis have been associated with the use of phenindione. Patients should be instructed to report promptly prodromal symptoms such as marked fatigue, chill, fever, and sore throat. Periodic blood studies and liver function tests should be performed. Use of the drug should be discontinued if leukopenia occurs or if evidence of hypersensitivity, such as dermatitis or fever, appears."

(b) Regulatory action may be initiated with respect to preparations of phenindione intended for use by man found within the jurisdiction of the act on or after November 25, 1961, unless such preparations are labeled in accordance with paragraph (a) of this section.

(Secs. 502(f), 52 Stat. 1051, 21 U.S.C. 352(f))

§ 201.311 Aminopyrine or dipyrone drug preparations for human use; directions and warnings.

(a) Because of the increasing number of reports of fatal agranulocytosis associated with the use of aminopyrine (4-dimethylamino-2,3-dimethyl-1-phenyl-3-pyrazolin-5-one) and dipyrone (1-phenyl-2,3-dimethyl-5-pyrazolone-4-methylaminomethanesulfonate sodium), the Commissioner of Food and Drugs convened an ad hoc Committee on Aminopyrine and Dipyrone. The members of the committee consisted of authorities in the fields of hematology, internal medicine, neurology, pediatrics, and pharmacology. This committee considered the questions of safety and effectiveness of aminopyrine and dipyrone and reported its findings and recommendations to the Commissioner of Food and Drugs. Copies of the committee's report and recommendations are available upon request, directed to the office of the Assistant Commissioner for Public Affairs, 5600 Fishers Lane, Rockville, MD 20852. The committee found:

(1) Aminopyrine and dipyrone, a derivative of aminopyrine, are capable of causing and have caused fatal agranulocytosis.

(2) Relatively small amounts of these drugs given intermittently over a period of time, as well as regular and continued administration, can precipitate the reaction of agranulocytosis.

(3) In most instances, other antipyretics and analgesics that are much safer should be used in preference to aminopyrine or dipyrone.

(4) The only conditions in which aminopyrine or dipyrone are known to be possibly indicated are febrile convulsions in children, where a parenteral antipyretic may be needed, and in rare instances of Hodgkin's disease and similar malignant diseases in which the fever cannot be controlled by any other means.

(b) The committee summarized its recommendations as follows:

1. It is recommended that aminopyrine and dipyrone for the present be retained on the market, but that the following statements be included in the labeling of the drugs:

All brochures, mailing pieces, detail pieces, advertising, and other labeling should contain the following paragraphs, in this order:

Warning—THIS DRUG MAY CAUSE FATAL AGRANULOCYTOSIS. (This should immediately follow the name of the drug.)

Caution—This drug should be used only in those conditions in which it is specifically indicated and in which other less toxic drugs have proved ineffective or are not tolerated. The potential benefit accruing from the use of this drug must be weighed against the possibility of fatal agranulocytosis.

Indications for use. Aminopyrine and aminopyrine derivates (dipyrone preparations) should be restricted for use in serious or life-threatening situations where salicylates or similar drugs are known to be ineffective or are contraindicated or not tolerated.

Duration of administration. Fatal agranulocytosis has been reported after short-term use, intermittent use, and after long-term administration. Therefore, the use of these agents should be as brief as possible.

Precautions. Frequent white blood cell and differential counts should be carried out. However, it is emphasized that agranulocytosis may occur precipitously without prior warning. The drug should be discontinued at the first evidence of any alteration of the blood count or sign of agranulocytosis, and the patient should be instructed to discontinue use of the drug at the first indication of sore throat or sign of other infection in the mouth or throat (pain, swelling, tenderness, ulceration).

Dosage. Adults: The usual antipyretic dose should not exceed ½ to 1 gram per dose, nor should more than 3 grams total daily dosage be used. If the desired effect is not achieved within a very few days, use of the drug should be discontinued.

Children: 250 to 500 milligrams per dose, repeated in 3 to 4 hours if necessary. Use of the drug should be as brief as possible.

2. It is recommended that every effort be made through educational media to emphasize the identical nature of aminopyrine and dipyrone insofar as toxicity is concerned.

3. It is further recommended that the official name of dipyrone be changed to aminopyrinesulfonate sodium, if possible. The purpose of this is to achieve the objective of Item 2 above.

4. The committee suggests that the panel be recalled by the Commissioner of the Food and Drug Administration within approximately one year after these recommendations have been fully implemented. The purpose of such a meeting would be to ascertain whether the use of dipyrone and aminopyrine and the cases of fatal agranulocytosis associated with the use of these drugs had been noticeably reduced by the method proposed. If the recommended labeling changes do not have the desired effect, other recommendations would need to be considered at that time.

(c) The committee also decided that a letter should be sent to all physicians to remind them of the close similarity and toxicity of aminopyrine and dipyrone.

(d) On the basis of the available evidence, including the findings and recommendations of the committee, the Commissioner of Food and Drugs finds and determines with respect to any drug preparation intended for administration to man that contains aminopyrine or dipyrone:

(1) Such drugs are unsafe and are regarded as misbranded within the meaning of section 502(f) (1) and (2) and (j) of the Federal Food, Drug, and Cosmetic Act when labeled or advertised for routine use as antipyretics or analgesics.

(2) Regulatory proceedings may be initiated with regard to the continued marketing of any such preparations with labeling or advertising offering such drugs for routine use as antipyretics or analgesics.

(3) Such preparations may be approved as safe and effective for marketing on the basis of new-drug applications containing labeling to the following effect, which labeling differs substantially from the labeling that has been commonly employed for many years in the marketing of such drugs:

(i) The label and labeling of the drug contains prominently and conspicuously, immediately following the trade name of the drug, without any intervening written, printed or graphic matter, the following:

(*a*) A quantitative declaration of the aminopyrine content; or

(*b*) A quantitative declaration of the dipyrone content with the name "dipyrone" followed immediately and conspicuously in parentheses by the declaration "aminopyrine derivative"; and

(*c*) The statement "Warning:—This drug may cause fatal agranulocytosis."

(ii) Labeling on or within the package from which the drug is to be dispensed and any other labeling for the drug that furnishes or purports to furnish information for use, or which prescribes, recommends, or suggests a dosage for the use of the drug, bears, in addition to the information required in this subparagraph, information to the following effect:

WARNING—THIS DRUG MAY CAUSE FATAL AGRANULOCYTOSIS.

CAUTION: This drug should be used only in those conditions in which it is specifically indicated and in which other less toxic drugs have proved ineffective or are not tolerated. The potential benefit accruing from the use of this drug must be weighed against the possibility of fatal agranulocytosis.

Indications for use. Aminopyrine and aminopyrine derivatives (dipyrone preparations) should be restricted to use for their antipyretic effect in serious or life-threatening situations where salicylates or similar drugs are known to be ineffective or are contraindicated or not tolerated.

Duration of administration. Fatal agranulocytosis has been reported after short-term use, intermittent use, and after long-term administration. Therefore, the use of these agents should be as brief as possible.

Precautions. Frequent white blood cell and differential counts should be carried out. However, it is emphasized that agranulocytosis may occur precipitously without prior warning. The drug should be discontinued at the first evidence of any alteration of the blood count or sign of agranulocytosis, and the patient should be instructed to discontinue use of the drug at the first indication of sore throat or sign of other infection in the mouth or throat (pain, swelling, tenderness, ulceration).

Dosage. Adults: The usual antipyretic dose should not exceed ½ to 1 gram per dose, nor should more than 3 grams total daily dosage be used. If the desired effect is not achieved within a very few days, use of the drug should be discontinued.

Children: 250 to 500 milligrams per dose, repeated in 3 to 4 hours if necessary. Use of the drug should be as brief as possible.

(4) A new-drug application for such a preparation should include a commitment that all advertising for the drug will bear the information required by paragraph (d) (3) (i) of this section, and that any advertisement that provides any information regarding indications or dosage recommendations will include the information required to appear in the package labeling by paragraph (d) (3) (ii) of this section and will not recommend or suggest use of the drug under any other conditions.

(5) A new-drug application will be regarded as approvable if it contains satisfactory information of the kinds required by items 4, 5, 6, 7, and 8 of the new-drug application form set forth in § 314.1(c) (2) of this chapter.

(6) Regulatory proceedings may be initiated with regard to the interstate shipment of any such preparations for which a new-drug application is not approved or which is labeled or advertised contrary to the labeling approved in such application consistent with this statement of policy.

(Sec. 502 (f), (j); 52 Stat. 1051; 21 U.S.C. 352 (f), (j))

§ 201.312 Magnesium sulfate heptahydrate; label declaration on drug products.

Magnesium sulfate heptahydrate should be listed on the label of a drug product as epsom salt, which is its common or usual name.

(Sec. 502, 52 Stat. 1051; 21 U.S.C. 352)

§ 201.313 Estradiol labeling.

The article presently recognized in The National Formulary under the heading "Estradiol" and which is said to be "17-cis-beta estradiol" is the same substance formerly recognized in the United States Pharmacopeia under the designation "Alpha Estradiol." The substance should no longer be referred to in drug labeling as "Alpha Estradiol." The Food and Drug Administration would not object to label references to the article as simply "Estradiol"; nor would it object if the label of a preparation containing this substance referred to the presence of "Estradiol (formerly known as Alpha Estradiol)."

(Secs. 201, 502, 52 Stat. 1040, 1051; 21 U.S.C. 321, 352)

§ 201.314 Labeling of drug preparations containing salicylates.

(a) The label of any oral drug preparation intended for sale without prescription and which contains any salicylate ingredient (including aspirin, salicylamide, other salicylates, and combinations) must bear a conspicuous warning statement in heavy block type on clearly contrasting background, such as: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately," or "Warning—Keep out of the reach of children," except that if the article is an aspirin preparation, it shall bear the first of these warning statements. Such a warning statement is required for compliance with section 502(f) (2) of the Federal Food, Drug, and Cosmetic Act and is intended to guard against accidental poisonings. Safety closures that prevent access to the drug by young children are also recommended to guard against accidental poisonings.

(b) Effervescent preparations and preparations containing para-aminosalicylate as the only salicylate ingredient are exempted from this labeling requirement.

(c) Aspirin tablets sold as such and containing no other active ingredients, except tablets which cannot be readily subdivided into a child's dose because of their coating or size, should always bear

dosage directions for each age group down to 3 years of age, with a statement such as "For children under 3 years of age, consult your physician." It is recommended that:

(1) Aspirin tablets especially made for pediatric use be produced only in 1¼-grain size to reduce the hazard of errors in dosage;

(2) By June 1, 1967, manufacturers and distributors of 1¼-grain size aspirin tablets discontinue the distribution of such tablets in retail containers containing more than 36 tablets, to reduce the hazard of accidental posoning;

(3) The flavoring of 5-grain aspirin tablets or other "adult aspirin tablets" be discontinued; and

(4) Labeling giving undue emphasis to the pleasant flavor of flavored aspirin tablets be discontinued.

(d) Salicylate preparations other than aspirin tablets sold as such may, at the option of the distributor, be labeled for use by adults only. If their labeling and advertising clearly offer them for administration to adults only.

(e) (1) It is the obligation of the distributor who labels a salicylate preparation for administration to children to make certain that the article is suitable for such use and labeled with adequate directions for use in the age group for which it is offered, but in no case should such an article bear directions for use in children under 3 years of age. If the directions provide for administration to children as young as 3 years of age, the label should bear the statement, "For children under 3 years of age consult your physician." However, if the directions provide for administration to children only of an age greater than 3 years (for example, the dosage instructions provide for administration of the article to children only down to age 6), the label should bear a statement such as, "For younger children consult your physician."

(2) A statement such as, "For children under 3 years of age consult your physician" or "For younger children consult your physician" is not required on the label of an article clearly offered for administration to adults only.

(f) If the labeling or advertising of a salicylate preparation offers it for use in arthritis or rheumatism, the label and labeling should clearly state that the beneficial effects claimed are limited to: "For the temporary relief of minor aches and pains of arthritis and rheumatism." The qualifying phrase "for the temporary relief of minor aches and pains" should appear with the same degree of prominence and conspicuousness as the phrase "arthritis and rheumatism". The label and labeling should bear in juxtaposition with such directions for use conspicuous warning statements to the effect: "Caution: If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately." The salicylate dosage should not exceed 60 grains in a 24-hour period or 10 grains in a 4-hour period. If the article contains other analgesics, the salicylate dosage should be appropriately reduced.

(g) (1) The label of any drug containing more than 5 percent methyl salicylate (wintergreen oil) should bear a conspicuous warning such as: "Warning: Do not use otherwise than as directed. Keep out of the reach of children to avoid accidental poisoning."

(2) If the preparation is a counter-irritant or rubefacient, it should also bear a caution such as, ""Caution: Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes." (See also § 201.303.)

(Sec. 502, 52 Stat. 1051; 21 U.S.C. 352)

§ 201.315 Over-the-counter drugs for minor sore throats; suggested warning.

The Food and Drug Administration has studied the problem of the labeling of lozenges or troches containing a local anesthetic, chewing gum containing aspirin, various mouth washes and gargles and other articles sold over the counter for the relief of minor irritations of the mouth or throat. It will not object to the labeling of suitable articles of this type "For the temporary relief of minor sore throats", provided this is immediately followed in the labeling with a warning statement in prominent type essentially as follows: "Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician."

(Sec. 502, 52 Stat. 1051; 21 U.S.C. 352)

Subpart H—Special Requirements for Specific Devices

§ 201.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.

(a) The American Dental Association and leading dental authorities have advised the Food and Drug Administration of their concern regarding the safety of denture reliners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in the repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the Food and Drug Administration that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Layman cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary situations pending the services of a licensed dentist.

(b) The Food and Drug Administration therefore regards such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act, unless the labeling:

(1) (i) Limits directions for use for denture repair kits to emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture;

(ii) Limits directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture;

(2) Contains in a conspicuous manner the word "emergency" preceding and modifying each indication-for-use statement for denture repair kits and the word "temporary" preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and

(3) Includes a conspicuous warning statement to the effect:

(i) For denture repair kits: *"Warning—For emergency repairs only.* Long-term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay."

(ii) For denture reliners, pads, and cushions: *"Warning—For temporary use only.* Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen."

(c) Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefor, and the importance of adhering to the warnings. Accordingly, the labeling should contain substantially the following information:

(1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long-term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(2) For denture reliners, pads, and cushions: Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit properly. Special training and tools are needed to repair a denture to fit properly. Dentures that do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury

may lead to cancer in the mouth. You must see your dentist as soon as possible.

(3) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: "This reliner becomes fixed to the denture and a completely new denture may be required because of its use."

(d) Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under sections 201(n) and 502(a) of the Federal Food, Drug, and Cosmetic Act.

(e) Regulatory action may be initiated with respect to any article found within the jurisdiction of the act contrary to the provisions of this policy statement after 90 days following the date of publication of this section in the FEDERAL REGISTER.

§ 201.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicate that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of either plastic lenses, heat-treated crown glass lenses, or lenses made impact-resistant by other methods.

(c) To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses and gives written notification thereof to the patient.

(d) The physician or optometrist shall have the option of ordering heat-treated glass lenses, plastic lenses, laminated glass lenses, or glass lenses made impact resistant by other methods; however, all such lenses must be capable of withstanding an impact test in which a 5/8-inch steel ball weighing approximately 0.56 ounces is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5/8-inch diameter circle located at the geometric center of the lens. The ball may be guided, but not restricted, in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. In order to pass the test, the lens must not fracture (for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces or if any lens material visable to the naked eye becomes detached from the ocular surface). The test shall be conducted with the lens supported by a tube (1-inch inside diameter, 1 1/4-inch outside diameter, and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than 1 1/4 inches may be used. The support tube shall be made of rigid acrylic plastic, steel or other suitable substance and shall have securely bonded on the top edge a 1/8- by 1/8-inch neoprene gasket having a hardness of 40±5, as determined by ASTM Method D 1415; a minimum tensile strength of 1,200 pounds, as determined by ASTM Method D 412; and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412. The diameter and/or contour of the lens support may be modified as necessary so that the 1/8- by 1/8-inch neoprene gasket supports the lens at its periphery. Each finished impact-resistant glass lens for prescription use shall be subjected to the impact test prescribed by this paragraph. Raised ledge multifocal lenses must be impact-resistant but need not be tested beyond initial design testing. To demonstrate that all other types of impact-resistant lenses (including impact-resistant laminated glass lenses) are capable of withstanding this impact test, the manufacturer of such lenses shall subject to the impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer (including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance). Plastic prescription and all nonprescription lenses, tested on the basis of statistical significance, may be tested in uncut finished or semifinished form at the point of original manufacture. This statement of policy will be appropriately amended to provide for use of alternate methods of testing the impact resistance of lenses if it can be shown that the alternate method is equal to or superior to the method prescribed in this paragraph.

(e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses (including finished eyeglasses and sunglasses) shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.

(f) In addition, those persons conducting impact tests in accordance with paragraph (d) of this section, shall keep and maintain the results thereof for a period of 3 years. Such records and results shall be made available, upon request at all reasonable hours by any officer or employee acting on behalf of the Secretary of Health, Education, and Welfare and shall permit such officer or employee to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.

(g) For the purpose of this section, the term "manufacturer" includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable.

(h) The transition to impact-resistant lenses must be completed as promptly as possible; however, to provide for the development of an adequate supply of impact-resistant lenses and to facilitate an orderly changeover to these lenses, all lenses manufactured after January 31, 1972, must be impact-resistant, except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements of a particular patient.

(i) This statement of policy does not apply to contact lenses.

(Secs. 502(j), 52 Stat. 1051; 21 U.S.C. 352(j))

PART 202—PRESCRIPTION DRUG ADVERTISING

Sec.
202.1 Prescription-drug advertisements.

AUTHORITY: Secs. 201(n), 502, 505, 507, 701, 52 Stat. 1041, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 59 Stat. 463 as amended (21 U.S.C. 321(n), 352, 355, 357, 701).

§ 202.1 Prescription drug advertisements.

(a) (1) The ingredient information required by section 502(n) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names.

(2) The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product.

(3) The advertisement shall not employ a fanciful proprietary name for the drug or any ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The advertisement shall not feature inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) The advertisement shall not designate a drug or ingredient by a proprie-

tary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(b) (1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured in the advertisement for the drug; but, except as provided below in this subparagraph, the established name need not be used with the proprietary name or designation in the running text of the advertisement. On any page of an advertisement in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text in association with such proprietary name or designation and in the same type size used in the running text: *Provided, however,* That if the proprietary name or designation is used in the running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such running text. If any advertisement includes a column with running text containing detailed information as to composition, prescribing, side effects, or contraindications and the proprietary name or designation is used in such column but is not featured above or below the column, the established name shall be used at least once in such column of running text in association with such proprietary name or designation and in the same type size used in such column of running text: *Provided, however,* That if the proprietary name or designation is used in such column of running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such column of running text. Where the established name is required to accompany or to be used in association with the proprietary name or designation, the established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of" preceding the established name, by brackets surrounding the established name, or by other suitable means.

(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(c) In the case of a prescription drug containing two or more active ingredients, if the advertisement bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required in the advertisement by section 502(n) of the act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

(d) (1) If the advertisement employs one proprietary name or designation to refer to a combination of active ingredients present in more than one preparation (the individual preparations differing from each other as to quantities of active ingredients and/or the form of the finished preparation) and there is no established name corresponding to such proprietary name or designation, a listing showing the established names of the active ingredients shall be placed in direct conjunction with the most prominent display of such proprietary name or designation. The prominence of this listing of active ingredients shall bear a reasonable relationship to the prominence of the proprietary name and the relationship between such proprietary name or designation, and the listing of active ingredients shall be made clear by use of such phrase as "brand of", preceding the listing of active ingredients.

(2) The advertisement shall prominently display the name of at least one specific dosage form and shall have the quantitative ingredient information required by section 502(n) of the act in direct conjunction with such display. If other dosage forms are listed in the advertisement, the quantitative ingredient information for such dosage forms shall appear in direct conjunction and in equal prominence with the most prominent listing of the names of such dosage forms.

(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) *When required.* All advertisements for any prescription drug ("prescription drug" as used in this section means drugs defined in section 503(b)(1) of the act and § 201.105, applicable to drugs for use by man and veterinary drugs, respectively), except advertisements described in paragraph (e)(2) of this section, shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section "side effects, contraindications" include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness. Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications.

(2) *Exempt advertisements.* The following advertisements are exempt from the requirements of paragraph (e)(1) of this section under the conditions specified:

(i) *Reminder advertisements.* Reminder advertisements if they contain only the proprietary or trade name of a drug (which necessitates declaring the established name, if any, and furnishing the formula showing quantitatively each ingredient of the drug to the extent required for labels) and, optionally, information relating to dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug: *Provided, however,* That if the Commissioner finds that there is evidence of significant incidence of fatalities or serious damage associated with the use of a particular prescription drug, he may notify the manufacturer, packer, or distributor of the drug by mail that this exemption does not apply to such drug by reason of such finding: *And provided, however,* That reminder advertisements are not permitted for a drug for which an announcement has been published pursuant to a review of the labeling claims for the drug by the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, and for which no claim has been evaluated as higher than "possibly effective." If the Commissioner finds the circumstances are such that a reminder advertisement may be misleading to prescribers of drugs subject to NAS–NRC evaluation such advertisements will not be allowed and the manufacturer, packer, or distributor will be notified either in the publication of the conclusions on the effectiveness of the drug or by letter.

(ii) *Advertisements of bulk-sale drugs.* Advertisements of bulk-sale drugs that promote sale of the drug in bulk packages in accordance with the practice of the trade solely to be processed, manufactured, labeled, or repackaged in substantial quantities and that contain no claims for the therapeutic safety or effectiveness of the drug.

(iii) *Advertisements of prescription-compounding drugs.* Advertisements of prescription-compounding drugs that promote sale of a drug for use as a prescription chemical or other compound for use by registered pharmacists in compounding prescriptions if the drug otherwise complies with the conditions for the labeling exemption contained in § 201.120 and the advertisement contains no claims for the therapeutic safety or effectiveness of the drug.

(3) *Scope of information to be included; applicability to the entire advertisement.* (i) The requirement of a true statement of information relating

to side effects, contraindications, and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement of a brief statement containing true information relating to side effects, contraindications, and effectiveness of the drug. If any part or theme of the advertisement would make the advertisement false or misleading by reason of the omission of appropriate qualification or pertinent information, that part or theme shall include the appropriate qualification or pertinent information, which may be concise if it is supplemented by a prominent reference on each page to the presence and location elsewhere in the advertisement of a more complete discussion of such qualification or information.

(ii) The information relating to effectiveness is not required to include information relating to all purposes for which the drug is intended but may optionally be limited to a true statement of the effectiveness of the drug for the selected purpose(s) for which the drug is recommended or suggested in the advertisement. The information relating to effectiveness shall include specific indications for use of the drug for purposes claimed in the advertisement; for example, when an advertisement contains a broad claim that a drug is an antibacterial agent, the advertisement shall name a type or types of infections and microorganisms for which the drug is effective clinically as specifically as required, approved, or permitted in the drug package labeling.

(iii) The information relating to side effects and contraindications shall disclose each specific side effect and contraindication (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.; see paragraph (e) (1) of this section) contained in required, approved, or permitted labeling for the advertised drug dosage form(s): *Provided, however,*

(*a*) The side effects and contraindications disclosed may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement to the extent that such limited disclosure has previously been approved or permitted in drug labeling conforming to the provisions of §§ 201.100 or 201.105; and

(*b*) The use of a single term for a group of side effects and contraindications (for example, "blood dyscrasias" for disclosure of "leukopenia," "agranulocytosis," and "neutropenia") is permitted only to the extent that the use of such a single term in place of disclosure of each specific side effect and contraindication has been previously approved or permitted in drug labeling conforming to the provisions of §§ 201.100 or 201.105.

(4) *Substance of information to be included in brief summary.* (i) (*a*) An advertisement for a prescription drug covered by a new-drug application approved pursuant to section 505 of the act after October 10, 1962 or section 512 of the act after August 1, 1969, or any approved supplement thereto, shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement. The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e) (3) (iii) of this section.

(*b*) If a prescription drug was covered by a new-drug application or a supplement thereto that became effective prior to October 10, 1962, an advertisement may recommend or suggest:

(*1*) Uses contained in the labeling accepted in such new-drug application and any effective, approved, or permitted supplement thereto.

(2) Additional uses contained in labeling in commercial use on October 9, 1962, to the extent that such uses did not cause the drug to be an unapproved "new drug" as "new drug" was defined in section 201(p) of the act as then in force, and to the extent that such uses would be permitted were the drug subject to paragraph (e) (4) (iii) of this section.

(3) Additional uses contained in labeling in current commercial use to the extent that such uses do not cause the drug to be an unapproved "new drug" as defined in section 201(p) of the act as amended or a "new animal drug" as defined in section 201(w) of the act as amended.

The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e) (3) (iii) of this section.

(ii) An advertisement for a prescription drug subject to certification under section 507 or 512 of the act shall not recommend or suggest any use that is not in the labeling covered by the certification or the applicable certification regulations or regulations providing for exemption from certification. The advertisement shall present information from such labeling covered by the certification or the applicable certification regulations or regulations providing for exemption from certification, relating to each specific side effect and contraindication in such labeling and such regulations for the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e) (3) (iii) of this section.

(iii) In the case of an advertisement for a prescription drug other than a drug the labeling of which causes it to be an unapproved "new drug" and other than drugs covered by paragraph (e) (4) (i) and (ii) of this section, an advertisement may recommend and suggest the drug only for those uses contained in the labeling thereof:

(*a*) For which the drug is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of such drugs; or

(*b*) For which there exists substantial evidence of safety and effectiveness, consisting of adequate and well-controlled investigations, including clinical investigations (as used in this section "clinical investigations," "clinical experience," and "clinical significance" mean in the case of drugs intended for administration to man, investigations, experience, or significance in humans, and in the case of drugs intended for administration to other animals, investigations, experience, or significance in the specie or species for which the drug is advertised), by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses; or

(*c*) For which there exists substantial clinical experience (as used in this section this means substantial clinical experience adequately documented in medical literature or by other data (to be supplied to the Food and Drug Administration, if requested)), on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses; or

(*d*) For which safety is supported under any of the preceding clauses in paragraph (e) (4) (iii) (*a*), (*b*), and (*c*) of this section and effectiveness is supported under any other of such clauses.

The advertisement shall present information relating to each specific side effect and contraindication that is required, approved, or permitted in the package labeling by §§ 201.100 or 201.105 of this chapter of the drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e) (3) (iii) of this section.

(5) *"True statement" of information.* An advertisement does not satisfy the requirement that it present a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if:

(i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or

(ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by section 502(n) of the act and this information is not fairly balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug; *Provided, however,* That no advertisement shall be considered to be in violation of this section if the presentation of true information relating to side effects and contraindications is comparable in depth and de-

tail with the claims for effectiveness or safety.

(iii) It fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.

(6) *Advertisements that are false, lacking in fair balance, or otherwise misleading.* An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

(i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in this section "patients" means humans and in the case of veterinary drugs, other animals), safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraph (e) (4) (iii) (*b*) and (*c*) of this section) whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

(iii) Contains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience.

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

(vi) Contains references to literature or studies that misrepresent the effectiveness of a drug by failure to disclose that claimed results may be due to concomitant therapy, or by failure to disclose the credible information available concerning the extent to which claimed results may be due to placebo effect (information concerning placebo effect is not required unless the advertisement promotes the drug for use by man).

(vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

(viii) Uses a statement by a recognized authority that is apparently favorable about a drug but fails to refer to concurrent or more recent unfavorable data or statements from the same authority on the same subject or subjects.

(ix) Uses a quote or paraphrase out of context to convey a false or misleading idea.

(x) Uses literature quotations or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim.

(xi) Uses literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling.

(xii) Offers a combination of drugs for the treatment of patients suffering from a condition amenable to treatment by any of the components rather than limiting the indications for use to patients for whom concomitant therapy as provided by the fixed combination drug is indicated, unless such condition is included in the uses permitted under paragraph (e) (4) of this section.

(xiii) Uses a study on normal individuals without disclosing that the subjects were normal, unless the drug is intended for use on normal individuals.

(xiv) Uses "statistics" on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such "statistics" are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

(xv) Uses erroneously a statistical finding of "no significant difference" to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference.

(xvi) Uses statements or representations that a drug differs from or does not contain a named drug or category of drugs, or that it has a greater potency per unit of weight, in a way that suggests falsely or misleadingly or without substantial evidence or substantial clinical experience that the advertised drug is safer or more effective than such other drug or drugs.

(xvii) Uses data favorable to a drug derived from patients treated with dosages different from those recommended in approved or permitted labeling if the drug advertised is subject to section 505, 507, or 512 of the act, or, in the case of other drugs, if the dosages employed were different from those recommended in the labeling and generally recognized as safe and effective. This provision is not intended to prevent citation of reports of studies that include some patients treated with dosages different from those authorized, if the results in such patients are not used.

(xviii) Uses headline, subheadline, or pictorial or other graphic matter in a way that is misleading.

(xix) Represents or suggests that drug dosages properly recommended for use in the treatment of certain classes of patients or disease conditions are safe and effective for the treatment of other classes of patients or disease conditions when such is not the case.

(xx) Presents required information relating to side effects or contraindications by means of a general term for a group in place of disclosing each specific side effect and contraindication (for example employs the term "blood dyscrasias" instead of "leukopenia," "agranulocytosis," "neutropenia," etc.) unless the use of such general term conforms to the provisions of paragraph (e) (3) (iii) of this section.

Provided, however, That any provision of this paragraph shall be waived with respect to a specified advertisement as set forth in a written communication from the Food and Drug Administration on a petition for such a waiver from a person who would be adversely affected by the enforcement of such provision on the basis of a showing that the advertisement is not false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act. A petition for such a waiver shall set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of this paragraph from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act.

(7) *Advertisements that may be false, lacking in fair balance, or otherwise misleading.* An advertisement may be false, lacking in fair balance, or otherwise misleading or otherwise violative of section 502(n) of the act if it:

(i) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions.

(ii) Uses the concept of "statistical significance" to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results.

(iii) Uses statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

(iv) Uses tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied; for example, by failing to label abscissa and ordinate

so that the graph creates a misleading impression.

(v) Uses reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles of statistical theory, methodology, applied practice, and inference, or that are derived from clinical studies the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretations, or evaluations.

(vi) Contains claims concerning the mechanism or site of drug action that are not generally regarded as established by scientific evidence by experts qualified by scientific training and experience without disclosing that the claims are not established and the limitations of the supporting evidence.

(vii) Fails to provide sufficient emphasis for the information relating to side effects and contraindications, when such information is contained in a distinct part of an advertisement, because of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.

(viii) Fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(ix) Fails to provide adequate emphasis (for example, by the use of color scheme, borders, headlines, or copy that extends across the gutter) for the fact that two facing pages are part of the same advertisement when one page contains information relating to side effects and contraindications.

(x) In an advertisement promoting use of the drug in a selected class of patients (for example, geriatric patients or depressed patients), fails to present with adequate emphasis the significant side effects and contraindications or the significant dosage considerations, when dosage recommendations are included in an advertisement, especially applicable to that selected class of patients.

(xi) Fails to present on a page facing another page (or on another full page) of an advertisement on more than one page, information relating to side effects and contraindications when such information is in a distinct part of the advertisement.

(xii) Fails to include on each page or spread of an advertisement the information relating to side effects and contraindications or a prominent reference to its presence and location when it is presented as a distinct part of an advertisement.

(xiii) Contains information from published or unpublished reports or opinions falsely or misleadingly represented or suggested to be authentic or authoritative.

(f) through (i) [Reserved]

(j) (1) No advertisement concerning a particular prescription drug may be disseminated without prior approval by the Food and Drug Administration if:

(i) The sponsor or the Food and Drug Administration has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage;

(ii) The Commissioner (or in his absence the officer acting as Commissioner), after evaluating the reliability of such information, has notified the sponsor that the information must be a part of the advertisements for the drug; and

(iii) The sponsor has failed within a reasonable time as specified in such notification to present to the Food and Drug Administration a program, adequate in light of the nature of the information, for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements.

If the Commissioner finds that the program presented is not being followed, he will notify the sponsor that prior approval of all advertisements for the particular drug will be required. Nothing in this paragraph is to be construed as limiting the Commissioner's or the Secretary's rights, as authorized by law, to issue publicity, to suspend any new-drug application, to decertify any antibiotic, or to recomend any regulatory action.

(2) Within a reasonable time after information concerning the possibility that a drug may cause fatalities or serious damage has been widely publicized in medical literature, the Food and Drug Administration shall notify the sponsor of the drug by mail that prior approval of advertisements for the drug is no longer necessary.

(3) Dissemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded under section 502(n) of the act.

(4) Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment. If the advertiser is notified that the submitted advertisement is not in violation and, at some subsequent time, the Food and Drug Administration changes its opinion, the advertiser will be so notified and will be given a reasonable time for correction before any regulatory action is taken under this section. Notification to the advertiser that a proposed advertisement is or is not considered to be in violation shall be in written form.

(k) An advertisement issued or caused to be issued by the manufacturer, packer, or distributor of the drug promoted by the advertisement and which is not in compliance with section 502(n) of the act and the applicable regulations thereunder shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded under section 502(n) of the act.

(l) (1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

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Subpart C—Procedures for Foreign Drug Establishments

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207.65 Exemptions for domestic establishments.

AUTHORITY: Secs. 201, 502, 505, 506, 507, 510, 512, 701(a), 704; 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055, 1057 as amended; 21 U.S.C. 321, 352, 355, 356, 357, 360, 360b, 371(a), 374; sec. 351, 58 Stat. 702 as amended; 42 U.S.C. 262; the Drug Listing Act of 1972, Pub. L. 92-387; 86 Stat. 559-563 (21 U.S.C. 360 note) unless otherwise noted.

Subpart A—Definitions

§ 207.3 Definitions.

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 et seq., as amended, 21 U.S.C. 301–392).

(b) "Establishment" means a place of business under one management at one general physical location. The term includes, among others, independent laboratories that engage in control activities for registered drug establishment (e.g.,

"consulting" laboratories), manufacturers of medicated feeds and of vitamin products that are "drugs" within the meaning of section 201(g) of the act, human blood donor centers, and animal facilities used for the production or control testing of licensed biologicals.

(c) Manufacture, preparation, propagation, compounding, or processing of a drug or drugs means the making by chemical, physical, biological, or other procedures of any articles which meet the definition of drugs as defined in section 201(g) of the act, and including manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The term includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(d) "Commercial distribution" means any distribution of a human drug except pursuant to the investigational use provisions of § 312.1 of this chapter, and any distribution of an animal drug or an animal feed bearing or containing an animal drug for noninvestigational uses but does not include internal or interplant transfer of a bulk drug substance between registered domestic establishments within the same parent, subsidiary, and/or affiliate company.

(e) "Representative sampling of advertisements" means typical advertising material (excluding labeling as determined in § 202.1(l) (2) of this chapter) which gives a balanced picture of the promotional claims being used for the drug (e.g., if more than one medical journal advertisement is used but their promotional content is essentially identical, only one need be submitted).

(f) "Representative sampling of any other labeling" as used in this part means typical labeling material (excluding labels and package inserts) which gives a balanced picture of the promotional claims being used for the drug (e.g., if more than one brochure is used but their promotional content is essentially identical, only one need be submitted).

(g) "Any material change" includes but is not limited to any change in the name of the drug, in the quantity or identity of the active ingredient(s) or in the quantity or identity of the inactive ingredient(s) where quantitative listing of all ingredients is required pursuant to § 207.31(a) (2), any significant change in the labeling of a prescription drug, and any significant change in the label or package insert of an over-the-counter drug. Changes that are not significant include changes in arrangement or printing or changes of an editorial nature.

(h) "Bulk drug substance" means any substance that is represented for use in a drug and when used in the manufacturing, processing, or packaging of a drug becomes an active ingredient or a finished dosage form of such drug, but does not include intermediates used in the synthesis of such substances.

(i) "Advertising" and "labeling" include the promotional material described in § 202.1(l) (1) and (2) of this chapter respectively.

(j) The definitions and interpretations contained in sections 201 and 510 of the act shall be applicable to such terms when used in this Part 207.

Subpart B—Procedures for Domestic Drug Establishments

§ 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or Subpart D of this Part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs are required to register and to submit a list of every drug in commercial distribution (except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Such owners or operators are required to register and to submit a list of every drug in commercial distribution (except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments), whether or not the output of such establishment or any particular drug so listed enters interstate commerce, except that drug listing is not required at this time for the manufacturing, preparation, propagation, compounding, or processing of an animal feed (including a feed concentrate, a feed supplement, and a complete animal feed) bearing or containing an animal drug.

(b) Distributors which are not otherwise required to register under section 510 of the act, may submit drug listing information directly to the Food and Drug Administration for those drugs which they distribute under their own label or trade name but which are manufactured, prepared, propagated, compounded, or processed by a registered establishment. Where drug listing information is submitted by a distributor, the registration number of the drug establishment which manufactured, prepared, propagated, compounded, or processed the drug shall be included for each drug listed. If a distributor does not elect to obtain a "Labeler Code" the registered establishment shall submit the drug listing information. Such submissions and requests for Labeler Codes shall be made on Form FD–2658 (Registered Establishments' Report of Private Label Distributors). All distributors submitting drug listing information to the Food and Drug Administration assume full responsibility for compliance with all of the requirements of this part. Each distributor at the time of each submission of drug listing information or updating as required under § 207.30 shall so certify to the registered establishment that such submission has been made by providing a signed copy of Form FD–2656 (Registration of Drug Establishment) to the registered establishment which manufactures, prepares, propagates, compounds, or processes the drug. The original of Form FD–2656 (Registration of Drug Establishment) showing such certification shall be submitted to the Food and Drug Administration. Such certification shall be accompanied by a list showing the National Drug Code number assigned to each drug product by the distributor.

(c) Preparatory to engaging in the manufacture, preparation, propagation, compounding, or processing of a drug, owners or operators of establishments who are submitting new drug applications, new animal drug applications, Form FD–1800 (Medicated Feed Application), antibiotic Forms 5 and 6, or an establishment license application in order to manufacture biological products are required to register before the new drug application, new animal drug application, Form FD–1800, antibiotic Form 5 or 6, or establishment license application is approved.

(d) No registration fee is required. Registration and listing do not constitute an admission or agreement or determination that a product is a "drug" within the meaning of section 201(g) of the act.

§ 207.21 Times for registration and drug listing.

The owner or operator of an establishment entering into an operation defined in § 207.3(c) shall register such establishment within 5 days after the beginning of such operation and submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment defined in § 207.3(c) has not previously entered into such operation, registration shall follow within 5 days after the submission of a new drug application, new animal drug application, Form FD–1800, antibiotic Form 5 or 6, or an establishment license application in order to manufacture biological products. Owners or operators of all establishments so engaged shall register annually between November 15 and December 31 and shall update their drug listing information every June and December.

§ 207.22 How and where to register and list drugs.

(a) The first registration of an establishment shall be on Form FD–2656 (Registration of Drug Establishment) obtainable on request from the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Drugs, Registration Section, 5600 Fishers Lane, Rockville, MD 20852, or from Food and Drug Administration district offices. Subsequent annual registration shall also be accomplished on Form FD–2656 (Registration of Drug Establishment), which will be furnished by the Food and Drug Administration before November 15 of each year to estab-

lishments whose drug registration for that year was validated pursuant to § 207.35. The completed form shall be mailed to the above address before December 31 of that year.

(b) The first list of drugs and subsequent June and December updatings shall be on Form FD-2657 (Drug Product Listing), obtainable upon request as described in paragraph (a) of this section. In lieu of Form FD-2657 (Drug Product Listing), tapes for computer inputs may be submitted if equivalent in all elements of information as specified in Form FD-2657 (Drug Product Listing). All formats proposed for such use will require initial review and approval by the Food and Drug Administration.

§ 207.25 Information required in registration and drug listing.

(a) Form FD-2656 (Registration of Drug Establishment) requires furnishing or confirming information required by the act. This information includes the name and street address of the drug establishment, including post office ZIP code; all trade names used by the establishment; the kind of ownership or operation (that is, individually owned partnership, or corporation); and the name of the owner or operator of such establishment. The term "name of the owner or operator" shall include in the case of a partnership the name of each partner, and in the case of a corporation the name and title of each corporate officer and director and the name of the State of incorporation. The information required shall be given separately for each establishment, as defined in § 207.3(b).

(b) Form FD-2657 (Drug Product Listing) requires furnishing information required by the act as follows:

(1) A list of drugs, including bulk drug substances and drug premixes for use in the manufacture of animal feeds as well as finished dosage forms, by established name as defined in section 502(e) of the act and by proprietary name, which are being manufactured, prepared, propagated, compounded, or processed for commercial distribution and which have not been included in any list previously submitted on Form FD-2657 (Drug Product Listing) or in conjunction with the Food and Drug Administration voluntary inventory on Form FD-2422 (Survey Report of Marketed Drugs), or Form FD-2250 (National Drug Code Directory Input).

(2) For each drug so listed which is regarded by the registrant as subject to section 505, 506, 507, or 512 of the act, the new drug application number, abbreviated new drug application number, new animal drug application number, or Form 5 or Form 6 number, and a copy of all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement.

(3) For each drug so listed which is regarded by the registrant as subject to section 351 of the Public Health Service Act, the license number of the manufacturer.

(4) For each human drug so listed which is subject to section 503(b)(1) of the act and regarded by the registrant as not subject to section 505, 506, or 507 of the act or 351 of the Public Health Service Act, and which is not manufactured by a registered blood bank, a copy of all current labeling except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement and a representative sampling of advertisements.

(5) For each human over-the-counter drug or each animal drug so listed which is regarded by the registrant as not subject to section 505, 506, 507, or 512 of the act, or 351 of the Public Health Service Act, a copy of the label except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement, package insert, and a representative sampling of any other labeling.

(6) For each prescription or over-the-counter drug so listed which is regarded by the registrant as not subject to section 505, 506, 507, or 512 of the act, or 351 of the Public Health Service Act, and which is not manufactured by a registered blood bank, quantitative listing of the active ingredient(s). If the drug is in unit dosage form the statements of the quantity of ingredient shall express the amount, not the percent, of such ingredient in each such unit, unless the quantitative listing is expressed as a percentage in the official compendium. If the drug is not in unit dosage form, the statement of the quantity of an ingredient shall express the amount, not the percent, of such ingredient in a specific unit of weight or measure of the drug unless the quantitative listing is expressed as a percentage in the official compendium, except that for drug premixes for use in the manufacture of animal feeds such ingredient which is not an antibiotic may be expressed in terms of percent. If a drug premix has been assigned a Product Code as provided for in § 207.35(b)(2)(iii), the quantitative listing of ingredients may be limited to each variation of level of active drug ingredient.

(7) For each drug listed, the registration number of every drug establishment within the parent company at which it is manufactured, prepared, propagated, compounded, or processed.

(8) For each drug so listed, the National Drug Code (NDC) number. If no NDC Labeler Code number has been assigned, the Product Code and Package Code will be included and a Labeler Code will be assigned as described in § 207.35(b)(2)(i).

§ 207.26 Amendments to registration.

Changes in individual ownership, corporate or partnership structure location or drug-handling activity, shall be submitted by Form FD-2656 (Registration of Drug Establishment) as amendment to registration within 5 days of such changes. Changes in the names of officers and directors of the corporations do not require such amendment but must be shown at time of annual registration.

§ 207.30 Updating drug listing information.

(a) After submission of the initial drug listing information, every person who is required to list drugs pursuant to § 207.20 shall submit on Form FD-2657 (Drug Product Listing) during each subsequent June and December, or at the discretion of the registrant at the time the change occurs, the following information:

(1) A list of each drug introduced by the registrant for commercial distribution which has not been included in any list previously submitted. All of the information required by § 207.25(b) shall be provided for each such drug.

(2) A list of each drug formerly listed pursuant to § 207.25(b) for which commercial distribution has been discontinued, including for each drug so listed the NDC number, the identity by established name and proprietary name, and date of discontinuance. It is requested but not required that the reason for discontinuance of distribution be included with this information.

(3) A list of each drug for which a notice of discontinuance was submitted pursuant to paragraph (a)(2) of this section and for which commercial distribution has been resumed, including for each drug so listed the NDC number, the identity by established name as defined in section 502(e) of the act and by any proprietary name, the date of resumption, and any other information required by § 207.25(b) not previously submitted.

(4) Any material change in any information previously submitted.

(b) When no changes have occurred since the previously submitted list, no report is required.

§ 207.31 Additional drug listing information.

(a) In addition to the information routinely required by §§ 207.25 and 207.30, the Commissioner may require submission of the following information by letter or by FEDERAL REGISTER notice:

(1) For a particular drug so listed which is subject to section 503(b)(1) of the act and regarded by the registrant as not subject to section 505, 506, or 507 of the act, upon request made by the Commissioner for good cause, a copy of all advertisements.

(2) For a particular drug product so listed which is regarded by the registrant as not subject to section 505, 506, 507, or 512 of the act, upon a finding by the Commissioner that it is necessary to carry out the purposes of the act, a quantitative listing of all ingredients.

(3) For a particular drug product upon request by the Commissioner, a brief statement of the basis upon which the registrant has determined that the drug product is not subject to section 505, 506, 507, or 512 of the act.

(4) For each registrant, upon a finding by the Commissioner that it is necessary to carry out the purposes of the act, a list of each listed drug product containing a particular ingredient.

(b) It is requested but not required that information concerning the quantity

of drug distributed be submitted in conjunction with the annual registration in the format prescribed in a section of Form FD–2656A (Optional Distribution Data), for each drug currently listed.

(c) It is requested but not required that a qualitative listing of the inactive ingredients be submitted for all listed drugs in the format prescribed in Form FD–2657 (Drug Product Listing).

(d) It is requested but not required that a quantitative listing of the active ingredients be submitted for all drugs listed which are subject to section 505, 506, 507, or 512 of the act or section 351 of the Public Health Service Act.

§ 207.35 Notification of registrant; drug establishment registration number and drug listing number.

(a) The Commissioner will provide to the registrant a validated copy of Form FD–2656 (Registration of Drug Establishment) as evidence of registration. This validated copy will be sent only to the location shown for the registering establishment. A permanent registration number will be assigned to each drug establishment registered in accordance with these regulations.

(b) A drug listing number will be assigned, using the National Drug Code numbering system, to each drug or class of drugs listed as follows:

(1) If a drug is already listed in the National Drug Code System or in the National Health Related Items Code System, the number will be the same as that assigned pursuant to those codes. A lead zero will be added by the Food and Drug Administration to the first three characters of the code, which identifies the manufacturer or distributor, to expand the "Labeler Code" segment to four characters. The National Drug Code, Product Code and Package Code configurations used to describe such drugs, or any new drugs added to the product line, will remain the same (i.e., a four-character Product Code and a two-character Package Code). Alphanumeric characters where already used in the Product Code and Package Code segments of the National Drug Code may be retained; however, these alphanumeric characters may be converted to all numeric digits. The manufacturer or distributor shall inform the Food and Drug Administration of such changes.

(2) If a registered establishment or distributor has not previously participated in the National Drug Code system, or in the National Health Related Items Code system, the National Drug Code numbering system will be used in assigning a number, as follows (only numerics will be used):

(i) The first five numeric characters of the 10-character code identify the manufacturer or distributor and are known as the Labeler Code. The Food and Drug Administration will expand the Labeler Code from five to six numeric characters when the available five-character code combinations are exhausted. These code numbers are assigned by the Food and Drug Administration and provided to the registrant along with the validated copy of Form FD–2656 (Registration of Drug Establishment). Any registered firm that does not have an assigned "Labeler Code" will be assigned one when registration and listing information is submitted.

(ii) The last five numeric characters of the 10-character code identify the drug and the trade package size and type. The segment which identifies the drug formulation is known as the Product Code and the segment which identifies the trade package size and type is known as the Package Code. The Product Code and the Package Code shall be assigned by the manufacturer or distributor prior to drug listing and included in Form FD–2657 (Drug Product Listing). Either of two methods may be used by the manufacturer or distributor in assigning the Product and Package Codes; a 3–2 Product-Package Code configuration (i.e., 542–12) or a 4–1 Product-Package Code configuration (i.e., 5421–2). Only one such Product-Package Code configuration may be used by a manufacturer or distributor with a given Labeler Code and this same configuration shall be used in assigning the Product-Package Codes for all drugs included in the drug listing. The manufacturer or distributor shall report to the Food and Drug Administration the Product-Package Code configuration he used in assigning these codes. Once a Product Code has been assigned to a specific drug, this same code may never again be used for any other drug regardless whether the drug has been discontinued.

(iii) If the drug formulation is a custom premix intended for use in the manufacture of an animal feed, a separate Product Code is required only for each variation of level of active drug ingredient.

(3) The NDC number is requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer. If the NDC number is shown on a drug label it shall be placed as follows:

(i) The NDC number shall be placed prominently in the top third of the center panel of the label of the immediate container and of the outside container or wrapper if such there be.

(ii) The NDC number shall be preceded by the initials NDC, in a different color or different type style (font) than that used to print the number if the label is printed rather than typewritten, whenever it is used on a label or in labeling.

(iii) The Product-Package Code configuration shall be indicated and the segments of the number shall be separated by a dash (i.e., NDC 15643–542–12 or NDC 15643–5421–2).

(iv) All 10 characters shall appear and the leading zeros in any segment of the NDC number shall be shown: *Provided, however,* That when the NDC number is used for product identification by direct imprinting on dosage forms, leading zeros may be dropped from the Product Code segment of the NDC number.

(v) The placing of the assigned NDC number on a label or in labeling does not require the submission of a supplemental new drug application, supplemental new animal drug application, or supplemental antibiotic Form 5 or 6.

(4) If any material change occurs in product characteristics (including but not limited to a change in dosage form, active ingredient(s) or active ingredient(s) strength or concentration, route of administration, or product name, etc.) a new NDC number shall be assigned by the registrant to the new product version and the information submitted to the Food and Drug Administration. If a change in packaging only is involved the trade package code can be revised without the necessity of assigning a new product code segment, but the Food and Drug Administration shall be informed about the new trade package code and characteristics.

(c) Although registration and drug listing are required to engage in the drug activities described in § 207.20, validation of registration and the assignment of a drug listing number do not, in themselves, establish that the holder of the registration is legally qualified to deal in such drugs.

NOTE: The provisions of § 207.35(b)(3) shall not be effective until printing plates are revised or until July 1, 1975 (38 FR 27593).

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FD–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection pursuant to section 510(f) of the act, at the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Drugs, Registration Section, 5600 Fishers Lane, Rockville, MD 20852. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, vertification of registration number, or location of a registered concern will be provided.

(1) The following information submitted pursuant to the drug listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

(i) A list of all drug products.

(ii) A list of all drug products broken down by labeled indications or pharmacological category.

(iii) A list of all drug products, broken down by manufacturer.

(iv) A list of a drug product's active ingredients.

(v) A list of drug products newly marketed or where marketing is resumed.

(vi) A list of drug products discontinued.

(vii) All labeling.

(viii) All advertising.

(ix) All data or information that has already become a matter of public knowledge.

(2) The following information submitted pursuant to the drug listing requirement is illustrative of the type of

information that will not be available for public disclosure:

(i) Any data or information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505, 506, 507, or 512 of the act.

(ii) A list of a drug product's inactive ingredients.

(iii) A list of drugs containing a particular ingredient.

(iv) *Provided,* That any of the above information will be available for public disclosure if it has already become a matter of public knowledge or if the Commissioner finds that confidentiality would be inconsistent with protection of the public health.

(b) Requests for information about registrations and drug listings should be directed to the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Drugs, Registration Section, 5600 Fishers Lane, Rockville, MD 20852.

§ 207.39 Misbranding by reference to registration or to registration number.

Registration of a drug establishment or drug wholesaler or assignment of a registration number or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and constitutes misbranding.

Subpart C—Procedures for Foreign Drug Establishments

§ 207.40 Drug listing requirements for foreign drug establishments.

(a) Every foreign drug establishment shall comply with the drug listing requirements contained in Subpart B of this part, unless exempt under Subpart D of this part, whether or not it is also registered.

(b) No drug may be imported from a foreign drug establishment into the United States except a drug imported or offered for import pursuant to the investigational use provisions of § 312.1 of this chapter, unless it is first the subject of a drug listing as required in Subpart B of this part. The drug listing information shall be in the English language.

(c) Foreign drug establishments shall submit as part of the drug listing, the name and address of the establishment and the name of the individual responsible for submitting drug listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating drug listing information in § 207.30(a).

Subpart D—Exemptions

§ 207.65 Exemptions for domestic establishments.

The following classes of persons are exempt from registration and drug listing in accordance with this Part 207 under the provisions of section 510(g), (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4), that such registration is not necessary for the protection of the public health.

(a) Pharmacies that are operating under applicable local laws regulating dispensing of prescription drugs and that do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of the practice of the profession of pharmacy including the business of dispensing and selling drugs at retail. The supplying by such pharmacies of prescription drugs to a practitioner licensed to administer such drugs for his use in the course of his professional practice or to other pharmacies to meet temporary inventory shortages are not acts which require such pharmacies to register.

(b) Hospitals, clinics, and public health agencies which maintain establishments in conformance with any applicable local laws regulating the practices of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, other than human blood or blood products, upon prescription of practitioners licensed by law to administer such drug for patients under the care of such practitioners in the course of their professional practice.

(c) Practitioners who are licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice.

(d) Persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale.

(e) Manufacturers of harmless inactive ingredients which are excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under the provisions of this Part 207.

(f) Any person who uses drugs to prepare feed for his own animals: *Provided,* That under the act and its regulations such person would not be required to hold an approved new animal drug application (or supplement thereto) or a Form FD-1800 in order to possess and use the drug.

(g) Any manufacturer of a virus, serum, toxin, or analogous product intended for treatment of domestic animals, who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.): *Provided,* That such exemption from registration shall apply only with respect to the manufacture of such animal virus, serum, toxin, or analogous product.

(h) Carriers, by reason of their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

(i) Persons who are engaged solely in the manufacture, preparation, propagation, compounding, or processing of a general purpose laboratory reagent (as described in § 328.10(d) of this chapter) intended for use in in vitro diagnostic procedures in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae.

PART 210—CURRENT GOOD MANUFACTURING PRACTICES IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS: GENERAL

Sec.
210.3 Definitions.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049-1050 as amended, 1055-1056 as amended (21 U.S.C. 351, 371).

§ 210.3 Definitions.

(a) As used in this part, "act" means the Federal Food, Drug, and Cosmetic Act, sections 201-902, 52 Stat. 1052 (21 U.S.C. 321-392) with all the amendments thereto.

(b) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(c) As used in this part:

(1) The term "medicated feed" means any "complete feed," "feed additive supplement," or "feed additive concentrate," as defined in § 121.200 of this chapter, which feed contains one or more drugs as defined in section 201(g) of the act. Medicated feeds are subject to §§ 225.1 through 225.115 of this chapter, inclusive.

(2) The term "medicated premix" means a substance that meets the definition in § 121.200 of this chapter for a "feed additive premix," except that it contains one or more drugs as defined in section 201(g) of the act and is intended for manufacturing use in the production of a medicated feed. Medicated premixes are subject to §§ 226.1 through 226.115 of this chapter, inclusive.

(d) As used in §§ 211.1 through 211.115 of this chapter, inclusive:

(1) The term "component" means any ingredient intended for use in the manufacture of drugs in dosage form, including those that may not appear in the finished product.

(2) The term "batch" means a specific quantity of a drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(3) The term "lot" means a batch or any portion of a batch of a drug or, in the case of a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality within specified limits.

(4) The terms "lot number" or "control number" mean any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a batch or lot of drug can be determined.

(5) The term "active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of the drug and be present in the finished drug product in a modified form intended to furnish the specified activity or effect.

(6) The term "inactive ingredient" means any component other than an "active ingredient" present in a drug.

(7) The term "materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

(8) The term "strength" means:

(i) The concentration of the drug substance (for example, w/w, w/v, or unit dose/volume basis) and/or

(ii) The potency, that is, the therapeutic activity of the drug substance as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart A—General Provisions

Sec.
211.1 Finished pharmaceuticals; manufacturing practice.
211.10 Personnel.

Subpart B—Construction and Maintenance of Facilities and Equipment

211.20 Buildings.
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Subpart C—Product Quality Control

211.40 Production and control procedures.
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211.62 Expiration dating.

Subpart D—Packaging and Labeling

211.80 Packaging and labeling.

Subpart E—Records and Reports

211.101 Master production and control records; batch production and control records.
211.110 Distribution records.
211.115 Complaint files.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049–1050 as amended, 1055–1056 as amended (21 U.S.C. 351, 371).

Subpart A—General Provisions

§ 211.1 Finished pharmaceuticals; manufacturing practice.

(a) The criteria in §§ 211.20–211.115, inclusive, shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements of the act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess as required by section 501(a)(2)(B) of the act.

(b) The regulations in this part permit the use of precision automatic, mechanical, or electronic equipment in the production and control of drugs when adequate inspection and checking procedures are used to assure proper performance.

§ 211.10 Personnel.

(a) The personnel responsible for directing the manufacture and control of the drug shall be adequate in number and background of education, training, and experience, or combination thereof, to assure that the drug has the safety, identity, strength, quality, and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing or control operations they perform, the necessary training or experience, and adequate information concerning the reason for application of pertinent provisions of this part to their respective functions.

(b) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drugs shall be excluded from direct contact with drug products until the condition is corrected. All employees shall be instructed to report to supervisory personnel any conditions that may have such an adverse effect on drug products.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 211.20 Buildings.

Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, labeling, or holding of a drug. The buildings shall:

(a) Provide adequate space for:

(1) Orderly placement of equipment and materials to minimize any risk of mixups between different drugs, drug components, in-process materials, packaging materials, or labeling, and to minimize the possibility of contamination.

(2) The receipt, storage, and withholding from use of components pending sampling, identification, and testing prior to release by the materials approval unit for manufacturing or packaging.

(3) The holding of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.

(4) The storage of components, containers, packaging materials, and labeling.

(5) Any manufacturing and processing operations performed.

(6) Any packaging or labeling operations.

(7) Storage of finished products.

(8) Control and production-laboratory operations.

(b) Provide adequate lighting, ventilation, and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, microbiological, dust, humidity, and temperature controls to:

(1) Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage, or handling of another product.

(2) Minimize dissemination of microorganisms from one area to another.

(3) Provide suitable storage conditions for drug components, in-process materials, and finished drugs in conformance with stability information as derived under § 211.60.

(c) Provide adequate locker facilities and hot and cold water washing facilities, including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.

(d) Provide an adequate supply of potable water (§ 1250.82 of this chapter) under continuous positive pressure in a plumbing system free of defects that could cause or contribute to contamination of any drug. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

(e) Provide suitable housing and space for the care of all laboratory animals.

(f) Provide for safe and sanitary disposal of sewage, trash, and other refuse within and from the buildings and immediate premises.

§ 211.30 Equipment.

Equipment used for the manufacture, processing, packing, labeling, holding, testing, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose. The equipment shall:

(a) Be so constructed that all surfaces that come into contact with a drug product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(b) Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact drug products so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(c) Be constructed and installed to facilitate adjustment, disassembly cleaning and maintenance to assure the reliability of control procedures uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might

affect the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(d) Be of suitable type, size, and accuracy for any testing, measuring, mixing, weighing, or other processing or storage operations.

Subpart C—Product Quality Control

§ 211.40 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the safety, identity, strength, quality, and purity they purport to possess:

(a) Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical, or electronic equipment, their proper performance is adequately checked by one or more competent and responsible individuals. The written record of the significant steps in the process shall be identified by the individual performing these tests and by the individual charged with checking these steps. Such identifications shall be recorded immediately following the completion of such steps.

(b) All containers, lines, and equipment used during the production of a batch of a drug shall be properly identified at all times to accurately and completely indicate their contents and, when necessary, the stage of processing of the batch.

(c) To minimize contamination and prevent mixups, equipment, utensils, and containers shall be thoroughly and appropriately cleaned and properly stored and have previous batch identification removed or obliterated between batches or at suitable intervals in continuous production operations.

(d) Appropriate precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile or which by virtue of their intended use should be free from objectionable microorganisms.

(e) Appropriate procedures shall be established to minimize the hazard of cross-contamination of any drugs while being manufactured or stored.

(f) To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. In-process sampling shall be done at appropriate intervals using suitable equipment.

(g) Representative samples of all dosage form drugs shall be tested to determine their conformance with the specifications for the product before distribution.

(h) Procedures shall be instituted whereby review and approval of all production and control records, including packaging and labeling, shall be made prior to the release or distribution of a batch. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has already been distributed. This investigation shall be undertaken by a competent and responsible individual and shall extend to other batches of the same drug and other drugs that may have been associated with the specific failure. A written record of the investigation shall be made and shall include the conclusions and followup.

(i) Returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored, or shipped prior to or during their return, or the condition of the product, its container, carton, or labeling as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the drug, the returned goods shall be destroyed or subjected to adequate examination or testing to assure that the material meets all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of paragraph (h) of this section.

(j) Use of asbestos-containing or other fiber-releasing filters: (1) Filters used in the manufacture, processing or packaging of components of drug products for parenteral injection in humans shall not release fibers into such products. No asbestos-containing or other fiber-releasing filter may be used in the manufacture, processing or packaging of such products unless it is not possible to manufacture that drug product or component without the use of such a filter. Filtration, as needed, shall be through a nonfiber-releasing filter. For the purposes of this regulation a non-fiber-releasing filter is defined as a nonasbestos, nonglass fiber filter which, after any appropriate pretreatment such as washing or flushing, will not continue to release fibers into the drug product or component which is being filtered. A fiber is defined as any particle with length at least three times greater than its width.

(2) If use of a fiber-releasing filter is required, an additional non-fiber-releasing filter of maximum pore size of 0.22 microns (0.45 microns if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of any asbestos-form particles in the drug product or component. Use of an asbestos-containing filter with or without subsequent use of a specific nonfiber-releasing filter is permissible only upon submission of proof to the appropriate bureau of the Food and Drug Administration that use of a non-fiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the drug.

(3) Substitution for a fiber-releasing filter shall be achieved on or before September 14, 1976. If such substitution is not achieved on or before March 14, 1976, the manufacturer of the drug product for parenteral injection who requires the additional 6 months to develop new manufacturing procedures so as to utilize non-fiber-releasing filters in place of fiber-releasing filters shall submit monthly reports to the appropriate bureau of the Food and Drug Administration indicating progress in substituting the new filters. Such a substitution shall be shown to have been effected without loss of the safety or effectiveness of the drug.

Paragraph (j) is effective April 14, 1975.

§ 211.42 Components.

All components and other materials used in the manufacture, processing, and packaging of drug products, and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary, and orderly manner. Adequate measures shall be taken to prevent mixups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a materials approval unit. Control of components shall include the following:

(a) Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.

(b) An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one or more tests to establish the specific identity.

(c) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

(d) Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate specifications.

(e) Representative samples of components liable to microbiological contamination shall be subjected to microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

(f) Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity,

strength, quality, and purity at time of use. This requires the following:

(1) Approved components shall be handled and stored to guard against contaminating or being contaminated by other drugs or components.

(2) Approved components shall be rotated in such a manner that the oldest stock is used first.

(3) Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

(g) Appropriate records shall be maintained, including the following:

(1) The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.

(2) Examinations and tests performed and rejected components and their disposition.

(3) An individual inventory and record for each component used in each batch of drug manufactured or processed.

(h) An appropriately identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least 2 years after distribution of the last drug lot incorporating the component has been completed or 1 year after the expiration date of this last drug lot, whichever is longer.

§ 211.55 Product containers and their components.

Suitable specifications, test methods, cleaning procedures, and when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use. Containers for parenteral drugs, drug products or drug components shall be cleansed with water which has been filtered through a non-fiber-releasing filter equivalent to that indicated in § 211.40(j)

(2) Product containers and their components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the drug.

Effective date. This section effective April 14, 1975.

(Secs. 501, 502, 701, 52 Stat. 1049–1051, 1055–1056, as amended; (21 U.S.C. 351, 352, 371))

§ 211.58 Laboratory controls.

Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of drug components, product containers, and their components subject to deterioration.

(b) A reserve sample of all active ingredients as required by § 211.42(h).

(c) The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly identified.

(d) The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drug products. Such samples shall be adequately representative and properly identified.

(e) Adequate provisions for checking the identity and strength of drug products for all active ingredients and for assuring:

(1) Sterility of drugs purported to be sterile and freedom from objectionable microorganisms for those drugs which should be so by virtue of their intended use.

(2) The absence of pyrogens for those drugs purporting to be pyrogen-free.

(3) Minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances.

(4) That the drug release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.

(f) Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

(g) A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least 2 years after the drug distribution has been completed or at least 1 year after the drug's expiration date, whichever is longer.

(h) Provision for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least 2 years after distribution has been completed or 1 year after the drug's expiration date, whichever is longer.

(i) Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.

(j) Provision that firms which manufacture nonpenicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such nonpenicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.05 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

§ 211.60 Stability.

There shall be assurance of the stability of finished drug products. This stability shall be:

(a) Determined by reliable, meaningful, and specific test methods.

(b) Determined on products in the same container-closure systems in which they are marketed.

(c) Determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling), as well as on the reconstituted product.

(d) Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates.

§ 211.62 Expiration dating.

To assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, the label of all such drugs shall have suitable expiration dates which relate to stability tests performed on the product.

(a) Expiration dates appearing on the drug labeling shall be justified by readily available data from stability studies such as described in § 211.60.

(b) Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.

(c) When the drug is marketed in the dry state for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product.

Subpart D—Packaging and Labeling

§ 211.80 Packaging and labeling.

Packaging and labeling operations shall be adequately controlled: To assure that only those drug products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mixups between drugs during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the drug; and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day, or shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall:

(a) Be separated (physically or spatially) from operations on other drugs in a manner adequate to avoid mixups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.

(b) Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.

(c) Include the following labeling controls:

(1) The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.

(2) The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such a manner as to prevent mixups and provide proper identification.

(3) A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.

(4) Restriction of access to labels and package labeling to authorized personnel.

(5) Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting, and handling during and after printing.

(d) Provide strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of drug finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out according to § 211.40(h).

(e) Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met.

Subpart E—Records and Reports

§ 211.101 Master production and control records; batch production and control records.

(a) To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked, reconciled, dated, and signed or initialed by a second competent and responsible individual. The master production and control record shall include:

(1) The name of the product, description of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dated by the person or persons responsible for approval of such labeling.

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of the total weight or measure of any dosage unit.

(3) A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; an accurate statement of the weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

(4) A description of the containers, closures, and packaging and finishing materials.

(5) Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

(b) The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least 2 years after the batch distribution is complete or at least 1 year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include:

(1) An accurate reproduction of the appropriate master formula record checked, dated, and signed or initialed by a competent and responsible individual.

(2) A record of each significant step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including: Dates; individual major equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individual(s) actively performing and the individual(s) directly supervising or checking each significant step in the operation.

(3) A batch number that identifies all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

(4) A record of any investigation made according to § 211.40(h).

§ 211.110 Distribution records.

(a) Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug. Records shall be retained for at least 2 years after the distribution of the drug has been completed or 1 year after the expiration date of the drug, whichever is longer.

(b) To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed first whenever possible. (See 21 CFR 1304 for regulations relating to manufacturing and distribution records of drugs subject to the Drug Abuse Control Amendments of 1965; Public Law 89-74.)

§ 211.115 Complaint files.

Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with § 211.40(h). The record of each investigation shall be maintained for at least 2 years after distribution of the drug has been completed or 1 year after the expiration date of the drug, whichever is longer.

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

Subpart A—General Provisions

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225.1	Current good manufacturing practice.
225.10	Personnel.
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225.20	Buildings.
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225.40 Production and control procedures.
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Subpart D—Packaging and Labeling

225.80 Packaging and labeling.

Subpart E—Records and Reports

225.102 Formula and production records.
225.110 Distribution records.
225.115 Complaint files.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049–1050 as amended, 1055–1056 as amended (21 U.S.C. 351, 371).

Subpart A—General Provisions

§ 225.1 Current good manufacturing practice.

The criteria in §§ 225.10 through 225.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or holding of a medicated feed conform to or are operated or administered in conformity with current good manufacturing practice to assure that a medicated feed meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this Part 225 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a medicated feed when adequate inspection and checking procedures are used to assure proper performance.

§ 225.10 Personnel.

The key employees and/or consultants responsible for the formulation, manufacture, and control of the medicated feed shall have a background of education or experience or a combination thereof that is adequate to assure proper composition and labeling of the medicated feeds.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 225.20 Buildings.

Buildings in which medicated feeds are manufactured, processed, packaged, labeled, or held shall be maintained in a reasonably clean and orderly manner and shall be of suitable size, construction, and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The buildings shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which they are employed, to minimize any risk of mixups between different medicated feeds, their components, packaging, or labeling:

(1) The receipt, control, and storage of components.

(2) Any manufacturing and processing operations performed on the medicated feed.

(3) Any packaging and labeling operations.

(4) Storage of containers, packaging materials, labeling, and finishing products.

(b) Provide adequate lighting and other physical facilities necessary to prevent unsafe contamination of raw materials and finished products before, during, and after production.

(c) Provide for adequate washing, cleaning, toilet, and locker facilities.

Work areas and equipment used for the production of medicated feeds or for the storage of the components of medicated feeds shall not be used for the production, mixing, or storage of finished or unfinished insecticides, fungicides, or rodenticides or their components.

§ 225.30 Equipment.

Equipment used for the manufacture, processing, packaging, bulk shipment, labeling, holding or control of medicated feeds or their components shall be maintained in a reasonably clean and orderly manner and shall be of suitable design, size, construction, and location in relation to surroundings to facilitate maintenance and operation for its intended purpose. The equipment shall:

(a) Be so constructed that any surfaces that come into contact with medicated feeds are suitable, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the medicated feed or its components.

(b) Be so constructed that any substance required for the operation of the equipment, such as lubricants, coolants, etc., may be employed without hazard of becoming an unsafe additive to the medicated feed.

(c) Be constructed to facilitate adjustment, cleaning, and maintenance, and to assure uniformity of production and reliability of control procedures and to assure the exclusion from medicated feeds of unsafe contamination, including cross-examination from manufacturing operations.

(d) Be suitably grounded electrically to prevent lack of uniform mixing due to electrically charged particles.

(e) Be of suitable size and accuracy for use in any intended measuring, mixing or weighing operations.

Subpart C—Product Quality Control

§ 225.40 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the medicated feeds produced are of proper composition and labeling:

(a) Each critical step in the process, such as the selection, weighing, and measuring of components; the addition of drugs or components during the process; the control of mixing times; the adjustment of the equipment involved in continuous production processes; and the determination of the finished yield, shall be performed in a manner that has been determined by appropriate methods, including laboratory testing of the medicated feed, to be adequate to assure the integrity of the final product. If such steps in the processing are controlled by precision, automatic, mechanical, or electronic equipment, provision shall be made to adequately check its performance.

(b) All containers to be used for undiluted drugs, drug components, intermediate mixtures, and finished feeds shall be received, adequately identified, and properly stored and handled in a manner adequate to prevent mixups or contamination.

(c) Equipment, including dust-control and other equipment, such as that used for holding and returning recovered or flush-out materials back into production, shall be maintained and operated in such a manner as to prevent unsafe contamination of the medicated feed.

(d) The steps used to prevent unsafe contamination of medicated feed include one or more of the following, or other equally effective procedures:

(1) Cleaning of those parts of storage, mixing, conveying, and any other equipment coming in contact with the drug component of the medicated feed for the purpose of cleaning out of the equipment any drug, drug component, or medicated feed prior to the use of the same equipment for the production of a different medicated feed.

(2) The cleaning of the equipment as required in paragraph (d)(1) of this section, may be achieved by flushing all feed-contacting surfaces of such equipment used in the production of a medicated feed with a quantity of an appropriate drug-free feedstuff that has been found sufficient to remove any significant quantity of a drug component or an intermediate mix or complete medicated feed prior to the production of a different medicated feed. The yield from any such flushing operation may be incorporated in appropriate amounts in the subsequent production of a medicated feed intended to contain the same drug component (or components) to produce a complete medicated feed conforming to its composition and labeling specifications.

(e) If there is sequential production of batches of a medicated feed containing the same drug component (or components) at the same or lower levels, there shall be sufficient safeguards to avoid any buildup above the specified levels of the drug components in any of the batches of the complete feed.

(f) A sampling and assay schedule on the finished medicated feed, or a schedule at least as reliable, for checking on the composition of the finished article shall be applied as follows:

(1) In the case of a medicated feed that requires an approved Form FD–1800 for its manufacture and marketing, the schedule of assays established in such application shall be used.

(2) In the case of a medicated feed that does not require an approved Form FD–1800 for its marketing, three appropriately drawn samples from each 400 tons of such medicated feeds produced shall be taken at appropriately spaced intervals over the production period, and, in any event, not less than three such

samples of each particular medicated feed during any 1 year shall be collected and analyzed. For the purposes of this subparagraph, the term "each particular medicated feed" shall be construed to include all feeds containing the same drug components) at different levels. The colponent (or the same mixture of components) at different levels. The collection and analysis of samples shall be from the medicated feed containing the highest level of the drug component (or mixture of components).

(3) A medicated feed covered by paragraph (f)(2) of this section shall be exempt from the prescribed sampling and analytical schedule under the following conditions:

(i) The manufacturing practices used in the production of the medicated feed were consistent with the regulations of this part; and

(ii) The manufacturer of the medicated feed has produced at least 3 batches of such feed conforming to composition and labeling specifications during the 1-year period immediately preceding the date of manufacture of the feed and during that period has not been notified by the Food and Drug Administration or any State regulatory official that his manufacturing practices were in conflict with section 501(a)(2)(B) of the act or the regulations of this part and has not distributed a medicated feed during that period which has been proceeded against under the act because of failure of such feed to comply with its composition or labeling requirements or which has been analyzed by any State official and found to be deficient; and

(iii) The medicated feed contains only, as the drug component (or components), a low-level growth-promotion antibiotic (or antibiotics) as provided by and in accordance with the regulations in Part 558 of this chapter; it was manufactured from a feed additive premix, feed additive concentrate, or feed additive supplement that, at the time of receipt by the medicated-feed manufacturer, bore a label, or was accompanied by labeling, containing a quantitative composition statement of its antibiotic content together with directions for its use in the manufacturing of a legal medicated feed; and the medicated-feed manufacturer, in good faith, relied upon and followed the feed additive premix, concentrate, or supplement label or labeling information and directions for use in the manufacturing of the medicated feed; or

(iv) The medicated feed contains only, as the drug component (or components), a drug (or drugs) as provided by and in accordance with the regulations in Part 558 of this chapter; it was manufactured from a feed additive concentrate or feed additive supplement that, at the time of receipt by the medicated-feed manufacturer, bore a label, or was accompanied by labeling, containing the quantitative composition of its drug content together with directions for its use in the manufacturing of a legal medicated feed; and the medicated-feed manufacturer, in good faith, relied upon and followed the feed additive concentrate or supplement label or labeling information and directions for use in the manufacturing of the medicated feed; or

(v) The medicated feed contains only drug components as provided by and in accordance with the regulations in Part 558 of this chapter and was manufactured from a feed additive supplement, a low level growth-promotion antibiotic premix, a low level growth-promotion antibiotic concentrate, a feed additive concentrate, or a combination of any two of these used in accordance with the conditions set forth in paragraph (f)(3) (ii), (iii), and (iv) of this section.

(g) Production and control procedures shall include provision for discontinuing distribution of any medicated feed found by the assay procedures, or any other controls preformed, to fail to conform to appropriate specifications. Distribution of subsequent production shall not begin until it has been determined that proper control produres have been established.

§ 225.42 Components.

(a) Drug components, including undiluted drugs and any intermediate mixes containing drugs used in the manufacture and processing of medicated feeds, shall be received, stored, handled, and otherwise controlled in a manner to maintain the integrity and identification of such articles. Appropriate receipt and inventory records shall be maintained for 1 year and such records shall show the origin of any drug components, the batches in which they were used, and the results of any testing of them by or on behalf of the medicated-feed manufacturer.

(b) Nondrug components shall be stored and otherwise handled in a manner to avoid unsafe contamination, including cross-contamination from manufacturing operations.

(c) Statements relating to the identification and the quantitative composition appearing on the labels of undiluted drugs or other drug components received by the medicated-feed manufacturer from other suppliers may be relied upon by the medicated-feed manufacturer as acceptable evidence of the identity and composition of the drug or drug components in lieu of actual testing of each such drug or drug component if such reliance is made in good faith.

§ 225.58 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that the drug components and the finished medicated feeds conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications and a description of the test procedures used to check them for each kind of drug used in the manufacture of medicated feeds; this may consist of the manufacturer's or supplier's statement of specifications.

(b) The establishment of finished-product specifications for medicated feeds and a description of any necessary laboratory test procedures to check them, including methods of assay for the active drug ingredient.

(c) A determination that the drug components remain uniformly dispersed and stable in the medicated feed under ordinary conditions of shipment, storage, and use; this may consist of a supplier's or consultant's determination made on a feed of substantially the same formula.

(d) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedure used; the official Methods of Analysis of the Association of Official Agricultural Chemists, methods described in an official compendium, and any method, submitted as a part of a food additive petition or new-drug application, which has been accepted by the Food and Drug Administration shall be regarded as meeting this provision.

(e) Provision for the maintenance of the results of any assays, including dates and endorsement of analysts. Such records, together with records of analyses reported by any State feed control official shall be retained in the possession of the manufacturer or in the possession of a consulting laboratory operating in his behalf. Such records shall be maintained for a period of at least 1 year after distribution of the medicated feed has been completed.

Subpart D—Packaging and Labeling

§ 225.80 Packaging and labeling.

Packaging and labeling operations shall be adequately performed and controlled to assure that only those medicated feeds made in compliance with established formula records and manufacturing and control directions shall be distributed; to prevent mixups between the medicated feeds during the packaging and labeling operations; and to assure that correct labeling is employed for the medicated feed. In the case of medicated feeds distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery. Such labeling may consist of an invoice or placard identifying the medicated feed and bearing adequate information for the safe and effective use of the medicated feed. Labels and labeling shall be received, handled, and stored in a manner that avoids labeling mixups. Previously used containers shall be adequately cleaned and labeled before reuse to avoid adulteration or misbranding.

Subpart E—Records and Reports

§ 225.102 Formula and production records.

(a) For each medicated feed, a master formula record or card shall be prepared, checked, and maintained by a responsible key employee and retained for at least 1 year after production of the last batch. The formula record or card shall include at least the following:

(1) The name of the medicated feed, together with any other information necessary for the correct identification of the feed.

(2) The weight or measure of each ingredient, adequately identified, to be used in manufacturing a stated weight of the medicated feed.

(3) A copy, description, or notation adequately identifying the label, labeling, or placard necessary to be used on or with the complete medicated feed.

(4) Manufacturing instructions for each medicated feed produced on a batch or continuous operation basis, including mixing steps, mixing times, and batch formulas that have been determined to yield an adequately mixed medicated feed; and in the case of medicated feeds produced by continuous production run, any additional manufacturing directions including, when indicated, the settings of equipment that have been determined to yield an adequately mixed medicated feed of the specified formula.

(5) Appropriate control directions, including the manner and frequency with which any necessary samples of the medicated feed are to be taken for specified laboratory tests, the criteria for using laboratory test results to change formulations or manufacturing procedures, and the procedures to be observed to avoid unsafe contamination of the medicated feed with other medicated feeds or drug components.

(b) A production record shall be prepared for each batch or run of medicated feed produced, and shall be retained for at least 1 year. The production record shall include:

(1) Product identification, date of production, and endorsement by a responsible individual.

(2) A record of the quantity of drug components used.

(3) A record of the quantity of medicated feed produced.

(c) In the case of a customer-formula feed made to the specifications of a customer, the formula and production records required by this section may consist of copies of customers' purchase orders and sellers' invoices bearing the information required by this section.

§ 225.110 Distribution records.

Complete records shall be maintained for each shipment of medicated feeds in a manner that will facilitate the recall, diversion, or destruction of the medicated feed, if necessary. Such records shall be retained for at least 6 months after the date of the shipment, and shall include the name and address of the consignee, the date and quantity shipped, and the manufacturing dates, control numbers, or marks identifying the medicated feed shipped. If the medicated feed is held under control of the manufacturer for further shipment at establishments other than where produced, records as outlined in this section shall be maintained at these establishments.

§ 225.115 Complaint files.

The medicated-feed manufacturer shall evaluate by responsible key personnel each complaint received by him on a feed that is manufactured or distributed by him and, where indicated, make such further investigations or take such appropriate action as appears to be warranted in the circumstances. A record of complaints and the action taken by the feed manufacturer shall be maintained for a period of 2 years. If the medicated feed is the subject of an approved new-drug application held by the feed manufacturer, he shall make such reports as are required by § 510.301 of this chapter.

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED PREMIXES

Subpart A—General Provisions

Sec.
226.1 Current good manufacturing practice.
226.10 Personnel.

Subpart B—Construction and Maintenance of Facilities and Equipment

226.20 Buildings.
226.30 Equipment.

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226.40 Production and control procedures.
226.42 Components.
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Subpart D—Packaging and Labeling

226.80 Packaging and labeling.

Subpart E—Records and Reports

226.102 Master-formula and batch-production records.
226.110 Distribution records.
226.115 Complaint files.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049–1050 as amended; 1055–1056 as amended (21 U.S.C. 351, 371).

Subpart A—General Provisions

§ 226.1 Current good manufacturing practice.

The criteria in §§ 226.10 through 226.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for the manufacture, processing, packing, or holding of a medicated premix conform to or are operated or administered in conformity with current good manufacturing practice to assure that a medicated premix meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this Part 226 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a medicated premix when adequate inspection and checking procedures or other quality control procedures are used to assure proper performance.

§ 226.10 Personnel.

The key personnel and any consultants involved in the manufacture and control of the medicated premix shall have a background of appropriate education or appropriate experience or combination thereof for assuming responsibility to assure that the medicated premix has the proper labeling and the safety, identity, strength, quality, and purity that it purports to possess.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 226.20 Buildings.

Buildings in which medicated premixes are manufactured, processed, packaged, labeled, or held shall be maintained in a clear and orderly manner and shall be of suitable size, construction and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The building shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which they are employed to minimize risk of mixups between different medicated premixes, their components, packaging, or labeling:

(1) The receipt, sampling, control, and storage of components.

(2) Manufacturing and processing operations performed on the medicated premix.

(3) Packaging and labeling operations.

(4) Storage of containers, packaging materials, labeling, and finished products.

(5) Control laboratory operations.

(b) Provide adequate lighting and ventilation, and when necessary for the intended production or control purposes, adequate screening, dust and temperature controls, to avoid contamination of medicated premixes, and to avoid other conditions unfavorable to the safety, identity, strength, quality, and purity of the raw materials and medicated premixes before, during, and after production.

(c) Provide for adequate washing, cleaning, toilet, and locker facilities.

Work areas and equipment used for the production of medicated premixes or for the storage of the components of medicated premixes shall not be used for the production, mixing or storage of finished or unfinished insecticides, fungicides, rodenticides, or other pesticides or their components unless such materials are recognized as approved drugs intended for use in animal feeds.

§ 226.30 Equipment.

Equipment used for the manufacture, processing, packaging, bulk shipment, labeling, holding, or control of medicated premixes or their components shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate maintenance and operation for its intended purpose. The equipment shall:

(a) Be so constructed that any surfaces that come into contact with medicated premixes are suitable, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the medicated premix or its components.

(b) Be so constructed that any substance required for the operation of the equipment, such as lubricants, coolants, etc., may be employed without hazard of becoming an unsafe additive to the medicated premix.

(c) Be constructed to facilitate adjustment, cleaning, and maintenance, and to assure uniformity of production and reliability of control procedures and to assure the exclusion from medicated premixes of contamination, including cross-contamination from manufacturing operations.

(d) Be suitably grounded electrically to prevent lack of uniform mixing due to electrically charged particles.

(e) Be of suitable size and accuracy for use in any intended measuring, mixing, or weighing operations.

Subpart C—Product Quality Control

§ 226.40 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the medicated premixes produced have the identity, strength, quality, and purity they purport to possess:

(a) Each critical step in the process, such as the selection, weighing, and measuring of components; the addition of drug components during the process; weighing and measuring during various stages of the processing; and the determination of the finished yield, shall be performed by one or more competent, responsible individuals. If such steps in the processing are controlled by precision, automatic, mechanical, or electronic equipment, their proper performance shall be adequately checked by one or more competent, responsible individuals.

(b) All containers to be used for undiluted drugs, drug components, intermediate mixtures thereof, and medicated premixes shall be received, adequately identified, and properly stored and handled in a maner adequate to avoid mixups and contamination.

(c) Equipment, including dust-control and other equipment, such as that used for holding and returning recovered or flush-out materials back into production, shall be maintained and operated in a manner to avoid contamination of the medicated premixes and to insure the integrity of the finished product.

(d) Competent and responsible personnel shall check actual against theoretical yield of a batch of medicated premix, and, in the event of any significant discrepancies, key personnel shall prevent distribution of the batch in question and other associated batches of medicated premixes that may have been involved in a mixup with it.

(e) Adequate procedures for cleaning of those parts of storage, mixing conveying and other equipment coming in contact with the drug component of the medicated premix shall be used to avoid contamination of medicated premixes.

(f) If there is sequential production of batches of a medicated premix containing the same drug component (or components) at the same or lower levels, there shall be sufficient safeguards to avoid any buildup above the specified levels of the drug components in any of the batches of the medicated premix.

(g) Production and control procedures shall include provision for discontinuing distribution of any medicated premix found by the assay procedures, or other controls performed to fail to conform to appropriate specifications. Distribution of subsequent production of such medicated premix shall not begin until it has been determined that proper control procedures have been established.

§ 226.42 Components.

(a) Drug components, including undiluted drugs and any intermediate mixes containing drugs used in the manufacture and processing of medicated premixes, shall be received, examined or tested, stored, handled, and otherwise controlled in a manner to maintain the integrity and identification of such articles. Appropriate receipt and inventory records shall be maintained for 2 years, and such records shall show the origin of any drug components, the manufacturer's control number (if any), the dates and batches in which they were used, and the results of any testing of them.

(b) Nondrug components shall be stored and otherwise handled in a manner to avoid contamination, including cross-contamination from manufacturing operations.

§ 226.58 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that the drug components and the medicated premixes conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications and a description of the test procedures used to check them for each kind of drug component used in the manufacture of medicated premixes. This may consist of the manufacturer's or supplier's statement of specifications and methods of analyses.

(b) The establishment of specifications for medicated premixes and a description of necessary laboratory test procedures to check such specifications.

(c) Assays which shall be made of representative samples of finished medicated premixes in accordance with the following schedule:

(1) Each batch of a medicated premix manufactured from an undiluted drug shall be assayed for its drug component(s).

(2) In the case of medicated premixes which are manufactured by dilution of medicated premix(es) assayed in accordance with paragraph (c)(1) of this section, each batch shall be assayed for its drug component(s) with the first five consecutive batches assaying within the limitations, followed thereafter by assay of representative samples of not less than 5 percent of all batches produced. When any batch does not assay within limitations, each batch should again be assayed until five consecutive batches are within limitations.

(d) A determination establishing that the drug components remain uniformly dispersed and stable in the medicated premix under ordinary conditions of shipment, storage, and use. This may consist of a determination on a medicated premix of substantially the same formula and characteristics. Suitable expiration dates shall appear on the labels of the medicated premixes when needed to assure that the articles meet the appropriate standards of identity, strength, quality, and purity at the time of use.

(e) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedure used. The official methods in "Methods of Analysis of the Association of Official Analytical Chemists,"[1] methods described in an official compendium, and any method submitted as a part of a food additive petition or new-drug application that has been accepted by the Food and Drug Administration shall be regarded as meeting this provision.

(f) Provisions for the maintenance of the results of any assays, including dates and endorsement of analysts. Such records shall be retained in the possession of the manufacturer and shall be maintained for a period of at least 2 years after distribution by the manufacturer of the medicated premix has been completed.

Subpart D—Packaging and Labeling

§ 226.80 Packaging and labeling.

(a) Packaging and labeling operations shall be adequately controlled:

(1) To assure that only those medicated premixes that have met the specifications established in the master-formula records shall be distributed.

(2) To prevent mixups during the packaging and labeling operations.

(3) To assure that correct labeling is employed for each medicated premix.

(4) To identify medicated premixes with lot or control numbers that permit determination of the history of the manufacture and control of the batch of medicated premix.

(b) Packaging and labeling operations shall provide:

(1) For storage of labeling in a manner to avoid mixups.

(2) For careful checking of labeling for identity and conformity to the labeling specified in the batch-production records.

(3) For adequate control of the quantities of labeling issued for use with the medicated premix.

(c) Medicated premixes shall be distributed in suitable containers to insure the safety, identity, strength, and quality of the finished product.

Subpart E—Records and Reports

§ 226.102 Master-formula and batch-production records.

(a) For each medicated premix, master-formula records shall be prepared, endorsed, and dated by a competent and responsible individual and shall be independently checked, reconciled, endorsed, and dated by a second competent

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540; Ben Franklin Station, Washington, DC 20044.

and responsible individual. The record shall include:

(1) The name of the medicated premix and a specimen copy of its label.

(2) The weight or measure of each ingredient, adequately identified, to be used in manufacturing a stated weight of the medicated premix.

(3) A complete formula for each batch size, or of appropriate size in the case of continuous systems to be produced from the master-formula record, including a complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristics; an accurate statement of the weight or measure of each ingredient, except that reasonable variations may be permitted in the amount of ingredients necessary in the preparation of the medicated premix, provided that the variations are stated in the master formula; an appropriate statement concerning any calculated excess of an ingredient; and a statement of the theoretical yield.

(4) Manufacturing instructions for each type of medicated premix produced on a batch or continuous operation basis, including mixing steps and mixing times that have been determined to yield an adequately mixed medicated premix; and in the case of medicated premixes produced by continuous production run, any additional manufacturing directions including, when indicated, the settings of equipment that have been determined to yield an adequately mixed medicated premix of the specified formula.

(5) Control instructions, procedures, specifications, special notations, and precautions to be followed.

(b) A separate batch-production and control record shall be prepared for each batch or run of medicated premix produced and shall be retained for at least 2 years after distribution by the manufacturer has been completed. The batch-production and control record shall include:

(1) Product identification, date of production, and endorsement by a competent and responsible individual.

(2) Records of each step in the manufacturing, packaging, labeling, and controlling of the batch, including dates, specific identification of drug components used, weights or measures of all components, laboratory-control results, mixing times, and the endorsements of the individual actively performing or the individual actively supervising or checking each step in the operation.

(3) A batch number that permits determination of all laboratory-control procedures and results on the batch and all lot or control numbers appearing on the labels of the medicated premix.

§ 226.110 Distribution records.

Complete records shall be maintained for each shipment of medicated premixes in a manner that will facilitate the recall, diversion, or destruction of the medicated premix, if necessary. Such records shall be retained for at least 2 years after the date of the shipment by the manufacturer and shall include the name and address of the consignee, the date and quantity shipped, and the manufacturing dates, control numbers, or marks identifying the medicated premix shipped.

§ 226.115 Complaint files.

Records shall be maintained for a period of 2 years of all written or verbal complaints concerning the safety or efficacy of each medicated premix. Complaints shall be evaluated by competent and responsible personnel and, where indicated, appropriate action shall be taken. The record shall indicate the evaluation and the action.

PART 229—CURRENT GOOD MANUFACTURING PRACTICE FOR CERTAIN OTHER DRUG PRODUCTS

Sec.

229.25 Whole blood (human), red blood cells (human), and allergenic products; drugs subject to licensing by the Food and Drug Administration.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049–1050 as amended, 1055–1056 as amended (21 U.S.C. 351, 371).

§ 229.25 Whole blood (human), red blood cells (human), and allergenic products; drugs subject to licensing by the Food and Drug Administration.

(a) The methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of the drugs whole blood (human), red blood cells (human), and allergenic products do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that any such drug meets the requirements of the act as to safety and has the identity and strength and meets the quality and purity characteristics, which it purports or is represented to possess, unless the manufacture, processing, packing, and holding of such drugs conform to the licensing and other requirements as to such drugs and the practices and standards of manufacture, processing, packing, and holding applicable to such drugs set forth in Part 640 of this chapter. Applications for licensing shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, Bldg. 29A, 9000 Rockville Pike, Bethesda, MD 20014.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

Subpart A—Drugs Regarded as Misbranded

Sec.

250.10 Oral prenatal drugs containing fluorides intended for human use.
250.11 Thyroid-containing drug preparations intended for treatment of obesity in humans.
250.12 Stramonium preparations labeled with directions for use in self-medication regarded as misbranded.

Subpart B—New Drug or Prescription Status of Specific Drugs

250.100 Amyl nitrite inhalant as a prescription drug for human use.
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250.102 Drug preparations intended for human use containing certain "coronary vasodilators."
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250.104 Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act.
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Subpart C—Requirements for Drugs and Foods

250.201 Preparations for the treatment of pernicious anemia.
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Subpart D—Requirements for Drugs and Cosmetics

250.250 Hexachlorophene, as a component of drug and cosmetic products.

Subpart E—Special Packaging Requirements

250.300 Nitroglycerin for human use; packaging and warnings.

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 (21 U.S.C. 371) unless otherwise noted.

Subpart A—Drugs Regarded as Misbranded

§ 250.10 Oral prenatal drugs containing fluorides intended for human use.

(a) The Food and Drug Administration finds that there is neither substantial evidence of effectiveness nor a general recognition by qualified experts that prenatal drug preparations containing fluorides promote tooth development in the fetus, prevent dental caries in the offspring, or prevent dental caries in pregnant women.

(b) Any such drug preparation that is so labeled, represented, or advertised will be regarded as misbranded and subject to regulatory proceedings unless such recommendations are covered by a new-drug application, including substantial evidence of effectiveness, approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act. Any such drug preparation that is labeled, represented, or advertised as containing fluorides as an active ingredient of the drug for prenatal use will similarly be regarded as misbranded and subject to regulatory proceedings.

(c) A completed and signed "Notice of Claimed Investigational Exception for a New Drug." Form FD–1571 set forth in § 312.1 of this chapter, must be submitted to cover clinical investigations designed to obtain evidence that such preparations are effective for such uses.

(d) Regulatory proceedings may be initiated with respect to drug preparations shipped within the jurisdiction of

the act that are contrary to provisions of this statement after 30 days from the date of publication of this statement in the FEDERAL REGISTER.

(Secs. 502 (a), (f), 505, 52 Stat. 1050, 1051, 1052, as amended; 21 U.S.C. 352 (a), (f), 355)

§ 250.11 Thyroid-containing drug preparations intended for treatment of obesity in humans.

(a) Investigation by the Food and Drug Administration has revealed that a large number of drug preparations containing thyroid or thyrogenic substances in combination with central nervous system stimulants, with or without one or more additional drug substances such as barbiturates or laxatives, are being marketed for or as adjuncts to the treatment, control, or management of obesity in humans. The Commissioner of Food and Drugs finds that the administration of such combinations for said purposes is without medical rationale except possibly in those relatively uncommon instances where the condition is directly related to hypothyroidism and there exists a concurrent need for appetite control (in such instances the safety and effectiveness of such combinations are not generally recognized). In particular, the Commissioner of Food and Drugs finds that neither the consensus of informed medical opinion nor clinical experience justifies any representation that such combinations are safe and effective in connection with the treatment, control, or management of obesity in patients having normal thyroid function.

(b) Combinations of thyroid or other thyrogenic drugs with central nervous system stimulants with or without other drug substances when offered for or as adjuncts to the treatment, control, or management of obesity not related to hypothyroidism are regarded as misbranded. Such combinations when offered for obesity in humans directly attributable to established hypothyroidism are regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(Secs. 201(p), 502, 52 Stat. 1041–42, 1050, as amended; 21 U.S.C. 321(p), 352).

§ 250.12 Stramonium preparations labeled with directions for use in self-medication regarded as misbranded.

(a) Stramonium products for inhalation have been offered for use in the therapy of the acute attacks of bronchial asthma for many years although their reliability and effectiveness are questionable. Recently, a significantly increased number of reports have come to the attention of the Food and Drug Administration showing that such products have been subject to abuse and misuse on a fairly large scale, mostly by young people, through oral ingestion for the purpose of producing hallucinations. Reports of such use have been received from physicians and police and other law enforcement authorities. Reports have also appeared in the public press and in medical journals.

(b) Labeling these products with a warning that they are not for oral ingestion has not been effective in protecting the public. Misuse of stramonium preparations can cause serious toxic effects including toxic delirium, visual disturbances, fever, and coma. A number of serious reactions have already occurred from the oral ingestion of such products.

(c) On the basis of this information, the Commissioner of Food and Drugs has concluded that such articles have a potentiality for harmful effect through misuse and are not safe for use except under the supervision of a physician. In the interest of public health protection, therefore, the Food and Drug Administration adopts the following policy:

(1) Preparations containing stramonium supplied from the leaves, seeds, or any other part of the plant in the form of a powder, pipe mixture, cigarette, or any other form, with or without admixture of other ingredients, will be regarded as misbranded if they are labeled with directions for use in self-medication.

(2) The Food and Drug Administration will, on request, furnish comment on proposed labeling limiting any such preparation to prescription sale.

(d) The labeling or dispensing of stramonium preparations contrary to this statement after 60 days following the date of its publication in the FEDERAL REGISTER may be made the subject of regulatory proceedings.

(Secs. 502 (a), (f), 503(b); 52 Stat. 1050–51, 1052, as amended; 21 U.S.C. 352 (a), (f), 353(b))

Subpart B—New Drug or Prescription Status of Specific Drugs

§ 250.100 Amyl nitrite inhalant as a prescription drug for human use.

(a) Amyl nitrite inhalant has been available over-the-counter for emergency use by the patient in the management of angina pectoris for a number of years. As a result of a proposed policy statement published August 25, 1967 (32 FR 12404), the Commissioner of Food and Drugs received reports of the abuse of this drug by those who do not require it for medical purposes. Additionally, comment included a great deal of concern expressed by individual physicians, medical associations, pharmaceutical associations, manufacturers, and State and local health authorities. Based on the information available, it is the opinion of the Commissioner of Food and Drugs, concurred in by the Food and Drug Administration Medical Advisory Board, that amyl nitrite inhalant is a drug with a potentiality for harmful effect and that it should be removed from over-the-counter status and restricted to sale on the prescription of a practitioner licensed by law to administer such drug.

(b) Therefore, amyl nitrite inhalant will be regarded as misbranded unless the labeling on or within the package from which the drug is to be dispensed bears adequate information for its safe and effective use by physicians, in accordance with § 201.100(c) of this chapter, and its label bears the legend "Caution: Federal law prohibits dispensing without prescription."

(c) Regulatory proceedings may be initiated with regard to the interstate shipment of amyl nitrite inhalant that is labeled, advertised, or dispensed contrary to this statement of policy if such act occurs after July 1, 1969.

(Sec. 503(b), 52 Stat. 1052, as amended; 21 U.S.C. 353(b))

§ 250.101 Amphetamine and methamphetamine inhalers regarded as prescription drugs.

(a) Recurring reports of abuse and misuse of methamphetamine (also known as desoxyephedrine) inhalers show that they have a potentiality for harmful effect and that they should not be freely available to the public through over-the-counter sale. From complaints by law-enforcement officials, health officials, individual physicians, parents, and others as well as from Food and Drug Administration investigations, it is evident that the wicks from these inhalers are being removed and the methamphetamine they contain is being used as a substitute for amphetamine tablets. Amphetamine tablets and amphetamine inhalers have been restricted to prescription sale because of their potentiality for harm to the user.

(b) It is the considered opinion of the Food and Drug Administration that, in order to adequately protect the public health, inhalers containing methamphetamine or methamphetamine salts (d-desoxyephedrine, or dl-desoxyephedrine, or their salts), as well as amphetamine inhalers should be restricted to prescription sale and should be labeled with the legend "Caution: Federal law prohibits dispensing without prescription."

(Secs. 503(b)(1)(B), 52 Stat. 1052 as amended; 21 U.S.C. 353(b)(1)(B))

§ 250.102 Drug preparations intended for human use containing certain "coronary vasodilators."

(a)(1) The Food and Drug Administration finds that the following "coronary vasodilators" are extensively regarded by physicians as safe and useful as employed under medical supervision for the management of angina pectoris in some patients:

Amyl nitrite.
Erythrityl tetranitrate.
Mannitol hexanitrate.
Nitroglycerin.
Potassium nitrite.
Sodium nitrite.

(2) Additionally, new-drug applications have been approved for products containing:

Inositol hexanitrate.
Isosorbide dinitrate.
Octyl nitrite.
Pentaerythritol tetranitrate.
Triethanolamine trinitrate biphosphate (trolnitrate phosphate).

(b) The Food and Drug Administration also finds that there is neither substantial evidence of effectiveness nor a general recognition by qualified experts

that such drugs are effective for any of the other purposes for which some such drugs are promoted to the medical profession in labeling and advertising. In particular, neither clinical investigations nor clinical experience justify any representations that such drugs are effective in the management of hypertension; in the management of coronary insufficiency or coronary artery disease, except for their anginal manifestations; or in the management of the post coronary state, except angina pectoris present after coronary occlusion and myocardial infarction.

(c) Any preparation containing such drugs that is labeled or advertised for any use other than management of angina pectoris, or that is represented to be efficacious for any other purpose by reason of its containing such drug, will be regarded by the Food and Drug Administration as misbranded and subject to regulatory proceedings, unless such recommendations are covered by the approval of a new-drug application based on a showing of safety and effectiveness.

(d) Any such drug in long-acting dosage form is regarded as a new drug that requires an approved new-drug application before marketing.

(e) Any of the drugs listed in paragraph (a)(2) of this section is regarded as a new drug that requires an approved new-drug application. Articles for which new-drug approvals are now in effect should be covered by supplemental new-drug applications as necessary to provide for labeling revisions consistent with this policy statement.

(Secs. 502(f), 505; 52 Stat. 1051, 1052, 21 U.S.C. 352(f), 355)

§ 250.103 Thorium dioxide for drug use.

(a) Thorium dioxide is a source of naturally occurring radioactivity that has been used over a period of years as a radiopaque medium. When thorium dioxide is injected, it is permanently stored in the body. Because of its radioactivity, this storage causes scarring and carcinogenesis in the area of storage. There are reports in the medical literature of malignancy and deaths resulting from the injection of thorium dioxide. Therefore, the use in man of drugs containing thorium dioxide is justified only when this drug has a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age. The administration of the drug to food-producing animals cannot be justified since it may result in residues of the drug in food.

(b) Drugs containing thorium dioxide are unsafe and are regarded as misbranded within the meaning of section 502 (f) (1), (2), and (j) of the Federal Food, Drug, and Cosmetic Act when labeled or advertised for administration to man except when they have a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age.

(c) Drug preparations containing thorium dioxide may be approved for marketing on the basis of new-drug applications containing labeling bearing, in addition to other requirements, information to the following effect, which differs substantially from the labeling that has been employed in the past in the marketing of such drugs:

(1) *Warning.* For use only when this drug has a unique clinical usefulness and there is substantial evidence of limited life expectancy by reason of disease or advanced age. Not for administration to food-producing animals.

(2) *Precautions.* Special precautions should be taken to prevent soft tissue extravasation of the injected material. Precautions should be taken to prevent injection of thorium dioxide into the subarachnoid space.

(3) *Indications for use.* For demonstration of primary or secondary tumors in the liver; for the delineation of the wall of a cystic malignant brain tumor when such delineation is deemed advantageous for purposes of progressive monitoring in the course of therapy.

(4) *Dosage.* Minimum amount necessary for adequate visualization should be utilized.

(d) A new-drug application will be regarded as approvable if it contains appropriate labeling conforming to the provisions of paragraph (c) of this section and satisfactory information of the kinds required by items 2, 3, 4, 6, 7, and 9 of the new-drug application form contained in § 314.1(c) of this chapter.

(Secs. 502(f), 52 Stat. 1050 as amended; 21 U.S.C. 352(f); Secs. 402, 406, 52 Stat. 1046, as amended, 1049, as amended; 21 U.S.C. 342, 346)

§ 250.104 Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act.

(a) As a result of reported poisonings from salt substitutes containing lithium chloride, under date of March 8, 1949, the Food and Drug Administration announced that it would regard each salt substitute as a new drug within the meaning of section 201 (p) of the Federal Food, Drug, and Cosmetic Act, and that interstate distribution of each salt substitute should be discontinued until a new-drug application had been filed and become effective. Substantial information concerning the safety of many of the ingredients used in salt substitutes has been developed and published since the announcement was made. It is now possible to evaluate the safety of many individual salt substitutes and to determine whether they are new drugs requiring effective applications prior to distribution in interstate commerce.

(b) The Food and Drug Administration no longer regards all salt substitutes as new drugs. Upon request, the Administration will express its opinion whether a new-drug application is necessary for any particular product if complete information concerning its composition and proposed labeling is submitted.

§ 250.105 Gelsemium-containing preparations regarded as prescription drugs.

It is the consensus of informed medical opinion that the margin of safety between the therapeutic and toxic concentration of gelsemium is narrow and it is difficult to predict the point at which the dose will be toxic. Very small doses may cause toxic symptoms. It is therefore the view of the Food and Drug Administration that gelsemium is not a proper ingredient in any product that is to be sold without prescription. Accordingly, any drug containing gelsemium will be regarded as misbranded under section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act if its label fails to bear in a prominent and conspicuous fashion the statement "Caution: Federal law prohibits dispensing without prescription."

§ 250.106 Cobalt preparations intended for use by man.

(a) On January 17, 1967 (21 CFR 3.48; 32 FR 449), the Commissioner of Food and Drugs issued a revised statement of policy with respect to the status of cobalt-containing drug preparations intended for use by man, which revision was to be modified as needed following consideration of such drugs by a panel of hematologists. A panel consisting of authorities in the field of hematology met on March 8, 1967, with representatives of the Medical Advisory Board for the Food and Drug Administration to consider the status of cobalt-containing drugs and the following findings and recommendations were made:

(1) Cobalt salts are not suitable for over-the-counter sale to the public for the treatment of iron-deficiency anemia. They are associated with toxic effects and offer no advantage over iron alone.

(2) Potential toxic effects of these salts includes liver damage, claudication, myocardial damage, thyroid hyperplasia, hypothyroidism, dermatitis, nausea, and anorexia.

(3) Cobalt salts are not generally recognized as safe or effective therapy for any disease condition.

(b) On the basis of the available evidence and the findings and recommendations of the representatives of the Medical Advisory Board, the Commissioner of Food and Drugs finds and determines with respect to cobalt-containing drug preparations intended for use by man, except radioactive forms of cobalt and its salts and cobalamin and its derivatives, that:

(1) Such articles, because of their potential for causing toxic effects, are not suitable for over-the-counter use in iron-deficiency anemia; any such article that is labeled, represented, or advertised for over-the-counter use in the prevention or treatment of iron-deficiency anemia will be regarded as subject to regulatory proceedings.

(2) Such articles are not generally recognized by qualified experts as safe or effective therapeutic agents for iron-

deficiency anemia or for any condition whether for over-the-counter sale or for prescription dispensing; any such article labeled, represented, or advertised for any condition will be regarded as subject to regulatory proceedings unless such recommendations are covered by a new-drug application approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and based on a showing of safety and effectiveness.

(3) Cobalt salts added to drugs in small amounts are not effective for any purpose and should be removed.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug," Form FD-1571 set forth in § 312.1 of this chapter, must be submitted to cover clinical investigations to obtain evidence that such preparations are safe and effective for any purpose.

(d) (1) For such preparations for which new-drug approvals are in effect, supplemental new-drug applications may be submitted if changes consistent with this policy statement can be effected thereby. If the composition and labeling of an article are such that the cobalt is not significant in relation to the labeling claims, it will be permissible for the applicant to remove the cobalt salt from the formulation, delete all references to it in the labeling and resume marketing the reformulated drug, provided that a supplement is submitted within 30 days from the date of publication of this policy statement in the FEDERAL REGISTER furnishing full information regarding such changes, including the date on which such changes are being effected.

(2) Applicants holding other approved new-drug applications for such preparations should submit, within 30 days, a written statement waiving opportunity for a hearing preliminary to withdrawing approval of the application unless the applicant wishes to avail himself of the opportunity for a hearing.

(e) Regulatory proceedings may be initiated with respect to any drug within the jurisdiction of the act that is contrary to the provisions of:

(1) Paragraph (b) of this section and shipped after the date of publication of this policy statement in the FEDERAL REGISTER.

(2) Paragraphs (c) and (d) of this section and shipped after 30 days from the date of publication of this policy statement in the FEDERAL REGISTER.

(Secs. 502 (a), (f), (j), 505, 52 Stat. 1050–1053, as amended; 21 U.S.C. 352 (a), (f), (j), 355)

§ 250.107 Dimethylsulfoxide (DMSO) preparations; clinical testing and investigational use.

(a) (1) Chronic-toxicity studies with dimethylsulfoxide (DMSO) in animals, including dogs, rabbits, and swine, reported by a consulting laboratory in England and by a number of laboratories in the United States show that the administration of dimethylsulfoxide (DMSO) causes changes in the refractive index of the lens of the eyes of such animals. On the basis of these reports, clinical testing of dimethylsulfoxide (DMSO) preparations was discontinued for a time and later resumed under restricted conditions.

(2) An adequate, controlled human toxicity study (Phase I) involving short-term cutaneous application of 1 gram of dimethylsulfoxide (DMSO) per kilogram of body weight daily for 14 consecutive days has recently been completed. Data obtained, not previously available, show that when dimethylsulfoxide (DMSO) was applied topically to the skin of healthy volunteers, it did not produce adverse effects upon the eyes of the subjects. Mild, apparently reversible, changes were seen suggesting that the drug may have some effect upon the liver and upon the hemopoietic system in some subjects.

(b) A comprehensive evaluation of all available data on dimethylsulfoxide (DMSO) preparations justifies further clinical investigation of the drug in treating certain serious conditions. Although reports concerning the use of dimethylsulfoxide (DMSO) in relatively benign conditions are equivocal regarding its efficacy, short-term clinical use has been established as reasonably safe by adequate Phase I studies. Under appropriate protocols, further short-term clinical investigations in the treatment of such benign conditions can be justified.

(c) No person may ship dimethylsulfoxide (DMSO) within the jurisdiction of the Federal Food, Drug, and Cosmetic Act for clinical testing in man until a "Notice of Claimed Investigational Exemption for a New Drug," pursuant to § 312.1 of this chapter, is on file with the Food and Drug Administration and all the following conditions are met:

(1) Proposed long-term clinical studies (Phase II) are restricted to the use of DMSO to cutaneous application in serious conditions, such as the incapacitating arthropathies, scleroderma, dermatomyositis, and intractible pain due to malignancy, are to be conducted in medical centers having adequate facilities and well-trained, experienced medical personnel, and are to include the following essential conditions in the study protocol. All subjects will receive a full examination including:

(i) An eye evaluation by an ophthalmologist to include actual refractive error measurements and slit-lamp findings as well as other parameters of the ocular examination prior to receiving the drug, at intervals not exceeding 3 months during the study and 3 months after discontinuing the drug.

(ii) Liver function tests and a complete blood count (CBC) prior to receiving the drug, at intervals not exceeding 4 weeks during the study and 4 weeks after discontinuing the drug.

(2) Proposed short-term studies (Phase II) restrict the use of dimethylsulfoxide (DMSO) to cutaneous application for not more than 14 days in closely monitored investigations with appropriate control groups, that may include studies of use in such conditions as acute musculoskeletal conditions (acute arthritis, peri arthritis, capsulitis, bursitis, tendonitis, synovitis, and post-traumatic lesions) and soft tissue injuries. The proposed studies shall provide for pretreatment liver function studies and a complete blood count (CBC), to be repeated within 7 days after commencing treatment and at the conclusion of the study. Routine monitoring of effects upon the eye is not required.

(3) All proposals must show that patient consent requirements will be carefully observed and shall include a commitment that patients will be fully informed of: The effects of dimethylsultoxide (DMSO) in animals, the possibility that these may occur in humans, and the known possible effects of the drug in humans.

(d) Dimethylsulfoxide (DMSO) preparations may be shipped within the jurisdiction of the act.

(1) For tests in vitro and in laboratory research animals, in accord with § 312.9 (a) and § 511.1(a) of this chapter.

(2) For clinical investigations in animals in accord with § 511.1(b) of this chapter.

(Secs. 505, 512, 52 Stat. 1052, 1053, as amended; 82 Stat. 343-351; 21 U.S.C. 355, 360b)

§ 250.108 Potassium permanganate preparations as prescription drugs.

(a) There have been a number of reports in the medical literature of serious injuries to women resulting from the misuse of potassium permanganate in an effort to induce abortion. Reports from physicians who have treated such cases show that the injuries are commonly caused by introducing tablets or crystals of potassium permanganate into the vagina. Experience with these cases shows that such use of potassium permanganate is not effective in producing abortion, but that instead the drug produces serious and painful injury to the walls of the vagina, causing ulcers, massive hemorrhage, and infection. Such dangerous and useless employment of potassium permanganate is apparently encouraged among the misinformed by the mistaken idea that the vaginal bleeding caused by the corrosive action of the drug indicates a termination of pregnancy, which it does not.

(b) Potassium permanganate is a strong oxidizing agent, a highly caustic, tissue-destroying chemical, and a poison. There are no circumstances under which crystals and tablets of potassium permanganate constitute safe dosage forms for use in self-medication. It is the consensus of informed medical opinion that the only dosage forms of potassium permanganate known to be safe for use in self-medication are aqueous solutions containing not more than 0.04 percent potassium permanganate. Such solutions are safe for use in self-medication only by external application to the skin.

(c) In view of the very real potentiality for harmful effect, and the actual injuries caused by the misuse of potassium permanganate, the Food and Drug Administration believes that in order adequately to protect the public health:

(1) Potassium permanganate and potassium permanganate tablets intended

for human use are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and should be restricted to prescription sale. Such drugs will be regarded as misbranded if at any time prior to dispensing the label fails to bear the legend, "Caution: Federal law prohibits dispensing without prescription."

(2) Potassium permanganate labeled for use as a prescription component in human drugs under the exemption provided in § 201.120 of this chapter or labeled for manufacturing use under the exemption provided in § 201.122 of this chapter will be regarded as misbranded unless the label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

(3) These drugs will be regarded as misbranded when intended for veterinary use unless the label bears the legend, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian"; *Provided, however,* That this shall not apply to a drug labeled and marketed for veterinary use if such drug contains not more than 50 percent of potassium permanganate and includes other ingredients which make it unsuitable for human use and unlikely that the article would be used in an attempt to induce abortion.

(4) Any preparation of potassium permanganate intended for over-the-counter sale for human use internally or by application to any mucous membranes or for use in the vagina will be regarded as misbranded under the provisions of section 502(f) (1) and (2) and section 502(j) of the act.

(5) Any other preparation of potassium permanganate intended for over-the-counter sale for human use will be regarded as misbranded under section 502(f)(1) and (2) and section 502(j) of the act unless, among other things, all of the following conditions are met:

(i) It is an aqueous solution containing not more than 0.04 percent potassium permanganate.

(ii) The label and labeling bear, in juxtaposition with adequate directions for use, clear warning statements designated as "Warning," and to the effect: "Warning—For external use on the skin only. Severe injury may result from use internally or as a douche. Avoid contact with mucous membranes."

(d) The labeling or dispensing of any potassium permanganate preparations intended for drug use within the jurisdiction of the Federal Food, Drug, and Cosmetic Act contrary to this statement after 60 days from the date of its publication in the FEDERAL REGISTER may be made the subject of regulatory proceedings.

(Secs. 502(f) (1), (2), (j), 503(b)(1), 705(b), 52 Stat. 1050, 1051, 1052, as amended, 1057; 21 U.S.C. 352(f) (1), (2), (j), 353(b)(1), 375(b))

§ 250.109 Vitamin A preparations for oral use as drugs.

(a) Vitamin A is an essental nutrient for humans. It is widely recognized that large amounts of vitamin A can cause adverse effects, some of which are serious. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin A is 1500 International Units, (IU) for infants, 2500 IU for children under 4 years of age, 5000 IU for adults and children 4 or more years of age, and 8000 IU for pregnant or lactating women.

(b) In view of the toxicity of excessive consumption of vitamin A, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin A in excess of 10,000 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

(1) The label bears the legend, "Caution: Federal law prohibits dispensing without a prescription"; and

(2) The labeling bears full disclosure information as required by § 201.100(c)(1) of this chapter, and especially appropriate warnings regarding vitamin A toxicity.

(c) Preparations containing 10,000 or less IU of vitamin A per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 10,000 IU.

(Secs. 502(a), (f), and (j), 503(b), 701(a), 52 Stat. 1050–1052, as amended, 1055; 21 U.S.C. 352(a), (f), and (j), 353(b), 371(a))

§ 250.110 Vitamin D preparations for oral use as drugs.

(a) Vitamin D is an essential nutrient for humans. It is widely recognized that vitamin D, when ingested daily in large amounts, is toxic. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin D is 400 International Units (IU).

(b) In view of the toxicity of the excessive consumption of vitamin D, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin D in excess of 400 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

(1) The label bears the legend, "Caution: Federal law prohibits dispensing without a prescription"; and

(2) The labeling bears full disclosure information as required by § 201.100(c)(1) of this chapter, and especially appropriate warnings regarding vitamin D toxicity.

(c) Preparations containing 400 or less IU of vitamin D per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 400 IU.

(d) Foods which are represented for use solely under medical supervision to meet nutritional requirements of persons with poor vitamin D absorption may contain vitamin D not in excess of 1000 IU per dosage unit or recommended daily intake.

(Secs. 502(a), (f), and (j), 503(b), 701(a), 52 Stat. 1050–1052, as amended, 1055; 21 U.S.C. 352(a), (f), and (j), 353(b), 371(a))

Subpart C—Requirements for Drugs and Foods

§ 250.201 Preparations for the treatment of pernicious anemia.

(a) The ninth announcement of the Anti-anemia Preparations Advisory Board of the United States Pharmacopeia is concerned with the status of the treatment of pernicious anemia. It clearly presents the following facts:

(1) The Sixteenth Revision of the Pharmacopeia of the United States, which became official on October 1, 1960, does not include preparations intended for the treatment of pernicious anemia by oral administration.

(2) The U.S.P. unit for anti-anemia preparations no longer has any significance.

(3) The U.S.P. Anti-anemia Preparations Advisory Board was disbanded.

(b) On the basis of the scientific evidence and conclusions summarized in the statement of the U.S.P. Anti-anemia Preparations Advisory Board as well as pertinent information from other sources, the Commissioner of Food and Drugs finds it is the consensus of well informed medical opinion that:

(1) The parenteral administration of cyanocobalamin or vitamin B_{12} is generally recognized as a fully effective treatment of pernicious anemia. Parenteral cyanocobalamin preparations have not been and are not authorized for use except by or on the prescription of a duly licensed medical practitioner.

(2) Some patients afflicted with pernicious anemia do not respond to orally ingested products. There is no known way to predict which patients will fail to respond or will cease to respond to the treatment of pernicious anemia with orally ingested preparations.

(3) The substitution of a possibly inadequate treatment, such as the ingestion of oral preparations of vitamin B_{12} with intrinsic factor concentrate, in place of parenteral vitamin B_{12} products for a disease condition as serious as pernicious

anemia cannot be regarded as safe in all cases.

(4) The development of the classical symptoms of pernicious anemia that would cause a person to seek medical attention may in some cases be delayed by oral ingestion of intrinsic factor. Pernicious anemia is a disease that is associated, among other things, with a higher than normal incidence of cancer of the stomach and that for the safety of the patient, requires continuous expert medical supervision.

(5) With inadequate treatment there may be markedly deleterious effects on the nervous system. It is well established that whereas the development of anemia is completely reversible with adequate treatment, the involvement of the nervous system may not be completely reversible and thus may result in permanent damage.

(6) Some hematologists prescribe oral preparations of vitamin B_{12} in the treatment of pernicious-anemia patients.

(7) Intrinsic factor and intrinsic factor concentrate serve no known useful therapeutic or nutritive purpose except to the extent that they do increase the gastrointestinal absorption of vitamin B_{12} in patients with a deficiency or absence of intrinsic factor, which may eventually lead to pernicious anemia. This conclusion does not apply to diagnostic procedures using radioactive cyanocobalamin.

(8) Medical expertise is required for the diagnosis as well as the management of pernicious anemia.

(c) The Eleventh Edition of The National Formulary and its first Interim Revision include monographs for oral preparations of vitamin B_{12} with intrinsic factor concentrate, establish a unit of vitamin B_{12} with intrinsic factor concentrate, and provide for a National Formulary Anti-anemia Preparations Advisory Board to assign the potency of such preparations. This provides for the availability of such oral preparations, standardized within the meaning of the broad limits characteristic of the evaluation of such preparations.

(d) Any drug that is offered for or purports to contain intrinsic factor or intrinsic factor concentrate will be regarded as misbranded within the meaning of section 503(b) of the Federal Food, Drug, and Cosmetic Act unless it is labeled with the legend "Caution—Federal law prohibits dispensing without prescription."

(e) Any drug for oral ingestion intended, represented, or advertised for the prevention or treatment of pernicious anemia or which purports to contain any substance or mixture of substances described in paragraph (d) of this section (other than diagnostic drugs containing radioactive cyanocobalamin) will be regarded as misbranded under sections 502 (f) (2) and (j) of the act unless its labeling bears a statement to the effect that some patients afflicted with pernicious anemia may not respond to the orally ingested product and that there is no known way to predict which patients will respond or which patients may cease to respond to the orally ingested products. The labeling shall also bear a statement that periodic examinations and laboratory studies of pernicious-anemia patients are essential and recommended.

(f) Under section 409 of the Federal Food, Drug, and Cosmetic Act, intrinsic factor and intrinsic factor concentrate are regarded as food additives. No food additive regulation nor existing extension of the effective date of section 409 of the act authorizes these additives in foods, including foods for special dietary uses. Any food containing added intrinsic factor or intrinsic factor concentrate will be regarded as adulterated within the meaning of section 402(a) (2) (C) of the act.

(g) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the act contrary to the provisions of this policy statement after the 180th day following publication of this statement in the FEDERAL REGISTER.

(Secs. 402, 502, 503, 52 Stat. 1051, 1052 as amended; 65 Stat. 648, 72 Stat. 1784; 21 U.S.C. 342, 352, 353)

§ 250.203 Status of fluoridated water and foods prepared with fluoridated water.

(a) The program for fluoridation of public water supplies recommended by the Department of Health, Education, and Welfare, through the Public Health Service, contemplates the controlled addition of fluorine at a level optimum for the prevention of dental caries.

(b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. Nevertheless, a substantial number of inquiries have been received concerning the status of such water under the provisions of the act and the status, in interstate commerce, of commercially prepared foods in which fluoridated water has been used.

(c) The Department of Health, Education, and Welfare will regard water supplies containing fluorine, within the limitations recommended by the Public Health Service, as not actionable under the Federal Food, Drug, and Cosmetic Act. Similarly, commercially prepared foods within the jurisdiction of the act, in which a fluoridated water supply has been used in the processing operation, will not be regarded as actionable under the Federal law because of the flourine content of the water so used, unless the process involves a significant concentration of fluorine from the water. In the latter instance the facts with respect to the particular case will be controlling.

Subpart D—Requirements for Drugs and Cosmetics

§ 250.250 Hexachlorophene, as a component of drug and cosmetic products.

(a) *Antibacterial component.* The use of hexachlorophene as an antibacterial component in drug and cosmetic products has expanded widely in recent years. It is used in such products because of its bacteriostatic action against gram-positive organisms, especially against strains of staphylococcus; however, hexachlorophene offers no protection against gram-negative infections. In addition the antibacterial activity depends largely on repeated use. A notice published in the FEDERAL REGISTER of April 4, 1972 (37 FR 6775), invited data on OTC antimicrobial ingredients, including hexachlorophene, for review by an OTC Drug Advisory Review Panel to be convened under the procedures set forth in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464). This statement of policy will remain in effect unless and until replaced by a monograph resulting from the OTC Drug Advisory Review Panel.

(b) *Adverse effects.* Though considered safe for many years, recent information has become available associating hexachlorophene with toxic effects, including deaths. Studies have shown that toxic amounts of hexachlorophene can be absorbed through the skin of humans, especially the skin of premature babies or damaged skin. Human toxicity reports include data on symptomatology, blood

and tissue levels of hexachlorophene, and descriptions of neuropathologic lesions. Recent infant deaths due to use of baby powder accidentally contaminated with 6 percent hexachlorophene have occurred. The accumulated evidence of toxicity is sufficient to require that continued marketing of hexachlorophene containing products be carefully defined in order to protect consumers.

(c) *Prescription drugs.* (1) Because of their potential for harmful effect, drugs containing hexachlorophene, other than as a preservative as described below, are not considered to have been shown to be safe and effective, are regarded as new drugs requiring approved new drug applications, and would be misbranded for over-the-counter distribution. In the interest of public health protection, hexachlorophene containing drugs will be regarded as misbranded and subject to regulatory proceedings unless the label bears the legend "Caution: Federal law prohibits dispensing without a prescription," and the labeling on or within the package from which the drug is to be dispensed bears adequate information for its safe and effective use by practitioners, in accord with § 201.100(c) of this chapter.

(2) The Food and Drug Administration recognizes that hexachlorophene is useful as a bacteriostatic skin cleanser. It further concludes that the margin of safety is such that products containing hexachlorophene may appropriately be used within clearly delineated conditions of use.

(3) In order for such drugs to bear adequate information for safe and effective use the following statements are representative of the type of labeling for products shown to be effective bacteriostatic skin cleansers. Labeling for products other than bacteriostatic skin cleansers will be determined through the new drug procedures based on the available data.

(i) In the labeling other than on the immediate container label.

INDICATIONS

1. Bacteriostatic skin cleanser for surgical scrubbing or handwashing as part of patient care.

2. For topical application to control an outbreak of gram-positive infection where other infection control procedures have been unsuccessful. Use only as long as necessary for infection control.

CONTRAINDICATIONS

1. Not for use on burned or denuded skin or on mucous membranes.

2. Not for routine prophylactic total body bathing.

WARNINGS

Rinse thoroughly after use. Patients should be closely monitored and use should be immediately discontinued at the first sign of any of the symptoms described below.

Hexachlorophene is rapidly absorbed and may produce toxic blood levels when applied to skin lesions such as ichthyosis congenita or the dermatitis of Letterer-Siwe's syndrome or other generalized dermatologic conditions. Application to burns has also produced neurotoxicity and death.

Infants have developed dermatitis, irritability, generalized clonic muscular contractions and decerebrate rigidity following application of a 6 percent hexachlorophene powder. Examination of brainstems of these infants revealed vacuolization like that which can be produced in newborn experimental animals following repeated topical application of 3 percent hexachlorophene. Moreover, a study of histologic sections of premature infants who died of unrelated causes has shown a positive correlation between hexachlorophene baths and lesions in white matter of brains.

(ii) On the immediate container label prominently displayed and in bold print:

"Special Warning: This compound may be toxic if used other than as directed. Rinse thoroughly after use. Monitor patients closely for toxicity symptoms."

(4) Marketing of products for the indications listed in paragraph (c)(3) of this section may be continued if all the following conditions are met after the effectve date of this section (9-27-72):

(i) The product is labeled with the prescription legend and adequate information for safe and effective use as set forth in paragraph (c)(3) of this section.

(ii) Within 30 days, or by (10-27-72) the holder of an approved new drug application submits a supplement to provide for the revised label and full disclosure labeling. As the label and labeling will have been put into use, the supplement should be submitted under the provision of § 314.8(d) of this chapter.

(iii) Within 30 days, or by (10-27-72) the holder of an approved new drug application submits a supplement to provide for a revised formulation where appropriate to comply with this order.

(iv) Within 90 days, or by (12-26-72) the holder of an approved new drug application submits a supplement containing blood level data obtained from use of the drug as recommended, unless such information is a part of the new drug application file.

(v) Within 90 days, or by (12-26-72), the manufacturer or distributor of such a drug for which a new drug approval is not in effect submits a new drug application in accord with § 314.1 of the new drug regulations (21 CFR 314.1), including blood level data obtained from use of the drug as recommended.

(5) Prescription drug products may contain hexachlorophene as part of an effective preservative system only under the conditions and limitations provided for under paragraph (d) of this section.

(d) *Over-the-counter (OTC) drugs.* Over-the-counter drug products, other than those which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, may contain hexachlorophene only as part of an effective preservative system, at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. Such use of hexachlorophene shall be limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. This use of hexachlorophene will not, by itself, require an approved new drug application. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application, which must be submitted within the time set out in paragraph (c)(4) of this section.

(e) *Cosmetics.* Hexachlorophene may be used as a preservative in cosmetic products other than those which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. Such use of hexachlorophene shall be limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. The component of a preservative system, whether hexachlorophene or other antimicrobial agent, should be selected on the basis of the effect on the total microbial ecology of the product, not merely on gram-positive bacteria.

(1) Adequate safety data do not presently exist to justify wider use of hexachlorophene in cosmetics.

(2) Antibacterial ingredients used as substitutes for hexachlorophene in cosmetic products, and finished cosmetic products containing such ingredients, shall be adequately tested for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing may be adulterated and will in any event be deemed misbranded unless it contains a conspicuous front panel statement that the product has not been adequately tested for safety and may be hazardous.

(f) *Content statement.* All reference to hexachlorophene limit in this order is on a weight-in-weight (w/w) basis. Quantitative declaration of hexachlorophene content on the labeling of the products, where required, shall be on a w/w basis.

(g) *Shipments of products.* Shipments of products falling within the scope of paragraph (c), (d), or (e) of this section which are not in compliance with the guidelines stated herein shall be the subject of regulatory proceedings after the effective date of the final order.

(h) *Prior notices.* This order preempts any conditions for marketing products set forth in the following prior notices.

1. DESI No. 4749 (34 FR 15389, October 2, 1969), "Certain OTC Drugs for Topical Use."

2. DESI No. 2855 (35 FR 12423, August 4, 1970), "Certain Mouthwash and Gargle Preparations."

3. DESI No. 8940 (36 FR 14510, August 6, 1971), "Topical Cream Containing Pyrilamine Maleate, Benzocaine, Hexachlorophene, and Cetrimonium Bromide."

4. DESI No. 6615 (36 FR 18022, September 8, 1971), "Deodorant/Antiperspirant."

5. DESI No. 6270 (36 FR 23330, December 8, 1971), "Certain Preparations Containing Hexachlorophene".

(Secs. 201(n), 502(a), (f), (j), 503(b), 505, 601(a), 602 (a), (c), 701(a), 52 Stat. 1041, 1050-55 as amended; 21 U.S.C. 321(n), 352 (a), (f), (j), 353(b), 355, 361(a), 362 (a), (c), 371(a))

Subpart E—Special Packaging Requirements

§ 250.300 Nitroglycerin for human use; packaging and warnings.

(a) Nitroglycerin preparations have long been used under medical supervision for the management of angina pectoris. The volatility of nitroglycerin has been recognized for many years, and consequently packaging requirements for preparations containing this drug provide for storage in tight containers. When glass containers were used almost exclusively this limited packaging requirement was probably adequate, even though no provisions were made to inform the user that his filled prescription should be kept in a tight container. The recent trend toward packaging containers made of materials other than glass presents new problems because of the different properties of such materials. Recent information, including laboratory data, available to the Food and Drug Administration indicates that improper packaging of the drug either before or after dispensing to the patient will likely result in a substantial loss of nitroglycerin. The Food and Drug Administration's studies indicate that commonly used plastic containers and certain kinds of strip packaging allow appreciable evaporation of nitroglycerin from nitroglycerin tablets.

(b) The Commissioner views these findings as raising serious questions concerning the packaging practices for nitroglycerin preparations and their relationship to the potency characteristics of the drug at the time of dispensing and use by the patient. Stability studies with containers other than glass are needed before reasonable assurance can be made that packaging and storage in these containers does not contribute to the loss of nitroglycerin in any dosage form.

(c) The following packaging and labeling is required for preparations containing nitroglycerin:

(1) Preparations containing nitroglycerin shall be packaged in tight (as defined in the United States Pharmacopeia) glass containers with tightly fitting metal screw caps or in containers of materials approved by the Food and Drug Administration. No more than 100 dosage units shall be packaged in any such container.

(2) In addition to other required labeling information, the following shall be displayed on the container in a prominent and conspicious manner:

(i) A statement directed to the pharmacist that the drug should be stored at controlled room temperature (as defined in the United States Pharmacopeia) and dispensed only in the original, unopened container.

(ii) A warning statement to the patient as follows: "Warning. To prevent loss of potency, keep these tablets in the original container. Close tightly immediately after each use."

(d) The holder of an approved new drug application for a nitroglycerin preparation should either submit a supplement to his new-drug application under the provisions of § 314.8(d) of this chapter to provide for use of glass containers and labeling as described in this section or submit data or reference to data adequate to show that such changes are not necessary. The labeling and packaging requirements of this section must be met unless an approved supplement to a new-drug application provides for alternate packaging methods.

(e) For containers other than glass, approval must be obtained from the Food and Drug Administration on the basis of data submitted by interested persons establishing its suitability for packaging of nitroglycerin. Upon review and approval of alternate packaging this section will be amended to provide for such packaging. The data should be submitted to the Division of Cardiopulmonary Renal Drug Products (BD–110), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Such data should be accompanied with a request that an exemption be made as provided for in this paragraph. Until approval for containers other than glass is given by the Food and Drug Administration, such alternate containers are not considered suitable for the packaging of nitroglycerin preparations.

(f) Any nitroglycerin drug preparation which is shipped or dispensed within the jurisdiction of the act and contrary to the provisions of this section after its effective date will be the subject of regulatory proceedings.

(Secs. 501, 502, 505, 52 Stat. 1049–53 as amended, 1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 351, 352, 355)

PART 290—CONTROLLED DRUGS

Subpart A—General Provisions

Sec.

290.5 Drugs; statement of required warning.
290.6 Spanish-language version of required warning.
290.10 Definition of emergency situation.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs

290.35 Methadone in the maintenance treatment of narcotic addicts.

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended; 21 U.S.C. 371, unless otherwise noted.

Subpart A—General Provisions

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a "controlled substance" in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, § 290.5, promulgated under section 503(b) of the Federal Food, Drug, and Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." The Spanish version of this is: "Precaucion: La ley Federal prohibe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada."

(Secs. 502, 503; 53 Stat. 854, 65 Stat. 648; 21 U.S.C. 352, 353)

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term "emergency situation" means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act; and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B—[Reserved]

Subpart C—Requirements for Specific Controlled Drugs

§ 290.35 Methadone in the maintenance treatment of narcotic addicts.

(a) The Food and Drug Administration and the Drug Enforcement Administration recognize that the investigational use of methadone requiring the prolonged maintenance of narcotic dependence as part of a total treatment effort has shown promise in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied. It is further felt that additional research is urgently needed so that data may be accumulated which will permit sound determinations of safety, efficacy, and necessary procedural safeguards.

(b) Therefore, the Commissioner of Food and Drugs and the Director of the Drug Enforcement Administration, Department of Justice agree that interested professionals, municipalities, and organizations should be allowed to conduct further research in this area within a framework of adequate controls designed to protect the individual patients and the community. To facilitate this purpose, the Food and Drug Administration and the Drug Enforcement Administration, Department of Justice have jointly agreed upon acceptable criteria and guidelines which are set forth in pro-

posed 21 CFR 1319.505. In addition such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

(Sec. 505, 52 Stat. 1052–53, as amended; 21 U.S.C. 355)

PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

Subpart A—General Provisions

Sec.
299.3 Definitions and interpretations.
299.4 Established names for drugs.
299.5 Drugs; compendial name.

Subpart B—Designated Names

299.20 Drugs; official names.

AUTHORITY: Secs. 508, 701(a), 52 Stat. 1055, 76 Stat. 1789; 21 U.S.C. 358, 371(a), unless otherwise noted.

Subpart A—General Provisions

§ 299.3 Definitions and interpretations.

(a) As used in this Part 299, "act" means the Federal Food, Drug, and Cosmetic Act, sections 201–902, 52 Stat. 1040 (21 U.S.C. 321–392), with all amendments thereto.

(b) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this Part 299.

(c) The term "official name" means, with respect to a drug or ingredient thereof, the name designated in this Part 299 under section 508 of the act as the official name.

§ 299.4 Established names for drugs.

(a) Section 508 of the Federal Food, Drug, and Cosmetic Act (added by the Kefauver-Harris Drug Amendments of 1962; Public Law 87–781) authorizes the Commissioner of Food and Drugs to designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Section 502(e) of the act (as amended by said Drug Amendments) prescribes that the labeling of a drug must bear its established name, if there is one, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula) and, if the drug is fabricated from two or more ingredients, the established name of each active ingredient.

(b) The term "established name" is defined in section 502(e)(2) of the act as (1) an official name designated pursuant to section 508 of the act; (2) if no such official name has been designated for the drug and the drug is an article recognized in an official compendium, then the official title theretof in such compendium; and (3) if neither paragraph (b) (1) nor (2) of this section applies, then the common or usual name of the drug.

(c) The Food and Drug Administration recognizes the skill and experience of the U.S. Adopted Names Council (USAN) in deriving names for drugs. The U.S. Adopted Names Council is a private organization sponsored by the American Medical Association, the United States Pharmacopeia, and the American Pharmaceutical Association, and has been engaged in the assignment of names to drugs since January 1964. The Council negotiates with manufacturing firms in the selection of nonproprietary names for drugs.

(d) The Food and Drug Administration cooperates with and is represented on the USAN Council. In addition, the Food and Drug Administration is in agreement with the "Guiding Principles for Coining U.S. Adopted Names for Drugs," published in New Drugs Evaluated by A.M.A. Council on Drugs, 1967 edition, pages 556–561, and in U.S. Adopted Names (USAN), Cumulative List, number 5, 1961–1966, pages 100–105.[2] All applicants for new-drug applications and sponsors for "Notice of Claimed Investigational Exemption for a New Drug" (IND's) are encouraged to contact the USAN Council for assistance in selection of a simple and useful name for a new chemical entity. Approval of a new-drug application providing for the use of a new drug substance or a new antibiotic drug may be delayed if a simple and useful nonproprietary name does not exist for the substance and if one is not proposed in the application that meets the above-cited guidelines. Prior use of a name in the medical literature or otherwise will not commit the Food and Drug Administration to adopting such terminology as official.

(Secs. 502(e), 503, 52 Stat. 1050, as amended, 76 Stat. 789, 790, 21 U.S.C. 352(e), 358)

§ 299.5 Drugs; compendial name.

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

(Sec. 501, 52 Stat. 1050, as amended; 21 U.S.C. 351)

Subpart B—Designated Names

§ 299.20 Drugs; official names.

The following are designated official under section 508 of the act and are "established" names within the meaning of section 502(e) of the act:

[2] Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

Official name	Chemical name or description	Molecular formula
Aceclidine	3-Quinuclidinol acetate (ester); 3-acetoxyquinuclidine	$C_9H_{15}NO_2$
Acedapsone	4',4'''-Sulfonylbis[acetanilide]	$C_{16}H_{16}N_2O_4S$
Acetylcysteine	*N*-Acetyl-L-cysteine	$C_5H_9NO_3S$
Acrisorcin	9-Aminoacridine, salt with 4-hexylresorcinol	$C_{13}H_{10}N_2C_{12}H_{18}O$
Acronine	3,12-Dihydro-6-methoxy-3,3,12-trimethyl-7*H*-pyrano[2,3-*c*]acridin-7-one.	$C_{19}H_{19}NO_3$
Adenosine	6-Amino-9-β-D-ribofuranosyl-9*H*-purine	$C_{10}H_{13}N_5O_4$
Adiphenine	2-(Diethylamino)ethyl diphenylacetate	$C_{20}H_{25}NO_2$ or $C_{18}H_{21}NO_2$
Aklomide	2-Chloro-4-nitrobenzamide	$C_7H_5ClN_2O_3$
Alamecin	An antibiotic substance derived from *Trichoderma viride Pers. ex fries.*	
Alcuronium	*N,N'*-Diallylnortoxiferinium; diallylbisnortoxiferin	$C_{44}H_{52}N_4O_2$
Alexidine	1,1'-Hexamethylenebis[5-(2-ethylhexyl)biguanide]	$C_{28}H_{58}N_{10}$
Algestone	16α,17-Dihydroxypregn-4-ene-3,20-dione	$C_{21}H_{30}O_4$
Allobarbital	5,5-Diallylbarbituric acid	$C_{12}H_{14}N_2O_3$
Allopurinol	1*H*-Pyrazolo[3,4-*d*]pyrimidin-4-ol; 4-hydroxypyrazolo (3,4-*d*)-pyrimidine.	$C_5H_4N_4O$
Alprenolol	1-(o-Allylphenoxy)-3-(isopropylamino)-2-propanol	$C_{15}H_{23}NO_2$
Ambuphylline	Theophylline, compound with 2-amino-2-methyl-1-propanol	$C_7H_8N_4O_2.C_4H_{11}NO$
Ambuside	N¹-Allyl-4-chloro-6-[(3-hydroxy-2-butenylidene)amino]-m-benzenedisulfonamide; 2-allylsulfamyl-5-chloro-4-sulfamyl-*N*-(3-hydroxy-2-buteneylidene) aniline.	$C_{14}H_{17}ClN_4O_5S_2$
Amiloride	*N*-Amidino-3,5-diamino-6-chloropyrazinecarboxamide	$C_6H_8ClN_7O$
Aminacrine	9-Aminoacridine	$C_{13}H_{10}N_2$
Amphomycin	A substance produced by *Streptomyces canus.*	
Ampicillin	6-(D-2-Amino-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylic acid.	$C_{16}H_{19}N_3O_4S$
Amquinate	Methyl 7-(diethylamino)-4-hydroxy-6-propyl-3-quinolinecarboxylate.	$C_{18}H_{24}N_2O_3$
Anisotropine	Tropine 2-propylvalerate	$C_{18}H_{33}NO_2$
Apazone	5-(Dimethylamino)-9-methyl-2-propyl-1*H*-pyrazolo[1,2-*a*][1,2,4] benzotriazine-1,3(2*H*)-dione.	$C_{15}H_{19}N_5O_2$
Aprotinin	Arg-Pro-Asp (tentative)-Phe-HCys-Leu-Glu (tentative)-Pro-Pro-Tyr-Thr-Gly-Pro-HCys-Lys-Ala-Arg-Ileu-Ileu-Arg-Tyr-Phe-Tyr-AspN-Ala-Lys-Ala-Gly-Leu-HCys-GluN-Thr-Phe-Val-Tyr-Gly-Gly-HCys-Arg-Ala-Lys-Arg-AspN-AspN-Phe-Lys-Ser-Ala-Glu-AspN-HCys-Met-Arg-Thr-HCys-Gly-Gly-Ala.	
Aranotin	5,5a,13,13a-Tetrahydro-5,13-dihydroxy-8*H*,16*H*-7a,13a-epidithio-7*H*,15*H*-bisoxepino[3',4':4,5]pyrrolo[1,2-*a*:1',2'-*d*]pyrazine-7,15-dione-5-acetate.	$C_{18}H_{18}N_2O_7S_2$
Arginine	*L*(+)-Arginine	$C_6H_{14}N_4O_2$
Artegraft	Arterial graft composed of a section of bovine carotid artery that has been subjected to enzymatic digestion with ficin and tanned with dialdehyde starch.	
Atolide	2-Amino-4'-(diethylamino)-o-benzotoluidide	$C_{18}H_{23}N_3O$
Azaperone	4' Fluoro-4-[4-(2-pyridyl)-5-piperazinyl]butyrophenone; 1[3-(4-fluorobenzoyl)-propyl]-4-(2-pyridyl)piperzaine.	$C_{19}H_{22}FN_3O$
Azaribine	2-β-D-Ribofuranosyl-as-triazine-3,5(2*H*,4*H*)-dione-2',3',5'-triacetate; (2',3',5'-triacetyl)-2-β-D-ribofurenosyl-as-triazine-(2*H*,4*H*)-dione.	$C_{14}H_{17}N_3O_9$
Azacerine	Serine diazoacetate (ester)	$C_5H_7N_3O_4$
Azathioprine	6-[1-Methyl-4-nitroimidazol-5-yl)thio]purine	$C_9H_7N_7O_2S$
Bamethan	α-[(Butylamino)methyl]-p-hydroxybenzyl alcohol	$C_{11}H_{17}NO_2$
Benzolline	2-[(2-Methylbenzo[*b*]thien-3-yl)methyl]-2-imidazoline; 2-methyl-3-(Δ2-imidazolinylmethyl)benzo[*b*]thiophene.	$C_{13}H_{14}N_2S$
Bendazac	[(1-Benzyl-1*H*-indazol-3-yl)oxy]acetic acid	$C_{16}H_{14}N_2O_3$

Official name	Chemical name or description	Molecular formula
Bensalan	3,5-Dibromo-*N*-(*p*-bromobenzyl) salicylamide	$C_{14}H_{10}Br_3NO_2$
Benzetimide	2-(1-Benzyl-4-piperidyl)-2-phenylglutarimide	$C_{23}H_{26}N_2O_2$
Benzoctamine	*N*-Methyl-9,10-ethanoanthracene-9(10*H*)-methylamine	$C_{18}H_{19}N$
Benzoxiquine	8-Quinolinol benzoate (ester); 8-benzoyl-oxyquinoline	$C_{16}H_{11}NO_2$
Betahistine	2-[2-(Methylamino)ethyl]pyridine	$C_8H_{12}N_2$
Bialamicol	5,5'-Diallyl-α,α'-bis(diethylamino)-*m*,*m*'-bitolyl-4,4'-diol	$C_{28}H_{42}N_2O_2$
Bisobrin	1,1'-Tetramethylenebis[1,2,3,4-tetrahydro-6,7-dimethoxyisoquinoline].	$C_{28}H_{36}N_2O_4$
Bisoxatin	2,2-Bis(*p*-hydroxyphenyl)-2*H*-1,4-benzoxazin-3(4*H*)-one	$C_{22}H_{15}NO_4$
Boldenone	17β-Hydroxyandrosta-1,4-dien-3-one	$C_{19}H_{26}O_2$
Bolenol	19-Nor-17α-pregn-5-en-17-ol; 17-α-ethyl-5-estren-17-ol	$C_{20}H_{32}O$
Boxidine	1-[2-[[4'-(Trifluoromethyl)-4-biphenylyl]oxy]ethyl]pyrrolidine	$C_{19}H_{22}F_3NO$
Bromazepam	7-Bromo-1,3-dihydro-5-(2-pyridyl)-2*H*-1,4-benzodiazepin-2-one	$C_{14}H_{10}BrN_3O$
Bromelains	A concentrate of proteolytic enzymes derived from the pineapple plant.	
Bromhexine	3,5-Dibromo-*N*α-cyclohexyl-*N*α-methyltoluene-α,2-diamine	$C_{14}H_{20}Br_2N_2$
Buclizine	1-(*p*-*tert*-Butylbenzyl)-4-(*p*-chloro-α-phenylbenzyl)-piperazine	$C_{32}H_{39}ClN_2$
Bucrylate	Isobutyl 2-cyanoacrylate	$C_8H_{11}NO_2$
Bunolol	(±)-5-[3-(*tert*-Butylamino)-2-hydroxypropoxy]-3,4-dihydro-1(2*H*)-naphthalenone.	$C_{17}H_{23}NO_3$
Butalbital	5-Allyl-5-isobutylbarbituric acid	$C_{11}H_{16}N_2O_3$
Butaperazine	1-[10-[3-(4-Methyl-1-piperazinyl)propyl]phenothiazin-2-yl]-1-butanone.	$C_{24}H_{31}N_3OS$
Buthiazide	6-Chloro-3,4-dihydro-3-isobutyl-2*H*-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide.	$C_{11}H_{16}ClN_3O_4S_2$
Calcitonin	Hormone from the thyroid gland, a polypeptide of molecular weight less than 10,000.	
Calcium carbaspirin	Calcium salicylate diacetate compound with urea	$C_{18}H_{14}CaO_4.CH_4N_2O$
Candicidin	An antibiotic substance derived from *Streptomyces griseus* Waksman and Henrici.	
Canrenone	17-Hydroxy-3-oxo-17α-pregna-4,6-diene-21-carboxylic acid gamma-lactone; 17α-(2-carboxyethyl)-17β-hydroxy and rosta-4,6-dien-3-one lactone.	$C_{22}H_{28}O_3$
Capreomycin	An antibiotic substance derived from *Streptomyces capreolus*	
Captamine	2-(Dimethylamino)ethanethiol; N-(2-mercaptoethyl)dimethylamine	$C_4H_{11}NS$
Carbadox	Methyl-3-(2-quinoxalinylmethylene)carbazate-*N*^{1},*N*^{4}-dioxide	$C_{11}H_{10}N_4O_4$
Carbamazepine	5*H*-Dibenz[*b*,*f*]-azepine-5-carboxamide	$C_{15}H_{12}N_2O$
Carbenicillin	*N*-(2-Carboxy-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]-hept-6-yl)-2-phenylmalonamic acid; 6-(2-carboxy-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.	$C_{17}H_{18}N_2O_6S$
Carbocloral	Ethyl (2,2,2-trichloro-1-hydroxyethyl)carbamate	$C_5H_8Cl_3NO_3$
Carbomer	A polymer of acrylic acid crosslinked with allyl sucrose	
Carphenazine	1-[10-(3-[4-(2-Hydroxyethyl)-1-piperazinyl]propyl)phenothiazin-2-yl]-1-propanone.	$C_{24}H_{31}N_3O_2S$
Casanthranol	A purified mixture of the anthranol glycosides derived from *Cascara sagrada*.	
Cellaburate	Cellulose acetate butyrate	
Cellulase	A concentrate of cellulose-splitting enzymes derived from *Aspergillus niger* and other sources.	
Cephalexin	D-7-(2-Amino-2-phenylacetamido)-3-methyl-8-oxo-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid.	$C_{16}H_{17}N_3O_4S$
Cephaloglycin	7-(D-2-Amino-2-phenylacetamido)-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, acetate.	$C_{18}H_{19}N_3O_6S$
Cephaloridine	1-[[2-Carboxy-8-oxo-7-[2-(2-thienyl)acetamido]-5-thia-1-azabicyclo-[4.2.0]oct-2-en-3-yl]methyl]pyridinium hydroxide, inner salt.	$C_{19}H_{17}N_3O_4S_2$
Cephalothin	3-(Hydroxymethyl)-8-oxo-7-[2-(2-thienyl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, acetate.	$C_{16}H_{16}N_2O_6S_2$
Cetalkonium	Benzylhexadecyldimethylammonium ion	$C_{25}H_{46}N^+$
Cetophenicol	D-*threo*-*N*-[*p*-Acetyl-β-hydroxy-α-(hydroxymethyl)phenethyl]-2,2-dichloroacetamide.	$C_{13}H_{16}Cl_2NO_4$
Chlophedianol	2-Chloro-α-[2-(dimethylamino)ethyl]benzhydrol	$C_{17}H_{20}ClNO$
Chlordantoin	5-(1-Ethylpentyl)-3-[(trichloromethyl)thio]hydrantoin	$C_{11}H_{17}Cl_3N_2O_2S$
Chlorhexidine	1,1'-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide]	$C_{22}H_{30}Cl_2N_{10}$
Chlorindanol	7-Chloro-4-indanol	C_9H_9ClO
Chlormadinone	6-Chloro-17-hydroxypregna-4,6-diene-3,20-dione; 6-chloro-6-dehydro-17α-hydroxyprogesterone.	$C_{21}H_{27}ClO_3$
Chlorphenesin	3-(*p*-Chlorophenoxy)-1,2-propanediol	$C_9H_{11}ClO_3$
Chlorphentermine	4-Chloro-α,α-dimethylphenethylamine	$C_{10}H_{14}ClN$
Chlorprothixene	2-Chloro-*N*,*N*-dimethylthioxanthene Δ^9,γ-propylamine	$C_{18}H_{18}ClNS$
Chlorthalidone	2-Chloro-5-(1-hydroxy-3-oxo-1-isoindolinyl) benzenesulfonamide	$C_{14}H_{11}ClN_2O_4S$
Cingestol	19-Nor-17α-pregn-5-en-20-yn-17-ol; 17α-ethynyl-5-estren-17-ol	$C_{20}H_{28}O$
Cinnamedrine	α-[1-(Cinnamylmethylamino)-ethyl]benzyl alcohol; 2-(*N*-cinnamyl-methylamino)-1-phenylpropanol.	$C_{19}H_{23}NO$
Cinnarizine	1-Cinnamyl-4-diphenylmethylpiperazine	$C_{26}H_{28}N_2$
Cinoxate	2-Ethoxyethyl *p*-methoxycinnamate	$C_{14}H_{18}O_4$
Cinperene	2-(1-Cinnamyl-4-piperidyl)-2-phenylglutarimide; 1-cinnamyl-4-(2,6-dioxo-3-phenyl-3-piperidyl)piperidine.	$C_{25}H_{28}N_2O_2$

Official name	Chemical name or description	Molecular formula
Cintazone	2-Pentyl-6-phenyl-1*H*-pyrazolo[1,2*a*] cinnoline-1,3(2*H*)-dione	$C_{22}H_{22}N_2O_2$
Cirolemycin	An antibiotic substance derived from *Streptomyces bellus* var. *cirolerosis* var. *nova*.	
Cisclomiphene	2-[*p*-(2-Chloro-*cis*-1,2-diphenylvinyl)phenoxy]-triethylamine	$C_{26}H_{28}ClNO$
Citenamide	5*H*-Dibenzo[*a*,*d*]cycloheptene-5-carboxamide	$C_{16}H_{13}NO$
Clemastine	(+)-2-[2-[*p*-Chloro-α-methyl-α-phenylbenzyl]oxy]ethyl]-1-methyl-pyrrolidine.	$C_{21}H_{26}ClNO$
Clindamycin	Methyl 7(*S*)-chloro-6,7,8-trideoxy-6-*trans*-(1-methyl-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-α-D-galacto-octopyranoside; 7(*S*)-chloro-7-deoxylincomycin.	$C_{18}H_{33}ClN_2O_5S$
Cloxanilide	4'-Chloro-3,5-diiodosalicylanilide acetate; 2-acetoxy-4'-chloro-3,5-diiodobenzanilide.	$C_{15}H_{10}ClI_2NO_3$
Clodazon	5-Chloro-1-[3-(dimethylamino)propyl]-3-phenyl-2-benzimidazolinone	$C_{18}H_{20}ClN_3O$
Clofazimine	3-(*p*-Chloroanilino)-10-(*p*-chlorophenyl)-2,10-dihydro-2-(isopropylimino)phenazine.	$C_{27}H_{22}Cl_2N_4$
Clofibrate	Ethyl 2-(*p*-chlorophenoxy)-2-methylpropionate	$C_{12}H_{15}ClO_3$
Clofucarban	4,4'-Dichloro-3-(trifluoromethyl)carbanilide	$C_{15}H_{10}Cl_2F_3N_2O$
Clogestone	6-Chloro-3β,17-dihydroxypregna-4,6-dien-20-one	$C_{21}H_{29}ClO_3$
Clomacran	2-Chloro-9-[3-(dimethylamino)-propyl] acridan	$C_{18}H_{21}ClN_2$
Clomegestone	6-Chloro-17-hydroxy-16α-methylpregna-4,6-diene-3,20-dione	$C_{22}H_{29}ClO_3$
Clomiphene	2-[*p*-(2-Chloro-1,2-diphenylvinyl)phenoxy]-triethylamine	$C_{26}H_{28}ClNO$
Clonazepam	5-(*o*-Chlorophenyl)-1,3-dihydro-7-nitro-2*H*-1,4-benzodiazepin-2-one	$C_{15}H_{10}ClN_3O_3$
Clonidine	2-(2, 6-Dichloroanilino)-2-imidazoline	$C_9H_9Cl_2N_3$
Clonixeril	2,3-Dihydroxypropyl 2-(3-chloro-*o*-toluidino)nicotinate	$C_{18}H_{19}ClN_2O_4$
Clonixin	2-(3-Chloro-*o*-toluidino)nicotinic acid	$C_{13}H_{11}ClN_2O_2$
Clopidol	3,5-Dichloro-2,6-dimethyl-4-pyridinol	$C_7H_7Cl_2NO$
Chlorazepic acid	7-Chloro-2,3-dihydro-2,2-dihydroxy-5-phenyl-1*H*-1,4-benzodiazepine-3-carboxylic acid.	$C_{15}H_{11}ClN_2O_4$
Clorexolone	6-Chloro-2-cyclohexyl-3-oxo-5-isoindoline-sulfonamide; 5-chloro-2-cyclohexyl-1-oxo-6-sulfamoylisoindoline.	$C_{14}H_{18}ClN_3O_3S$
Clortermine	*o*-Chloro-α,α-dimethylphenethylamine	$C_{10}H_{14}ClN$
Closiramine	8-Chloro-11-[2-(dimethylamino)ethyl]-6,11-dihydro-5*H*-benzo[5,6]-cyclohepta[1,2-*b*]pyridine.	$C_{18}H_{21}ClN_2$
Cloxacillin	6-[3-(*o*-Chlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.	$C_{19}H_{18}ClN_3O_5S$
Clozapine	8-Chloro-11-(4-methyl-1-piperazinyl)-5*H*-dibenzo[*b*,*e*][1,4] diazepine	$C_{18}H_{19}ClN_4$
Colestipol	Tetraethylenepentamine polymer with 1-chloro-2,3-epoxypropane	
Cosyntropin	H-Ser-Tyr-Ser-Met-Glu-His-Phe-Arg-Try-Gly-Lys-Pro-Val-Gly-Lys-Lys-Arg-Arg-Pro-Val-Lys-Val-Tyr-Pro-OH.	
Cromolyn	5,5'-[(2-Hydroxytrimethylene)dioxy]bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; 1,3-bis(2-carboxychromon-5-yloxy)-2-hydroxypropane.	$C_{23}H_{14}O_{11}$
Crufomate	4-*tert*-Butyl-2-chlorophenyl methyl methylphosphoramidate	$C_{12}H_{19}ClNO_3P$
Cyclacillin	6-(1-Aminocyclohexanecarboxamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.	$C_{16}H_{25}N_3O_4S$
Cycloguanil	4,6-Diamino-1-(*p*-chlorophenyl)-1,2-dihydro-2,2-dimethyl-*s*-triazine	$C_{11}H_{14}ClN_5$
Cyclophenazine	10-[3-(4-Cyclopropyl-1-piperazinyl) propyl]-2-(trifluoromethyl) phenothiazine; 10-[3-(4-cyclopropylpiperazino)-propyl]-2-trifluoromethylphenothiazine.	$C_{23}H_{24}F_3N_3S$
Cyclopenthiazide	6-Chloro-3-(cyclopentylmethyl)-3,4-dihydro-2*H*-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide.	$C_{13}H_{18}ClN_3O_4S_2$
Cyclothiazide	6-Chloro-3,4-dihydro-3-(5-norbornen-2-yl)-2*H*-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide.	$C_{14}H_{16}ClN_3O_4S_2$
Cyproquinate	Ethyl 6,7-bis(cyclopropylmethoxy)-4-hydroxy-3-quinolinecarboxylate.	$C_{22}H_{27}NO_5$
Cyproximide	1(*p*-Chlorophenyl)-1,2-cyclopropanedicarboximide	$C_{11}H_8ClNO_2$
Cytarabine	1-Arabinofuranosylcytosine	$C_9H_{13}N_3O_5$
Dactinomycin	Actinomycin D	$C_{62}H_{86}N_{12}O_{16}$
Danazol	17α-Pregna-2,4-dien-20-yno[2,3-*d*]isoxazol-17-ol; 1-ethynyl-2,3,2a,3b,4,5,10,10a, 10b, 11, 12, 12a-dodecahydro-10a, 12a-dimethyl-1*H*-cyclopenta[7,8]-phenanthro[3,2-*d*]pyrazol-1-ol.	$C_{22}H_{27}NO_2$
Decoquinate	Ethyl 6-(decyloxy)-7-ethoxy-4-hydroxy-3-quinolinecarboxylate	$C_{24}H_{37}NO_5$
Deferoxamine	*N*-[5-[3-[(5-Aminopentyl)hydroxycarbamoyl]propionamido]pentyl]-3-[[5-*N*-hydroxyacetamido)pentyl]carbamoyl]propionohydroxamic acid.	$C_{25}H_{48}N_6O_8$
Desipramine	10,11-Dihydro-5-[3-(methylamino)propyl]-5*H*-dibenz[*b*,*f*]azepine	$C_{18}H_{22}N_2$
Dexivacaine	(+)-1-Methyl-2',6'-pipecoloxylidide; (+)-1-*N*-methylpipecolic acid 2,6-dimethylanilide.	$C_{15}H_{22}N_2O$
Dexpanthenol	D(+)-2,4-Dihydroxy-*N*-(3-hydroxypropyl)-3,3-dimethylbutyramide	$C_9H_{19}NO_4$
Dextran 40	A polysaccharide having a weight average molecular weight of 40,000; produced by the action of *Leuconostoc mesenteroides* on sucrose.	
Diamocaine	1-(2-Anilinoethyl)-4-[2-(diethylamino)ethoxy]-4-phenylpiperidine	$C_{31}H_{41}N_3O$
Diapamide	4-Chloro-*N*-methyl-3-(methylsulfamoyl) benzamide	$C_9H_{11}ClN_2O_3S$
Diatrizoic acid	3,5-Diacetamido-2,4,6-triiodobenzoic acid	$C_{11}H_9I_3N_2O_4$
Diazepam	7-Chloro-1,3-dihydro-1-methyl-5-phenyl-2*H*-1,4-benzodiazepin-2-one	$C_{16}H_{13}ClN_2O$

Official name	Chemical name or description	Molecular formula
Dibromsalan	4',5-Dibromosalicylanilide	$C_{13}H_9Br_2NO_2$
Dicloxacillin	6-[3-(2,6-Dichlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.	$C_{19}H_{17}Cl_2N_3O_5S$
Difluanine	1-(2-Anilinoethyl)-4-[4,4-bis(*p*-fluorophenyl)butyl]piperazine; 1-[4,4-di(4-fluorophenyl)butyl]-4-(2-anilinoethyl)piperazine.	$C_{32}H_{33}F_2N_3$
Diflucortolone	6α,9-Difluoro-11β,21-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione.	$C_{22}H_{29}F_2O_4$
Diflumidone	3'-Benzoyl-1,1-difluoromethanesulfonanilide	$C_{14}H_{11}F_2NO_3S$
Difluprednate	6α, 9-Difluoro-11β,17,21-trihydroxypregna-1,4-diene-3,20-dione 21-acetate 17-butyrate.	$C_{27}H_{34}F_2O_7$
Dimethindene	2-[1-[2-[2-(Dimethylamino)ethyl]inden-3-yl]ethyl]pyridine	$C_{22}H_{24}N_2$
Dimethisterone	17β-Hydroxy-6α-methyl-17-(1-propynyl)androst-4-en-3-one	$C_{23}H_{32}O_2$
Dioxybenzone	2,2'-Dihydroxy-4-methoxybenzophenone	$C_{14}H_{12}O_4$
Diphenidol	α,α-Diphenyl-1-piperidinebutanol	$C_{21}H_{27}NO$
Dipyridamole	2,2',2'',2'''-[(4,8-Dipiperidinopyrimido[5,4-*d*]pyrimidine-2,6-diyl)dinitrilo]tetraethanol.	$C_{24}H_{40}N_8O_4$
Dipyrone	Sodium (antipyrinylmethylamino)methanesulfonate hydrate	$C_{13}H_{16}N_3NaO_4S \cdot H_2O$
Domiphen	Dodecyldimethyl(2-phenoxyethyl)ammonium	$C_{22}H_{40}NO$
Dopamine	4-(2-Aminoethyl)pyrocatechol	$C_8H_{11}NO_2$
Doxapram	1-Ethyl-4-(2-morpholinoethyl)-3,3-diphenyl-2-pyrrolidinone	$C_{24}H_{30}N_2O_2$
Doxepin	*N,N*-Dimethyldibenz[*b,e*]oxepin-$\Delta^{11(6H)}$,γ-propylamine	$C_{19}H_{21}NO$
Doxycycline	4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide.	$C_{22}H_{24}N_2O_8$
Droperidol	1-[1-[3-(*p*-Fluorobenzoyl)propyl]-1,2,3,6-tetrahydro-4-pyridyl]-2-benzimidazolinone.	$C_{22}H_{22}FN_3O_2$
Dydrogesterone	9β,10α-Pregna-4,6-diene-3,20-dione	$C_{21}H_{28}O_2$
Epimestrol	3-Methoxyestra-1,3,5,(10)-triene-16α,17α-diol	$C_{19}H_{28}O_3$
Estrazinol	DL-*trans*-3-Methoxy-8-aza-19-nor-17α-pregna-1,3,5-trien-20-yn-17-ol	$C_{22}H_{29}NO$
Ethacrynic acid	[2,3-Dichloro-4-(2-methylenebutyryl)phenoxy]acetic acid	$C_{13}H_{12}Cl_2O_4$
Ethambutol	(+)-2,2'-(Ethylenediimino)-di(1-butanol)	$C_{10}H_{24}N_2O_2$
Ethamivan	*N,N*-Diethylvanillamide	$C_{12}H_{17}NO_3$
Ethionamide	2-Ethylthioisonicotinamide	$C_8H_{10}N_2S$
Ethonam	Ethyl-1-(1,2,3,4-tetrahydro-1-naphthyl) imidazole-5-carboxylate; 1-(1,2,3,4-tetrahydro-1-naphthyl)-5-ethoxycarbonyl) imidazole.	$C_{16}H_{18}N_2O_2$
Ethosuximide	2-Ethyl-2-methylsuccinimide	$C_7H_{11}NO_2$
Ethoxazene	4-[(*p*-Ethoxyphenyl)azo]-*m*-phenylenediamine	$C_{14}H_{16}N_4O$
Ethynodiol	19-Nor-17α-pregn-4-en-20-yne-3β, 17-diol	$C_{21}H_{30}O_2$
Ethylestrenol	19-Nor-17α-pregn-4-en-17β-ol	$C_{20}H_{32}O$
Etidronic Acid	(1-Hydroxyethylidene)diphosphonic acid	$C_2H_8O_7P_2$
Etoxadrol	(+)-2-(2-Ethyl-2-phenyl-1,3-dioxolan-4-yl)piperidine	$C_{15}H_{21}NO_2$
Euprocin	*O*-6'-Isopentylhydrocupreine	$C_{24}H_{34}N_2O_2$
Famotine	1-[(*p*-Chlorophenoxy)methyl]-3,4-dihydroisoquinoline	$C_{16}H_{14}ClNO$
Fantridone	5-[3-(Dimethylamino)propyl]-6-(5*H*)-phenanthridone	$C_{18}H_{20}N_2O$
Fenalamide	Ethyl-*N*-[2-(diethylamino)]ethyl-2-ethyl-2-phenylmalonamate; phenylethylmalonic acid monethylester diethylaminoethylamide.	$C_{19}H_{32}N_2O_3$
Fenclonine	DL-3-(*p*-Chlorophenyl)alanine	$C_9H_{10}ClNO_2$
Fenestrel	5-Ethyl-6-methyl-4-phenyl-3-cyclohexene-1-carboxylic acid; 2-methyl-3-ethyl-4-phenyl-4-cyclohexenecarboxylic acid.	$C_{16}H_{20}O_2$
Fentanyl	*N*-(1-Phenethyl-4-piperidyl)propionanilide	$C_{22}H_{28}N_2O$
Fenticlor	2,2'-Thiobis[4-chlorophenol]	$C_{12}H_8Cl_2O_2S$
Ferric fructose	Fructose iron complex, compound with potassium (2:1)	$(C_6H_9FeO_7)_2K_2/_3$
Fetoxylate	2-Phenoxyethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotate.	$C_{35}H_{36}N_2O_3$
Filipin	3,5,7,9,11,13,15,25,27-Nonahydroxy-2-(1-hydroxyhexyl)-16-methyl-16,18,20,22,24-octacosapentaenoic acid 1,27-lactone.	$C_{35}H_{53}O_{11}$
Flavoxate	2-Piperidinoethyl 3-methyl-4-oxo-2-phenyl-4*H*-1-benzopyran-8-carboxylate.	$C_{24}H_{25}NO_4$
Floxuridine	2'-Deoxy-5-fluorouridine	$C_9H_{11}FN_2O_5$
Flucrylate	2,2,2-Trifluoro-1-methylethyl 2-cyanoacrylate	$C_7H_8F_3NO_2$
Flucytosine	5-Fluorocytosine	$C_4H_4FN_3O$
Fludorex	β-Methoxy-*N*-methyl-*m*-(trifluoromethyl) phenethylamine	$C_{11}H_{14}F_3NO$
Flufenisal	4'-Fluoro-4-hydroxy-3-biphenylcarboxylic acid acetate	$C_{15}H_{11}FO_4$
Flumethasone	6α,9-Difluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione.	$C_{22}H_{28}F_2O_5$
Flunidazole	2-(*p*-Fluorophenyl)-5-nitroimidazole-1-ethanol	$C_{11}H_{10}FN_3O_3$
Fluocinolone	6α,9-Difluoro-11β.16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione; 6α,9α-difluoro-16α-hydroxyprednisolone.	$C_{24}H_{30}F_2O_6$
Fluocinonide	6α,9-Difluoro-11β, 16α, 17,21-tetrahydroxypregna-1,4-diene-3,20-dione, cyclic 16,17-acetal with acetone, 21-acetate.	$C_{26}H_{32}F_2O_7$
Fluprednisolone	6α-Fluoro-11β, 17α,21-trihydroxypregna-1,4-diene-3,20-dione; 6α-fluoroprednisolone.	$C_{21}H_{27}FO_5$
Flurazepam	7-Chloro-1-[2-(diethylamino)ethyl]-5-(*o*-fluorophenyl)-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one.	$C_{21}H_{23}ClFN_3O$
Flurothyl	Bis(2,2,2-trifluoroethyl)ether	$C_4H_4F_6O$
Fluroxene	2,2,2-Trifluoroethyl vinyl ether	$C_4H_5F_3O$
Flutiazin	8-(Trifluoromethyl)phenothiazine-1-carboxylic acid	$C_{14}H_8F_3NO_2S$
Fonazine	10-[2-(Dimethylamino)propyl]-*N,N*-dimethylphenothiazine-2-sulfonamide.	$C_{19}H_{25}N_3O_2S_2$
Fospirate	Dimethyl 3,5,6-trichloro-2-pyridyl phosphate	$C_7H_7Cl_3NO_4P$
Furosemide	4-Chloro-*N*-furfury-5-sulfamoylanthranilic acid	$C_{12}H_{11}ClN_2O_5S$
Fursalan	3,5-Dibromo-*N*-(tetrahydrofurfuryl)salicylamide; 3,5-dibromosalicyl-*N*-tetrahydrofurfurylamide.	$C_{12}H_{13}Br_2NO_3$
Gentamicin	An antibiotic substance derived from *Micromonospora purpurea*, nonspecific.	----------

Official name	Chemical name or description	Molecular formula
Glorazone	3-Ethoxy-2-oxobutyraldehyde-bis(thiosemicarbazone); α-ethoxyethylglyoxal dithiosemicarbazone.	$C_8H_{18}N_8OS_2$
Glucosamine	2-Amino-2-deoxy-β-D-glucopyranose	$C_6H_{13}NO_5$
Glyburide	1-[[p-[2-(5-chloro-o-anisamido)ethyl]phenyl]sulfonyl]-3-cyclohexylurea; *N*-[4-(β-(2-methoxy-5-chlorobenzamido)-ethyl)benzosulfonyl]-*N'*-cyclohexylurea.	$C_{23}H_{28}ClN_3O_5S$
Glycopyrrolate	3-Hydroxy-1,1-dimethylpyrrolidinium bromide α-cyclopentylmandelate.	$C_{19}H_{28}BrNO_3$
Guanacline	[2-(3,6-Dihydro-4-methyl-1(2*H*)-pyridyl)ethyl]guanidine	$C_9H_{18}N_4$
Guanadrel	(1,4-Dioxaspiro[4.5]dec-2-ylmethyl)guanidine	$C_{10}H_{21}N_3O_2$
Haloperidol	4-[4-(p-Chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone.	$C_{21}H_{23}ClFNO_2$
Halquinols	5,7-Dichloro-8-quinolinol, 5-chloro-8-quinolinol, and 7 chloro-8-quinolinol in proportions resulting naturally from chlorination of of 8-quinolinol.	$C_9H_5Cl_2NO$ and C_9H_6ClNO.
Hetacillin	6-(2,2-Dimeth-5-oxo-4-phenyl-1-imidazolidinyl)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.	$C_{18}H_{22}O_4S$
Hexafluorenium	Hexamethylenebis[9-fluorenyldimethylammonium] ion	$C_{42}H_{42}N_2^{++}$
Hoquizil	2-Hydroxy-2-biethylpropyl 4-(6,7-dimethoxy-4-quinazolinyl)-1-piperazinecarboxylate.	$C_{22}H_{32}N_4O_4$
Hydroxocobalamin	Cobinamide hydroxide phosphate, 3'-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole, inner salt.	$C_{62}H_{89}CoN_{13}O_{15}P$
Hydroxyurea	Hydroxyurea	$CH_4N_2O_2$
Ibuprofen	*p*-Isobutylhydratropic acid; 2(p-isobutylphenyl)propionic acid	$C_{13}H_{18}O_2$
Ictasol	The sodium salt of a sulfonated derivative of bituminous slate	
Idoxuridine	2'-Deoxy-5-iodouridine	$C_9H_{11}IN_2O_5$
Indomethacin	1-(p-Chlorobenzoyl)-5-methoxy-2-methylindole-3-acetic acid	$C_{19}H_{16}ClNO_4$
Indriline	*N,N*-Dimethyl-1-phenylindene-1-ethylamine	$C_{19}H_{23}N$
Inositol niacinate	*myo*-Inositol hexanicotinate	$C_{36}H_{30}N_6O_{12}$
Iocetamic acid	*N*-Acetyl-*N*-(3-amino-2,4,6-triiodophenyl)-2-methyl-β-alanine	$C_{12}H_{13}N_2O_3$
Iodamide	α,5-Diacetamido-2,4,6-triiodo-*m*-toluic acid	$C_{12}H_9I_3N_2O_4$
Iomethin I 125	4-[[3-(Dimethylamino)propyl]amino]-7-iodo-^{125}*I*-quinoline	$C_{14}H_{18}IN_3$ (in which the iodine atom is ^{125}I).
Iomethin I 131	4-[[3-(Dimethylamino)propyl]amino]-7-iodo-^{131}*I*-quinoline	$C_{14}H_{18}IN_3$ (in which the iodine atom is ^{131}I).
Iopydol	1-(2,3Dihydroxypropyl-3,5-diiodo-4(1*H*)-pyridone	$C_8H_9I_2NO_3$
Iopydone	3,5-Diiodo-4(1*H*)-pyridone	$C_5H_3I_2NO$
Iothalamic acid	5-Acetamido-2,4,6-triiodo-*N*-methylisophthalamic acid	$C_{11}H_9I_3N_2O_4$
Iproniazole	2-Isopropyl-1-methyl-5-nitroimidazole	$C_7H_{11}N_3O_2$
Iron sorbitex	A sterile, colloidal solution of a complex of trivalent iron, sorbitol, and citric acid, stabilized with dextrin and sorbitol.	
Isoetharine	3,4-Dihydroxy-α-[1-(isopropylamino)propyl]benzyl alcohol	$C_{14}H_{23}NO_3$
Isomylamine	2-(Diethylamino)ethyl 1-isopentylcyclohexanecarboxylate	$C_{18}H_{35}NO_2$
Kalafungin	An antibiotic substance derived from *Streptomyces tanashiensis* strain, *kala*.	
Ketamine	(±)-2-(o-Chlorophenyl)-2-(methylamino)cyclohexanone	$C_{13}H_{16}ClNO$
Kethoxal	3-Ethoxy-1,1-dihydroxy-2-butanone	$C_6H_{12}O_4$
Ketipramine	5-[3-(Dimethylamino)propyl]5,11-dihydro-10*H*-dibenz[*b,f*]-azepin-10-one.	$C_{20}H_{24}N_2O$
Kitasamycin	An antibiotic substance obtained from cultures of *Streptomyces kitasatoensis*.	$C_{35}H_{59-61}NO_{13-14}$
Levamfetamine	(−)-α-Methylphenethylamine	$C_9H_{13}N$
Levodopa	(-)-3-(3,4-Dihydroxyphenyl)-L-alanine	$C_9H_{11}NO_4$
Lincomycin	An antibiotic substance derived from *Streptomyces lincolnensis*; methyl 6-S-dideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-D-erythro-α-D-galacto-octopyranoside.	$C_{18}H_{34}N_2O_6S$
Liotrix	A mixture of: Sodium liothyronine (sodium L-3,3',5-triiodothyronine) and sodium levothyroxine (sodium L-3,3',5,5'-tetraiodo thyronine).	$C_9H_{11}I_3NNaO_4$ and $C_{15}H_{10}I_4NNaO_4 \cdot XH_2O$
Lithium carbonate	Lithium carbonate	Li_2CO_3
Lomofungin	An antibiotic substance derived from *Streptomyces lomondensis* var. *lomondensis*.	
Lorazepam	7-Chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-2*H*-1,4-benzodiazepin-2-one.	$C_{15}H_{10}Cl_2N_2O_2$
Lucanthone	1-[[2-(Diethylamino)ethyl]amino]-4-methylthioxanthen-9-one	$C_{20}H_{24}N_2OS$
Lydimycin	An antibiotic substance derived from *Streptomyces lydicus*	
Lypressin	8-Lysine vasopressin	$C_{46}H_{65}N_{13}O_{12}S_2$
Mafenide	α-Amino-*p*-toluenesulfonamide	$C_7H_{10}N_2O_2S$
Magaldrate	Tetrakis (hydroxymagnesium) decahydroxydialuminate dihydrate	$Al_2H_{14}Mg_5O_{18} \cdot 2H_2O$
Mebutamate	2-sec-Butyl-2-methyl-1,3-propanediol dicarbamate; or 2-methyl-2-*sec*-butyl-1,3-propanediol dicarbamate.	$C_{10}H_{20}N_2O_4$
Mecrylate	Methyl 2-cyanoacrylate	$C_5H_5NO_2$
Medazepam	7-Chloro-2,3-dihydro-1-methyl-5-phenyl-1*H*-1, 4-benzodiazepine	$C_{16}H_{15}ClN_2$
Medrysone	11β-Hydroxy-6α-methylpregn-4-ene-3,20-dione	$C_{22}H_{32}O_3$
Mefenamic acid	*N*-(2,3-Xylyl)anthranilic acid	$C_{15}H_{15}NO_2$
Mefenorex	*N*-(3-Chloropropyl)-α-methylphenethylamine	$C_{12}H_{18}ClN$
Mefexamide	*N*-[2-(Diethylamino)ethyl]-2-(p-methoxy-phenoxy)acetamide	$C_{15}H_{24}N_2O$
Melitracen	*N,N*,10,10-Tetramethyl-Δ^9(10*H*),γ-anthracenepropylamine; 9-(3-dimethylaminlpropylidine)-10,10-dimethyl-9,10-dihydroanthracene.	$C_{21}H_{25}N$
Melphalan	L-3-[p[Bis(2-chloroethyl)aminophenyll alanine	$C_{13}H_{18}Cl_2N_2O_2$

Official name	Chemical name or description	Molecular formula
Memotine	3,4-Dihydro-1-[(*p*-methoxyphenoxy)methyl]isoquinoline	$C_{17}H_{17}NO_2$
Menoctone	6-(8-Cyclohexyloctyl)-3-hydroxy-1,4-naphthoquinone	$C_{24}H_{32}O_3$
Mephenytoin	5-ethyl-3-methyl-5-phenylhydantoin	$C_{12}H_{14}N_2O_2$
Meprednisone	17,21-Dihydroxy-16β-methylpregna-1,4-diene-3,11,20-trione	$C_{22}H_{28}O_5$
Mequidox	3-Methyl-2-quinoxalinemethanol 1,4-dioxide	$C_{12}H_{12}N_2O_3$
Mesoridazine	10-[2(1-Methyl-2-piperidyl)ethyl]-2-(methylsulfinyl)prenothiazine	$C_{21}H_{26}N_2OS_2$
Mestranol	3-Methoxy-19-nor-17α-pregna-1,3,5(10)-trien-20-yn-17-ol	$C_{21}H_{24}O_2$
Mesuprine	2'-Hydroxy-5'-[1-hydroxy-2-[(*p*-methoxyphenethyl)amino]propyl] methanesulfonanilide.	$C_{19}H_{24}N_2O_5S$
Metabromasalan	3,5-Dibromosalicylanilide	$C_{13}H_9Br_2NO_2$
Metalol	4'-[1-Hydroxy-2-(methylamino)propyl]methanesulfonanilide	$C_{11}H_{18}N_2O_3S$
Metaxalone	5-[3,5-Xylyoxy)methyl]-2-oxazolidinone	$C_{12}H_{15}NO_3$
Metformin	1,1-Dimethylbiguanide	$C_4H_{11}N_5$
Methacycline	4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydrc-3,5,10,12,12a-pentahydroxy-6-methnylene-1,11-dioxo-2-naphthacenecarboxamide; 6-deoxy-6-demethyl-6-methylene 5-oxytetracycline.	$C_{22}H_{22}N_2O_8$
Methallibure	1-Methyl-6-(1-methylallyl)-2,5-dithiobiurea	$C_7H_{14}N_4S_2$
Methaqualone	2-Methyl-3-o-tolyl-4(3*H*)-quinazolinone	$C_{15}H_{14}N_2O$
Methixene	1-Methyl-3-(thioxanthen-9-yimethyl)piperidine	$C_{20}H_{23}NS$
Methoxyflurane	2,2-Dichloro-1,1-difluoroethyl methyl ether	$C_3H_3Cl_2F_2O$
Methyldopa	*l*-3-(3,4-Dihydroxyphenyl)-2-methylalanine	$C_{10}H_{13}NO_4$
Metiapine	2-Methyl-11-(4-methyl-1-piperazinyl)dibenzo[*b,f*][1,4]thiazepine	$C_{19}H_{21}N_3S$
Metizoline	2-[(2-Methylbenzo[*b*]thien-3-yl)methyl]-2-imidazoline	$C_{13}H_{14}N_2S$
Metolazone	7-Chloro-1,2,3,4-tetrahydro-2-methyl-4-oxo-3-o-tolyl-6-quinazolinesulfonamide.	$C_{16}H_{16}ClN_3O_3S$
Metoserpate	Methyl 11,17α,18α-trimethoxy-3β,20α-yohimban-16β-carboxylate	$C_{24}H_{32}N_2O_5$
Metronidazole	2-Methyl-5-nitroimidazole-1-ethanol	$C_6H_9N_3O_3$
Mianserin	1,2,3,4,10,14b-Hexahydro-2-methyldibenzo[*c,f*]pyrazino[1,2-*a*] azepine.	$C_{18}H_{20}N_2$
Midaflur	4-Amino-2,2,5,5-tetrakis(trifluoromethyl)-3-imidazoline	$C_7H_3F_{12}N_3$
Milipertine	5,6-Dimethoxy-3-[2-[4-(o-methoxyphenyl)-1-piperazinyl] ethyl]-2-methylindole.	$C_{24}H_{31}N_3O_3$
Minocycline	4,7-Bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydro-1,11-dioxo-2-naphthacenecarboxamide.	$C_{23}H_{27}N_3O_7$
Mithramycin	From *Streptomyces argillaceus* n.sp. and *Streptomyces tanashiensis*	
Mitocromin	An antibiotic substance produced by *Streptomyces viridochromogenes*	
Mitomalcin	An antibiotic substance produced by *Streptomyces malayensis*	
Mitotane	1,1-Dichloro-2-(o-chlorophenyl)-2-(*p*-chlorophenyl)ethane	$C_{14}H_{10}Cl_4$
Molindone	3-Ethyl-6,7-dihydro-2-methyl-5-(morpholinomethyl)indol-4(5*H*)-one	$C_{15}H_{21}N_2O_2$
Monensin	2-[5-Ethyltetrahydro-5-[tetrahydro-3-methyl-5-[tetrahydro-6-hydroxy-6-(hydroxymethyl)-3,5-dimethylpyran-2-yl]-2-furyl]-2-furyl]-3-hydroxy-β-methoxy-α,γ 2,8-tetramethyl-1,6-dioxaspiro [4,5] decane-7-butyric acid.	$C_{21}H_{32}O_{11}$
Morantel	(*E*)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(3-methyl-2-thienyl)vinyl] pyrimidine.	$C_{12}H_{16}N_2S$
Nadide	3-Carbamoyl-1-β-D-ribofuranosylpyridinium hydroxide, 5'-ester with adenosine-5'-pyrophosphate, inner salt; codehydrogenase I.	$C_{21}H_{27}N_7O_{14}P_2$
Nafcillin	6-(2-Ethoxy-1-naphthamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]-heptane-2-carboxylic acid; 6-(2-ethoxy-1-naphthamido) penicillanic acid.	$C_{21}H_{22}N_2O_5S$
Nafronyl	2-(Diethylamino)ethyl tetrahydro-α-(1-naphthylmethyl)-2-furanpropionate.	$C_{21}H_{33}NO_3$
Nalbuphine	17-(Cyclobutylmethyl)-4,5α-epoxymorphinan-3,6α,14-triol	$C_{21}H_{27}NO_4$
Nalidixic acid	1-Ethyl-1,4-dihydro-7-methyl-4-oxo-1,8-naphthyridine-3-carboxylic acid.	$C_{12}H_{12}N_2O_3$
Nalmexone	7,7a,8,9-Tetrahydro-3,7a-dihydroxy-12-(3-methyl-2-butenyl)-6*H*-8,9c-imino-ethanophenanthro[4,5-bcd]furan-5(4a*H*)-one; *N*-3,3'-dimethylallylnoroxymorphone.	$C_{21}H_{23}NO_4$
Naloxone	(−)-17-Allyl-4,5α-epoxy-3,14-dihydroxymorphinan-6-one	$C_{19}H_{21}NO_4$
Nandrolone	17β-Hydroxyester-4-en-3-one	$C_{18}H_{26}O_2$
Naranol	8,9,10,11,11a,12-Hexahydro-8,10-dimethyl-7a*H*-naphthol[1',2':5,6] pyrano[3,2-c]pyridin-7a-ol.	$C_{13}H_{23}NO_2$
Nebramycin	An antibiotic substance derived from *Streptomyces tenebrarius*	
Nequinate	3-Acetoxy-6-butyl-7-benzyloxy-4-oxoquinoline	$C_{22}H_{23}NO_4$
Nifuraldezone	5-Nitro-2-furaldehyde semioxamazone	$C_7H_6N_4O_5$
Nifurimide	(±)-4-Methyl-1-(5-nitrofurfurylideno)amino]-2-imidazolidinone	$C_9H_{12}N_4O_4$
Nifursol	3,5-Dinitrosalicylic acid (5-nitrofurfurylidene)hydrazide	$C_{12}H_7N_5O_9$
Nimazone	3-(*p*-Chlorophenyl)-4-imino-2-oxo-1-imidazolidineacetonitrile	$C_{11}H_7ClN_4O$
Niridazole	1-(5-Nitro-2-thiazolyl)-2-imidazolidinone	$C_6H_6N_4O_3S$
Nisobamate	Isopropylcarbamic acid ester with 2-(hydroxymethyl)-2,3-dimethylpentyl carbamate.	$C_{13}H_{25}N_2O_4$
Nonoxynol 4	Nonylphenoxypolyethyleneoxyethanol	$C_{15}H_{24}O(C_2H_4O)_n$ (n=approximately 4)
Nonoxynol 9	do	$C_{15}H_{24}O(C_2H_4O)_n$ (n=approximately 9)
Nonoxynol 15	do	$C_{15}H_{24}O(C_2H_4O)_n$ (n=approximately 15)
Nonoxynol 30	do	$C_{15}H_{24}O(C_2H_4O)_n$ (n=approximately 30)
Norethindrone	17-Hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one	$C_{20}H_{26}O_2$
Norethynodrel	17-Hydroxy-19-nor-17α-pregn-5(10)-en-20-yn-3-one; 17α-ethynyl-17-hydroxy-5(10)-estren-3-one.	$C_{20}H_{26}O_2$

Official name	Chemical name or description	Molecular formula
Norflurane	1,1,1,2-Tetrafluoroethane	$C_2H_2F_4$
Norgestrel	(±)-13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one	$C_{21}H_{28}O_2$
Nortriptyline	10,11-Dihydro-*N*-methyl-5*H*-dibenzo[*a*,*d*]cycloheptene-Δ^{5},γ-propylamine.	$C_{19}H_{21}N$
Ocrylate	Octyl 6-cyanoacrylate	$C_{12}H_{17}NO_2$
Octicizer	2-Ethylhexyl diphenyl phosphate	$C_{20}H_{27}O_4P$
Octodrine	1,5-Dimethylhexylamine	$C_8H_{19}N$
Opipramol	4-[3-(5*H*-dibenz[*b*,*f*]azepin-5-yl)propyl]-1-piperazine ethanol	$C_{23}H_{29}N_3O$
Orgotein	A pure, water-soluble, highly compact protein of fairly low molecular weight (about 34,000) with a predominantly alpha-helical configuration; the molecule is chelated with from two (2) to four (4) atoms of divalent metals, for example, Mg, Zn, and Cu, and it is presently produced from bovine liver in a multistep process.	----------
Ormetoprim	2,4-Diamino-5-(6-methylveratryl)pyrimidine	$C_{14}H_{18}N_4O_2$
Oxandrolone	17β-Hydroxy-17-methyl-6-oxa-5α-androstan-3-one	$C_{19}H_{30}O_3$
Oxazepam	7-Chloro-1,3-dihydro-3-hydroxy-5-phenyl-2*H*-1,4-benzodiazepin-2-one	$C_{15}H_{11}ClN_2O_2$
Oxethazaine	2,2′-[(2-Hydroxyethyl)imino]-bis[*N*-(α,α-dimethylphenethyl)-*N*-methylacetamide].	$C_{32}H_{52}N_4O_3$
Oxisuran	(Methylsulfinyl)methyl 6-pyridyl ketone	$C_8H_9NO_2S$
Oxogestone	20,9-Hydroxy-19-norpregn-4-en-3-one;20,9-hydroxy-19-nor-4-pregnen-3-one.	$C_{21}H_{30}O_3$
Oxprenolol	1-(o-(Allyloxy)phenoxy]-3-(isopropylamino)-2-propanol	$C_{15}H_{23}NO_3$
Oxybenzone	2-Hydroxy-4-methoxybenzophenone	$C_{14}H_{12}O_3$
Oxychlorosene	The hypochlorous acid complex of a mixture of the phenyl sulfonate derivatives of aliphatic hydrocarbons.	
Oxycodone	Dihydrohydroxycodeinone	$C_{18}H_{21}NO_4$
Oxymetazoline	6-*tert*-Butyl-3-(4-imidazolin-2-ylmethyl)-2,4-dimethylphenol	$C_{16}H_{24}N_2O$
Oxymetholone	17β-Hydroxy-2-(hydroxymethylene)-17α-methyl-5α-androstan-3-one	$C_{20}H_{32}O_3$
Oxypertine	5,6-Dimethoxy-2-methyl-3-[2-(4-phenyl-1-piperazinyl)ethyl]-indole	$C_{24}H_{29}N_3O_2$
Pancrelipase	A concentrate of pancreatic enzymes standardized for lipase content	----------
Pancuronium	1,1′-(3α, 17β-Dihydroxy-5α-androstan-2β, 16β-ylene)bis[5-methylpiperidinium] ion diacetate.	$C_{35}H_{60}N_2O_4$**
Panthenol	(±)2,4-Dihydroxy-*N*-(3-hydroxypropyl)-3,3-dimethylbutyramide; pantothenyl alcohol.	$C_9H_{19}NO_4$
Paramethasone	6α-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione.	$C_{22}H_{29}FO_5$
Parbendazole	Methyl 5-butyl-2-benzimidazolecarbamate	$C_{13}H_{17}N_3O_2$
Pargyline	*N*-Methyl-*N*-2-propynylbenzylamine	$C_{11}H_{13}N$
Pemoline	2-Amino-5-phenyl-5-oxazolin-4-one	$C_9H_8N_2O_2$
Penicillamine	p-3-Mercaptovaline	$C_5H_{11}NO_2S$
Pentagastrin	*N*-(α-Carbamoylphenethyl)-3-[2-[2-[3-(carboxyamino)propionamido]-3-indol-3-ylpropionamido]-4-(methylthio)butyramido]succinamic acid *N-tert*-butyl ester; *N-tert*-butyloxycarbonyl-β-alanyl-L-tryptophyl-L-methionyl-L-aspartyl-L-phenylalanine amide.	$C_{37}H_{49}N_9O_9S$
Pentazocine	(±)1,2,3,4,5,6-Hexahydro-*cis*-6,11-dimethyl-3-(3-methyl-6-butenyl)-2,6-methano-3-benzazocin-8-ol.	$C_{19}H_{27}NO$
Perhexilene	2-(2,2-Dicyclohexylethyl)piperidine	$C_{19}H_{35}N$
Perlapine	6-(4-Methyl-1-piperazinyl)morphanthridine	$C_{19}H_{23}N_3$
Phentermine	α,α-Dimethylphenethylamine	$C_{10}H_{15}N$
Phenyramidol	α-(2-Pyridylamino)methyl]benzyl alcohol	$C_{13}H_{14}N_2O$
Phthalofyne	Mono(1-ethyl-1 methyl-2-propynyl) phthalate	$C_{13}H_{14}O_4$
Pimozide	1-[1-[4,4-Bis-(p-fluorophenyl)butyl]-4-piperidyl]-1-benzimidazolinone; 1-[4,4-bis(p-fluorophenyl)butyl]-4-(2-oxo-1-benzimidazolinyl)piperidine.	$C_{28}H_{29}F_2N_3O$
Pipazethate	2-(2-Piperidinoethoxy)ethyl 10*H*-pyrido[3,2-*b*][1,4]benzothiazine-10-carboxylate.	$C_{23}H_{29}N_3O_2S$
Piperacetazine	10-[3-[4-(2-Hydroxyethyl)piperidino]propyl]phenothiazin-2-yl methyl ketone.	$C_{24}H_{29}N_3O_2S$
Piprozolin	Ethyl 3-ethyl-4-oxo-5-piperidino-Δ^{2}-α-thiazolidineacetate	$C_{14}H_{24}N_2O_2S$
Piquizil	Isobutyl 4-(6-7-dimethoxy-4-quinazolinyl)-5-piperazinecarboxylate	$C_{21}H_{29}N_4O_4$
Polacrilin	A synthetic ion-exchange resin prepared through the polymerization of methacrylic acid and divinylbenzene and supplied in the hydrogen or free-acid form.	----------
Polacrilin potassium	The potassium salt of a synthetic ion-exchange resin derived through the copolymerization of methacrylic acid and divinylbenzene.	----------
Poldine	2-(Hydroxymethyl)-1,1-dimethylpyrrolidinium benzilate	$C_{22}H_{28}NO_3$
Poligeenan	3,6-Anhydro-4-*O*-β-D-galactopyranosyl-α-D-galactopyranose 2,4′-bis-(potassium/sodium sulfate) (1→3′)-polysaccharide.	$[C_{12}H_{18}M_2O_{22}S_2]_n$ where M=Na or K
Poloxalene	Liquid nonionic surfactant polymer of the polyoxypropylene polyoxyethylene type, having an average molecular weight of 3000.	
Polyglycolic acid	Poly(oxycarbonylmethylene)	$(C_2H_2O_2)_n$
Polymacon	Poly(2-hydroxyethyl methacrylate)	$(C_6H_{10}O_3)_n$
Polytef	Poly(tetrafluoroethylene)	$(C_2F_4)_n$
Polythiazide	6-Chloro-3,4-dihydro-2-methyl-3-[[(2,2,2-trifluoroethyl)thio]-methyl]-2*H*-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide.	$C_{11}H_{11}ClF_3N_5O_4S_3$
Poncuronium	1,1′-(3α, 17β-Dihydroxy-5α-androstan-2β,16β-ylene)bis[1-methylpiperidinium]diacetate.	$C_{34}H_{62}N_2O_4$
Povidone	Polyvinylpyrrolidone	----------
Pralidoxime	2-Formyl-1-methylpyridinium oxime	$C_7H_9N_2O$
Prednival	11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 17-valerate	$C_{26}H_{34}O_6$
Pregnenolone	3β-Hydroxypregn-5-en-20-one	$C_{21}H_{32}O_2$
Prilocaine	2-(Propylamino)-o-propionotoluidide	$C_{13}H_{20}N_2O$
Procarbazine	*N*-Isopropyl-α-(2-methylhydrazine)-*p*-toluamide	$C_{12}H_{19}N_3O$
Profadol	*m*-(1-Methyl-3-propyl-3-pyrrolidinyl)phenol	$C_{14}H_{21}NO$

Official name	Chemical name or description	Molecular formula
Propiolactone	2-Oxetanone; β-propiolactone	$C_3H_4O_2$
Propranolol	1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol	$C_{16}H_{21}NO_2$
Protriptyline	*N*-Methyl-5*H*-dibenzo[*a*,*d*]cycloheptene-5-propylamine	$C_{19}H_{21}N$
Pyrantel	(*E*)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine	$C_{11}H_{14}N_2S$
Pyrithione zinc	Bis[1-hydroxy-2(1*H*)-pyridinethionato]zinc	$C_{10}H_8N_2O_2S_2Zn$
Pyrrocaine	1-Pyrrolidineaceto-2′,6′-xylidide	$C_{14}H_{20}N_2O$
Pyrrolnitrin	3-Chloro-4-(3-chloro-2-nitrophenyl)pyrrole	$C_{10}H_6Cl_2N_2O_2$
Quazodine	4-Ethyl-6,7-dimethoxyquinazoline; 6,7-dimethoxy-4-ethylquinazoline	$C_{12}H_{14}N_2O_2$
Quinaldine blue	1-Ethyl-2-[3-(1-ethyl-2(1*H*)quinolylidene)propenyl] quinolinium chloride.	$C_{25}H_{23}ClN_2$
Quingestanol	3-(Cyclopentyloxy)-19-nor-17α-pregna-3,5-dien-20-yn-17-ol	$C_{23}H_{34}O_2$
Quinternol	8-Hydroxy-α-[(isopropylamino)methyl]-5-quinolinemethanol	$C_{14}H_{18}N_2O_2$
Racephenicol	(±)-*threo*-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-(methylsulfonyl)phenethyl]-acetamide.	$C_{12}H_{15}Cl_2NO_5S$
Ranimycin	An antibiotic substance derived from *Streptomyces lincolnensis*	$C_{12}H_{18}O_5$
Ribaminol	Ribonucleic acid compound with 2-(diethylamino)ethanol; 2-hydroxytriethylammonium ribonucleate.	
Riboprine	*N*-(3-Methyl-2-butenyl)adenosine; 6-*N*-(3-methyl-2-butenyl-amino(-9-β-D-ribofuranosyl-purine.	$C_{15}H_{21}N_5O_4$
Rifampin	5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,20,22-heptamethyl-8-[*N*-(4-methyl-1-piperazinyl)formimidoyl]-2,7-(epoxypentadeca[1,11,13]trienimino)naphtho[2,1-b]furan-1,11(2H)-dione 21-acetate; 3-(4-methylpiperazinyliminomethyl) rifamycin SV.	$C_{43}H_{58}N_4O_{12}$
Ritodrine	*Erythro*-*p*-hydroxy-α-[1-[(*p*-hydroxyphenethyl)amino]ethyl]benzyl alcohol.	$C_{17}H_{21}NO_3$
Ronidazole	(1-Methyl-5-nitroimidazol-2-yl)methylcarbamate	$C_6H_8N_4O_4$
Rotoxamine	*l*-2-[*p*-Chloro-α-[2-(dimethylamino)-ethoxy] benzyl]pyridine	$C_{16}H_{19}ClN_2O$
Roxarsone	4-Hydroxy-3-nitrobenzenearsonic acid	$C_6H_6AsNO_6$
Salethamide	*N*-[2-(Diethylamino)ethyl]salicylamide	$C_{13}H_{20}N_2O_2$
Seperidol	4-[4-(4-chloro-α,α,α-trifluoro-*m*-tolyl)-4-hydroxy-piperidinol]-4′-fluorobutyrophenone; 1-[3-(4-fluorobenzoyl)-propyl]-4-hydroxy-4-(3-trifluoromethyl-4-chlorophenyl)-piperidine.	$C_{22}H_{23}ClF_4NO_2$
Silandrone	17β-(Trimethylsiloxy)androst-4-en-3-one	$C_{22}H_{34}O_2Si$
Simethicone	A mixture of dimethyl polysiloxanes and silica gel	
Sotalol	4′-[1-Hydroxy-2-(isopropylamino)-ethyl]-methanesulfonanilide	$C_{12}H_{20}N_2O_3S$
Soterenol	2′-Hydroxy-5′-[1-hydroxy-2-(isopropylamino)ethyl]methane-sulfonanilide.	$C_{12}H_{20}N_2O_4S$
Stanozolol	17-Methyl-5α-androstano[3,2-c]pyrazol-17β-ol	$C_{21}H_{32}N_2O$
Steffimycin	An antibiotic substance derived from *Streptomyces steffisburgensis* var. *steffisburgensis* sp.n.	
Sulfadoxine	N^1-(5,6-Dimethoxy-4-pyrimidinyl)sulfanilamide	$C_{12}H_{14}N_4O_4S$
Sulfameter	N^1-(5-Methoxy-2-pyrimidinyl)sulfanilamide	$C_{11}H_{12}N_4O_3S$
Sulfamoxole	N^1-(4,5-Dimethyl-2-oxazolyl)sulfanilamide	$C_{11}H_{13}N_3O_3S$
Sulfanitran	4′[(*p*-Nitrophenyl)sulfamoyl]acetanilide	$C_{14}H_{13}N_3O_5S$
Sulfazamet	N^1-(3-Methyl-1-phenylpyrazol-5-yl)sulfanilamide	$C_{16}H_{16}N_4O_2S$
Sulisobenzone	5-Benzoyl-4-hydroxy-2-methoxybenzenesulfonic acid	$C_{14}H_{12}O_6S$
Sulpiride	*N*-[(1-Ethyl-2-pyrrolidinyl)methyl]-5-sulfamoyl-o-anisamide	$C_{15}H_{23}N_3O_4S$
Surgibone	Bone and cartilage obtained from bovine embryos and young calves.	
Temazepam	7-Chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2*H*-1, 4-benzodiazepin-2-one.	$C_{16}H_{13}ClN_2O_2$
Testolactone	13-Hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17cic acid δ-lactone	$C_{19}H_{24}O_3$
Tetrydamine	4,5,6,7-Tetrahydro-2-methyl-3-(methylamino)-2*H*-indazole; 2-methyl-3-methylamino-4,5,6,7-tetrahydroindazole.	$C_9H_{15}N_3$
Thiamphenicol	D-(+)-*threo*-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-(methylsulfonyl)-phenethyl]acetamide.	$C_{12}H_{15}Cl_2NO_5S$
Thioguanine	2-Aminopurine-6-thiol,hemihydrate	$C_5H_5N_5S \cdot \frac{1}{2}H_2O$
Thioridazine	10-[2-(1-Methyl-2-piperidyl)ethyl]-2-(methylthio)phenothiazine	$C_{21}H_{26}N_2S_2$
Thiosalan	3,4′,5-Tribromo-2-mercaptobenzanilide; 3,4′,5-tribromothiosalicyl-anilide.	$C_{13}H_8Br_3NOS$
Thiothixene	*N*,*N*-Dimethyl-9-[3-(4-methyl-1-piperazinyl)propylidene]thio-xanthene-2-sulfonamide.	$C_{23}H_{29}N_3O_2S_2$
Thiphenamil	*S*[2-(Diethylamino)ethyl] diphenylthioacetate	$C_{22}H_{31}NOS$
Thiram	Bis(dimethylthiocarbamoyl) disulfide	$C_6H_{12}N_2S_4$
Thonzonium	Hexadecyl[2-[(*p*-methoxybenzyl)-2-pyrimidinylamino]ethyl]-dimethylammonium ion.	$C_{32}H_{53}N_4O^+$
Tibolone	17-Hydroxy-7α-methyl-19-nor-17α-pregn-5(10)-en-20-yn-3-one	$C_{21}H_{28}O_2$
Tibrofan	4,4′,5-Tribromo-2-thiophenecarboxanilide; 4,5-dibromothiophene-2-carboxyl-4-bromanilide.	$C_{11}H_6Br_3NOS$
Tigestol	19-Nor-17α-pregn-5(10)-en-20-yn-17-ol; 17α-ethynyl-5(10)-estren-17-ol.	$C_{21}H_{28}O$
Tiletamine	2-(Ethylamino)-2-(2-thienyl)cyclohexanone	$C_{12}H_{17}NOS$
Tilidine	Ethyl 2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate	$C_{17}H_{23}NO_2$
Tinidazole	1-[2-(Ethylsulfonyl)ethyl]-2-methyl-5-nitroimidazole	$C_8H_{13}N_3O_4S$
Tocamphyl	1-(*p*,α-Dimethylbenzyl) camphorate 1:1 salt with 2,2′-iminodiethanol.	$C_{19}H_{33}O_4 \cdot C_4H_{11}NO_2$ or $C_{23}H_{47}NO_6$
Tofenacin	*N*-Methyl-2-[(o-methyl-α-phenylbenzyl)-oxy]ethylamine	$C_{17}H_{21}NO$
Tolazamide	1-(Hexahydro-1*H*-azepin-1-yl)-3-(*p*-tolylsulfonyl)urea	$C_{14}H_{21}N_3O_3S$
Tolnaftate	*O*-2-Naphthyl *m*,*N*-dimethylthiocarbanilate	$C_{19}H_{17}NOS$
Tramadol	(±)-*trans*-2-[(Dimethylamino)methyl]-1-(*m*-methoxyphenyl)cyclohexanol.	$C_{15}H_{23}NO_2$
Transclomiphene	2-[*p*-(2-Chloro-*trans*-1,2-diphenylvinyl)phenoxy]-triethylamine	$C_{26}H_{28}ClNO$
Triamterene	2,4,7-Triamino-6 phenylpteridine	$C_{12}H_{11}N_7$
Tribromsalan	3,4′5-Tribromosalicylanilide	$C_{13}H_8Br_3NO_2$
Triclocarban	3,4,4′-Trichlorocarbanilide	$C_{13}H_9Cl_3N_2O$

Official name	Chemical name or description	Molecular formula
Triclofos	2,2,2-Trichloroethyl dihydrogen phosphate	$C_2H_4Cl_3O_4P$
Triflocin	4-(α,α,α-Trifluoro-*m*-toluidino)nicotinic acid	$C_{13}H_9F_3N_2O_2$
Triflumidate	Ethyl *m*-benzoyl-*N*-[(trifluoromethyl)sulfonyl] carbanilate	$C_{17}H_{14}F_3NO_5S$
Trifluperidol	4'-Flouro-4-[4-hydroxy-4-(α,α,α-trifluoro-*m*-tolyl) piperidino] butyrophenone.	$C_{22}H_{23}F_4NO_2$
Trimipramine	5-[3-(Dimethylamino)-2-methylpropyl]-10,11-dihydro-5*H*-diben - [*b*,*f*]azepine.	$C_{20}H_{26}N_2$
Triorsalen	6-Hydroxy-3,2,7,-trimethyl-5-benzofuranacrylic acid, δ-lactone	$C_{14}H_{12}O_3$
Tromethamine	2-Amino-2-(hydroxymethyl)-1,3-propanediol	$C_4H_{11}NO_3$
Tropicamide	*N*-Ethyl-2-phenyl-*N*-(4-pyridylmethyl)-hydracrylamide	$C_{18}H_{21}N_3O_2$
Tybamate	2-Methyl-2-propyltrimethylene butylcarbamate carbamate; or 2-(hydroxymethyl)-2-methylpentyl butylcarbamate carbamate.	$C_{13}H_{26}N_2O_4$
Tyloxapol	*p*-(1,1,3,3-Tetramethylbutyl)phenol polymer with formaldehyde, ether with polyethylene glycol.	
Verapamil	5-[(3,4-Dimethoxyphenethyl)methylamino]-2-(3,4-dimethoxyphenyl)-2-isopropylvaleronitrile.	$C_{27}H_{38}N_2O_4$
Vinblastine	An alkaloid (vincaleukoblastine) extracted from *Vinca rosea*	$C_{46}H_{58}N_4O_9$
Vincristine	Alkaloid from *Vinca rosea*, Linn	$C_{46}H_{56}N_4O_{10}$
Volazocine	3-(Cyclopropylmethyl)-1,2,3,4,5,6-hexahydro-*cis*-6,11-dimethyl-2,6-methano-3-benzazocine.	$C_{19}H_{27}N$
Zolamine	2-[(2-Dimethylamino)ethyl](*p*-methoxybenzyl)amino]thiazole	$C_{14}H_{21}N_3OS$

NOTE.—Incorporation by reference materials approved by the Director, Office of the FEDERAL REGISTER March 20, 1973 and March 25, 1975.

[FR Doc.75-7952 Filed 3-26-75;8:45 am]