5-4-93
Vol. 58 No. 84
Pages 26499-26678

federal register

Tuesday
May 4, 1993

Briefings on How To Use the Federal Register
For information on briefings in Washington, DC, and Philadelphia, PA, see announcement on the inside cover of this issue.

FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The seal of the National Archives and Records Administration authenticates this issue of the **Federal Register** as the official serial publication established under the Federal Register Act. 44 U.S.C. 1507 provides that the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper, 24x microfiche format and magnetic tape. The annual subscription price for the **Federal Register** paper edition is $375, or $415 for a combined **Federal Register**, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the Federal Register Index and LSA is $353; and magnetic tape is $37,500. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $4.50 for each issue, or $4.50 for each group of pages as actually bound; or $1.50 for each issue in microfiche form; or $175.00 per magnetic tape. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA or MasterCard. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 58 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	202–783–3238
Magnetic tapes	512–1530
Problems with public subscriptions	512–2303
Single copies/back copies:	
Paper or fiche	783–3238
Magnetic tapes	512–1530
Problems with public single copies	512–2457
FEDERAL AGENCIES	
Subscriptions:	
Paper or fiche	523–5243
Magnetic tapes	512–1530
Problems with Federal agency subscriptions	523–5243

For other telephone numbers, see the Reader Aids section at the end of this issue.

THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: May 12 and June 15 at 9:00 am
WHERE: Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

PHILADELPHIA, PA

WHEN: May 25, at 1:00 pm
WHERE: William J. Green, Jr. Federal Building, Conference Room 6306–10, 600 Arch St. Philadelphia, PA
RESERVATIONS: Federal Information Center 1–800–347–1997

Printed on recycled paper containing 100% post consumer waste

Contents

Federal Register
Vol. 58, No. 83
Tuesday, May 4, 1993

Agriculture Department
See Cooperative State Research Service
See Forest Service

Arctic Research Commission
NOTICES
Meetings, 26531

Arts and Humanities, National Foundation
See National Foundation on the Arts and the Humanities

Christopher Columbus Quincentenary Jubilee Commission
NOTICES
Meetings, 26534

Coast Guard
NOTICES
Meetings:
Lower Mississippi River Waterway Safety Advisory Committee, 26582
National Boating Safety Advisory Council, 26582, 26583

Commerce Department
See International Trade Administration
See National Institute of Standards and Technology

Commodity Futures Trading Commission
NOTICES
Contract market proposals:
Chicago Mercantile Exchange—
Standard and Poor's 500 Stock Price Index, etc., 26534

Cooperative State Research Service
NOTICES
Meetings:
Agricultural Research and Extension Users National Advisory Board, 26529

Drug Enforcement Administration
NOTICES
Applications, hearings, determinations, etc.:
Ganes Chemical, Inc., 26559
Radian Corp., 26559

Education Department
RULES
Elementary and secondary education:
Educational agencies affected by Federal activities or unable to provide suitable free public education; assistance; CFR correction, 26524
Postsecondary education:
Student assistance general provisions—
Noncitizen applicants immigration status; determination system; reporting and recordkeeping requirements, 26674
NOTICES
Grants and cooperative agreements; availability, etc.:
National resource centers program for foreign language and area studies, 26534
Student Literacy Corps and Student Mentoring Corps program, 26535

Employment and Training Administration
NOTICES
Adjustment assistance:
Chevron Petroleum Technology Co., 26559
Hurlock Sportswear et al., 26560
Syntron, Inc., et al., 26561
Texaco Exploration & Production, Inc., 26561

Energy Department
See Energy Information Administration
See Federal Energy Regulatory Commission
NOTICES
Inventions available for license, 26535

Energy Information Administration
NOTICES
Agency information collection activities under OMB review, 26535
Energy Policy Act:
Data needs and user requirements examination, 26536

Environmental Protection Agency
NOTICES
Agency information collection activities under OMB review, 26541
Clean Water Act:
Confidential business information and data transfer to contractors, 26542
Hazardous waste:
State program adequacy determinations—
Kentucky, 26543
Toxic and hazardous substances control:
Premanufacture notices receipts, 26544

Executive Office of the President
See Presidential Documents

Federal Communications Commission
RULES
Radio stations; table of assignments:
Kentucky, 26524
Oklahoma, 26525
Texas, 26525
Television stations; table of assignments:
Nebraska, 26525
PROPOSED RULES
Radio stations; table of assignments:
Oregon, 26528

Federal Energy Regulatory Commission
RULES
Filing fees; annual update, 26522
NOTICES
Electric rate, small power production, and interlocking directorate filings, etc.:
Panther Creek Partners, 26539
Meetings; Sunshine Act, 26588
Applications, hearings, determinations, etc.:
El Paso Natural Gas Co., 26539
Massachusetts Electric Co., 26540
Northern Natural Gas Co., 26540
Northern States Power Co., 26541

Texas Eastern Transmission Corp., 26541

Federal Maritime Commission
NOTICES
Agreements filed, etc., 26545

Federal Reserve System
RULES
Loans to executive officers, directors, and principal shareholders of member banks (Regulation O):
Loans to holding companies and affiliates, 26507
Organization, functions, and authority delegations:
Secretary, Board of Governors et al., 26508
NOTICES
Federal Open Market Committee:
Domestic policy directives, 26546
Foreign currency operations—
Federal Reserve Bank of New York; authorization, 26546
Procedural instructions, 26546
Securities procedures; allocation, 26548
Meetings; Sunshine Act, 26588
Applications, hearings, determinations, etc.:
Caisse Nationale de Credit Agricole S.A., 26548

Federal Trade Commission
NOTICES
Prohibited trade practices:
Nature's Cleanser, Inc., et al., 26549

Fish and Wildlife Service
NOTICES
Meetings:
Aquatic Nuisance Species Task Force, 26558

Food and Drug Administration
RULES
Animal drugs, feeds, and related products:
Sponsor name and address changes—
PM Ag Products, Inc., 26523
Human drugs:
Antibiotic drugs—
Azithromycin, etc., 26655
Cefprozil, etc., 26658
Clarithromycin, etc., 26652
Idarubicin hydrochloride, 26662
Loracarbef, etc., 26665
Sterile imipenem monohydrate-cilastatin sodium, 26669
Tobramycin-fluorometholone acetate ophthalmic suspension, 26671
NOTICES
Food additive petitions:
E.I. du Pont de Nemours & Co., 26552
Medical devices; premarket approval:
Ciba Vision Disinfecting Solution, 26552
Meetings:
Advisory committees, panels, etc., 26553, 26554, 26555
Industry information exchange, 26555

Forest Service
NOTICES
Appealable decisions; legal notice:
Northern region, 26530
Appeal exemptions; timber sales:
Jefferson National Forest, VA, 26529
Environmental statements; availability, etc.:
Pacific Southwest Region; California spotted owl; Sierran province management, 26531

Health and Human Services Department
See Food and Drug Administration
See National Institutes of Health

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Public and Indian housing—
Urban revitalization demonstration program, 26556
Mortgagee Review Board; administrative actions, 26556

Interior Department
See Fish and Wildlife Service
See National Park Service

Internal Revenue Service
RULES
Federal regulatory review; correction, 26524

International Trade Administration
NOTICES
Antidumping:
Stainless steel wire rods from—
Brazil et al., 26531
Sulfur dyes, including sulfur vat dyes, from—
India, 26532
Applications, hearings, determinations, etc.:
University of—
Connecticut, 26533

Justice Department
See Drug Enforcement Administration

Labor Department
See Employment and Training Administration
See Occupational Safety and Health Administration

National Foundation on the Arts and the Humanities
NOTICES
Meetings:
Arts National Council, 26562
Dance Advisory Panel, 26562
Folk Arts Advisory Panel, 26563

National Highway Traffic Safety Administration
RULES
Motor vehicle safety standards:
Steering assembly control system; impact protection for driver, 26526
NOTICES
Motor vehicle safety standards:
Nonconforming vehicles—
Importation eligibility; determinations, 26583, 26584, 26586

National Institute of Standards and Technology
NOTICES
Patent licenses; non-exclusive, exclusive, or partially exclusive:
Techtrol Cyclonetics, Inc., 26533

National Institutes of Health
NOTICES
Meetings:
Recombinant DNA Advisory Committee, 26676
Recombinant DNA molecules research:
Actions under guidelines
Proposed, 26676

National Park Service
NOTICES
National Register of Historic Places:
Pending nominations, 26558

National Science Foundation
NOTICES
Meetings:
Biological Sciences Advisory Committee, 26563
International Programs Special Emphasis Panel, 26563
Meetings; Sunshine Act, 26588

Nuclear Regulatory Commission
NOTICES
Abnormal occurrence reports:
Periodic report to Congress, 26563
Meetings:
CONTAIN Peer Review Committee, 26564
Applications, hearings, determinations, etc.:
Capital Materials Testing, Inc., 26564
Wolf Creek Nuclear Operating Corp., 26565
Yale-New Haven Hospital, 26566

Occupational Safety and Health Administration
RULES
Construction safety and health standards:
Lead exposure, 26590

Physician Payment Review Commission
NOTICES
Grants and cooperative agreements; availability, etc.:
Research and analysis to support Commission's advice to Congress in specific policy areas, 26568

Presidential Documents
PROCLAMATIONS
Special observances:
Arbor Day, National (Proc. 6554), 26499
Day of Prayer, National (Proc. 6553), 26501
Law Day, U.S.A. (Proc. 6555), 26503
Loyalty Day (Proc. 6556), 26505

Public Health Service
See Food and Drug Administration
See National Institutes of Health

Securities and Exchange Commission
RULES
Securities:
Small business initiatives; financing facilitation and reporting requirements compliance, 26509
NOTICES
Preferred Group of Mutual Funds, 26581
Self-regulatory organizations; proposed rule changes:
National Securities Clearing Corp., 26570
Participants Trust Co., 26573
Applications, hearings, determinations, etc.:
American General Equity Accumulation Fund, Inc., 26574
Benchmark Funds et al., 26575
Liberty All-Star Equity Fund et al., 26579

Transportation Department
See Coast Guard
See National Highway Traffic Safety Administration

Treasury Department
See Internal Revenue Service
NOTICES
Agency information collection activities under OMB review, 26586

Separate Parts In This Issue

Part II
Labor Department, Occupational Safety and Health Administration, 26589

Part III
Health and Human Services Department, Food and Drug Administration, 26652

Part IV
Education Department, 26674

Part V
Health and Human Services Department, National Institutes of Health, 26676

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
Free **Electronic Bulletin Board** service for Public Law numbers, Federal Register finding aids, and a list of Clinton Administration officials is available on 202–275–1538 or 275–0920.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

6553.....26499
6554.....26501
6555.....26503
6556.....26505

12 CFR

215.....26507
265.....26508

17 CFR

228.....26509
230.....26509
239.....26509
240.....26509
249.....26509

18 CFR

381.....26522

21 CFR

430 (5 documents).....26652, 26655, 26658, 26662, 26665
436 (4 documents).....26652, 26655, 26658, 26665
441.....26669
442.....26658
443.....26665
444.....26671
450.....26662
452 (2 documents).....26652, 26655
510.....26523
520.....26523

26 CFR

1.....26524
5c.....26524

29 CFR

1926.....26590

34 CFR

222 (2 documents).....26524
668.....26674

47 CFR

73 (4 documents).....26524, 26525,

Proposed Rules:

73.....26528

49 CFR

571.....26526

Federal Register
Vol. 58, No. 84
Tuesday, May 4, 1993

Presidential Documents

Title 3—

The President

Proclamation 6553 of April 30, 1993

National Day of Prayer, 1993

By the President of the United States of America

A Proclamation

The American people were the first to define a nation in terms of both spirituality and human liberty. Throughout our Nation's history, America has been a beacon for millions in search of spiritual and religious freedom. Immigrants have come to the United States seeking not just freedom from persecution and discrimination, but also freedom for the right of self-determination. On this National Day of Prayer, we reaffirm this fundamental freedom of religion that has made our Nation so strong.

Thomas Jefferson understood the greater purpose of the liberty that our Founding Fathers sought during the creation of our Nation. Although it was against the British that the colonists fought for political rights, the true source of the rights of man was clearly stated in the Declaration of Independence. Jefferson wrote that all humans are "endowed by their Creator with certain unalienable Rights . . . ." It was self-evident to him that denying these rights was wrong and that he and others must struggle to win what was theirs.

The epic struggle of the Revolutionary War and the vigilance that the protection of our rights has required have embedded in our Nation a profound understanding of the true meaning and value of our freedom. With the rights of life, liberty, and the pursuit of happiness comes the duty to use those rights for the good of humankind. This belief is fundamental to the American tradition. The result of our Founding Fathers' conception of a state created by man through the responsible use of God-given rights is a Nation of unparalleled freedom and dazzling diversity.

Today we face great challenges. The diversity that gives us so much strength is often seen as a source of division. We are searching for solutions to the difficult challenges of providing a safe and rewarding future for our children, securing adequate health care for our people, and of building good, nurturing communities.

Through prayer our people take a moment away from the concerns of everyday life to understand the greater power that gives us guidance. We come together in an act common to all religions. Prayer gives us a quiet space to remember and contemplate the greater purpose of the activity that fills our lives. As a Nation, we understand the common bonds we all share, and we recommit ourselves to serving a greater good. Prayer enables us to rejoice in our freedoms and understand the implicit responsibility that accompanies them. We return to the guiding vision that gives our Nation so much vitality.

By joint resolution of the Congress, approved April 17, 1952, the people have recognized the role of spiritual reaffirmation and prayer in our history by setting aside a particular day each year as a "National Day of Prayer." Since 1952, each President has proclaimed an annual National Day of Prayer, resuming the tradition begun by our Founding Fathers in 1776. By Public Law 100–307, the first Thursday in May of each year has been set aside as a National Day of Prayer.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim May 6, 1993, as a National Day of Prayer. I call upon the citizens of this great Nation to pray, each after his or her own manner, to remember those who are in need, to achieve patience in tribulation, to resolve the problems that divide us, to rejoice in hope, and to express thanks for the abundance we have experienced throughout our history.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

William J. Clinton

[FR Doc. 93-10656
Filed 4-30-93; 4:59 pm]
Billing code 3195-01-P

Presidential Documents

Proclamation 6554 of April 30, 1993

National Arbor Day, 1993

By the President of the United States of America

A Proclamation

It is proper that we celebrate America's forests, which provide us with a link to our past, a thriving ecosystem, and indispensable resources that are vital to our economy.

Trees are one of the symbols of our culture. Our forebears explored America's forests; lived, hunted, and fought in them; and celebrated them in art, music, folktales, and literature. Our traditions speak of the Tree of Life, just as Thomas Paine spoke of the Tree of Liberty. Paul Bunyan and Babe made their living in the forest, and Huck Finn used trees to make his wooden raft to ride down the Mississippi River on his great American adventure. Today, a walk through the woods or a city park reminds us of our country's special ties to the land we inherited.

Our trees are valuable protectors of our ecosystem. They provide a thriving habitat for animal and plant life; their roots curb soil erosion; their leaves freshen our air by providing oxygen; and their branches shelter us from the sun and the wind.

On Arbor Day, we also recognize those whose lives and livelihoods are intertwined with our forests. Generations of Americans have depended on forests for the lumber to build houses and the fuel to heat their homes. Many Americans continue to harvest lumber and produce wood products, foresters help us manage our forests wisely, and civic associations help ensure the preservation of our woodlands.

Despite the critical importance of our forests, we have not always been diligent stewards of our inheritance. Not long after the Civil War, our ancestors realized that the need for wood products was placing too great a demand on our forests. And in 1872, concerned residents of the State of Nebraska came together on the first Arbor Day to look to the future and preserve America's forests for our generation and the ones yet to come. As we approach the 21st century, we must rededicate ourselves to a forest policy that sustains a strong forest economy and a healthy ecosystem.

Arbor Day is commemorated with an activity in which every American can take part: the planting of a tree—in a backyard, in a park, or on a mountainside. Each new sapling planted today connects us to our parks and wilderness areas here at home, as well as to the tropical forests and wetlands around the world. We must ensure that our children and their descendants have just as much to celebrate on Arbor Day 100 years from now.

The Congress, by House Joint Resolution 127, has designated the last Friday in April as "National Arbor Day."

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim April 30, 1993, as National Arbor Day. I call upon the people of the United States to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

William J. Clinton

[FR Doc. 93-10667
Filed 5-3-93; 10:19 am]
Billing code 3195-01-P

Presidential Documents

Proclamation 6555 of April 30, 1993

Law Day, U.S.A., 1993

By the President of the United States of America

A Proclamation

Ours is a Nation of laws, united not just by a common language and culture, but by a unique devotion to and belief in a national common law: our Constitution.

On Law Day, we celebrate our Constitution and all of the legal institutions that flow from it. Though often thought of as the province of lawyers, we must never forget that these laws and institutions were created not just by lawyers, but also by farmers and architects; businesspeople and laborers; doctors, ranchers, merchants, and machinists. The protection under our laws is the birthright of all Americans, the great inheritance we have received from those who have come before.

In times past, not all Americans have shared in the rights secured by our laws. Courageous and visionary men and women devoted their lives—and sometimes sacrificed them—because they believed that none of us can enjoy the blessings of liberty unless all of us do. To the people who continue to give of themselves each day to this pursuit goes my highest tribute on this Law Day.

Today, as a lawyer and as President, I challenge the members of America's legal profession to devote themselves to the great causes and the great challenges before us as a Nation. As did your predecessors, you must be the leaders in the struggle to promote equality in our society and justice in our courts. Just as our laws are meant to benefit us all, the practice of law cannot be conducted for private benefit alone. I call on all lawyers to make a commitment to public service and civic affairs. This is the heritage of our profession, and a duty arising from the privilege bestowed upon us as lawyers.

On Law Day, I want to reiterate the commitment of my Administration to the rule of law, both here at home and around the world. My Administration will work hard to improve the quality of justice in our courts by selecting the very best men and women to serve as Federal judges. We will dedicate ourselves to promoting justice in our communities by launching new and innovative measures to combat crime and ensure public safety. We will pledge to advance justice in our society by reinvigorating our civil rights laws and our application of them.

We will strive to strengthen our families by increasing enforcement of our child support laws; to strengthen our environment by demanding that polluters pay for the harm that they cause; to strengthen our economy by ensuring that all persons have an equal right to opportunity and employment. In all of these endeavors, our laws will play a critical role.

On this day, we cannot ignore the criticisms aimed at our legal system and the calls for changes in it. I share the view that our legal system needs reform. But even as we undertake these reforms, we should never forget that it is our legal system that is the envy of the world. As the nations around the globe emerge from the long, dark days of the past into the new light of freedom, it is to our laws, our courts, our private

bars—our legal institutions—that they look for inspiration. This should be a source of enormous pride for all lawyers and for all Americans.

From the days of our Nation's founding, the torch of freedom has been passed from one generation to the next. Today we hold it higher, and it burns more brightly than ever. Democracies around the world, new and old, look to us to lead the way. The law of our land stands as a beacon of hope for these people and for those still yearning to be free.

The turmoil in various parts of the world attests to the need to promote respect for international law and to strengthen international institutions for the protection of international peace and security and of human rights. My Administration will also pursue those objectives.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, in accordance with Public Law 87–20 of April 7, 1961, do hereby proclaim May 1, 1993, as "Law Day, U.S.A." I urge the people of the United States to use this occasion to reflect on our heritage of freedom, to familiarize themselves with their rights and responsibilities, and to aid others seeking to affirm their rights under law.

I call upon the legal profession, civic associations, educators, librarians, public officials, and the media to promote the observance of this day through appropriate programs and activities. I also call upon public officials to display the flag of the United States on all government buildings on Law Day, U.S.A.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

William J. Clinton

[FR Doc. 93–10668
Filed 5–3–93; 10:20 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 6556 of May 1, 1993

Loyalty Day, 1993

By the President of the United States of America

A Proclamation

"Loyalty Day" is an occasion on which we reaffirm our allegiance to our country and our devotion to the ideals on which it was founded. Our government "by the people" respects and protects the natural rights and freedoms of all citizens, without favor, and deserves our abiding fidelity.

For more than 200 years, people from around the world have immigrated to America, bringing their dreams and aspirations to a country that prides itself on its democratic ideals. There is no greater testament to the success of our system of governance than people's desire to be a part of the great American experiment. Our Founders designed that system on the principles of individual liberties and rights of self-determination. Our Nation stands as a beacon of hope for all those who embrace these ideas.

Generations of Americans have demonstrated loyalty and devotion to their country and have gone to great lengths to preserve their freedom. Many have fought and died so that future generations could continue the proud traditions of our Nation. To acknowledge this loyalty and love of country, the Congress, by a joint resolution approved July 18, 1958 (72 Stat. 369; 36 U.S.C. 162), has designated May 1 of each year as "Loyalty Day."

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim May 1, 1993, as Loyalty Day. I call upon all Americans to observe this day with appropriate ceremonies and activities, including public recitation of the Pledge of Allegiance to the Flag of the United States. I also call upon government officials to display the flag on all government buildings and grounds on this day.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of May, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

William J. Clinton

[FR Doc. 93–10669
Filed 5–3–93; 10:21 am]
Billing code 3195–01–P

Rules and Regulations

Federal Register
Vol. 58, No. 84
Tuesday, May 4, 1993

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 week.

FEDERAL RESERVE SYSTEM

12 CFR Part 215

[Regulation O; Docket No. R-0785]

Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks; Loans to Holding Companies and Affiliates

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending Regulation O to adopt three exceptions to the aggregate insider lending limit in the regulation substantially as they were set forth in the Board's proposed rule. Additional exceptions suggested by commenters will be considered in future rulemaking. The Board is taking this action on the basis of authority granted in the Housing and Community Development Act of 1992.

EFFECTIVE DATE: May 3, 1993.

FOR FURTHER INFORMATION CONTACT: Gordon Miller, Attorney (202/452-2534), Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Background

The Housing and Community Development Act of 1992 (HCDA), Pub. L. 102-550, 106 Stat. 3672 (1992), effective October 28, 1992, amended section 22(h) of the Federal Reserve Act (Act), 12 U.S.C. 375(b), to authorize the Board to adopt exceptions from the definition of "extension of credit" that pose minimal risk to the lending bank. The legislative history of this provision states that the Board should make a "zero-based review" of all exceptions. *See* 138 Cong. Rec. S17,914-15 (daily ed. October 8, 1992). The Board has proposed three exceptions to the aggregate lending limit in Regulation O (12 CFR part 215) to implement this amendment.

All of the proposed exceptions are found in the National Bank Act and are already incorporated in the individual lending limit in Regulation O. *See* 12 U.S.C. 84; 12 CFR 215.2(h) and 215.4(c). These exceptions are for certain categories of loans or extensions of credit that are deemed, as a result of the manner in which they are collateralized, to pose minimal risk of loss to a bank. The proposed exceptions are in the following three categories:

(1) Extensions of credit secured by obligations of the United States or other obligations fully guaranteed as to principal and interest by the United States;

(2) Extensions of credit to or secured by commitments or guarantees of a department or agency of the United States; and

(3) Extensions of credit secured by a segregated deposit account with the lending bank.

Proposal as Adopted

The Board has determined to adopt the three proposed exceptions, with the modifications discussed below. The Board anticipates that the final rule will reduce the regulatory and recordkeeping burden on banks and increase the ability of banks to make loans and other extensions of credit that pose little or no risk to the bank.

Although loans secured in accordance with these exceptions are removed from a bank's aggregate lending limit, such loans remain subject to the general prohibitions in Regulation O on extensions of credit to insiders found at §§ 215.4 (a) and (b), as a safeguard against abuse of these exceptions.

Comments

In response to its proposal, the Board received 40 comments: 15 by banks, 8 by state or national bankers' associations, 8 by bank holding companies, 6 by Federal Reserve banks, 2 from law firms, and 1 by a banker's bank. Thirty-four commenters favored the exceptions. Six commenters favored other or further exceptions, and did not comment on the proposed exceptions. There were no commenters that opposed the exceptions.

Among the 34 comments in favor of the exceptions, 27 expressed one or more reasons for their support. Twenty commenters noted that loans within these categories would pose minimal risk to the lending bank, 7 commenters favored the exceptions because they would improve the ability of member banks to retain qualified outside directors, and 5 commenters supported the exceptions because, by reducing the inconsistency between the aggregate lending limit and the individual lending limit, they would reduce the regulatory burden on member banks. Accordingly, the commenters felt that the proposal is in the public interest.

One commenter suggested clarifying the proposed exceptions by incorporating directly into Regulation O certain interpretations by the Office of the Comptroller of the Currency of the exceptions contained in the National Bank Act.[1] *See* 12 CFR 32.6 (d), (e), and (f). This commenter suggested that the Board clarify that the amount of an extension of credit that is excepted from the aggregate lending limit is limited to an amount equal to:

(1) The current fair market value of the United States obligations or other obligations fully guaranteed as to principal and interest by the United States securing the extension of credit;

(2) The amount of the commitment or guarantee of a department or agency of the United States securing the extension of credit; or

(3) The amount of the member bank's perfected security interest in the segregated, earmarked deposit account securing the extension of credit. This commenter also suggested that the Board clarify that an extension of credit is eligible in full for an exception if the unpaid principal amount thereof is secured or guaranteed as described above, and that is not required that accrued and unpaid interest on the extension of credit also be so covered.

The Board has determined that the suggested clarifications are consistent with the Comptroller's interpretations of 12 U.S.C. 84, and incorporate appropriate safeguards against abuse of

[1] All interpretations by the Comptroller of the exceptions contained in 12 U.S.C. 84 are applicable to Regulation O to the extent that these exceptions are incorporated by reference into or otherwise adopted in Regulation O.

the proposed exceptions. The Board also has clarified, consistent with the Comptroller's interpretation of 12 U.S.C. 84, that a member bank is required to obtain a perfected security interest in United States obligations or other obligations fully guaranteed as to principal and interest by the United States in order for this exception to be effective.

Twenty-one of the commenters proposed other or further exceptions. These comments presented a variety of proposals, including, among others, the adoption of one or more additional exceptions to the lending limits found in 12 U.S.C. 84, the adoption of certain exceptions not found in 12 U.S.C. 84, and the adoption of exemptions that would reduce or eliminate the additional regulatory restrictions imposed on extension of credit by a member bank to its executive officers.[2] These proposals will be considered by the Board in the near future. However, the Board has decided not to address these proposals at this time in order not to delay the adoption of a final rule concerning the 3 exceptions proposed by the Board.

Final Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Board hereby certifies that the final rule will not have a significant adverse effect on a substantial number of small institutions. The final rule should relieve the regulatory burden on all member banks, regardless of size, and will increase the ability of small member banks to make loans and other extensions of credit that pose little or no risk of loss to them, and to attract and retain outside directors to whom such loans may be made in the same manner and to the same extent as they may be made to persons who are not insiders of the member bank.

List of Subjects in 12 CFR Part 215

Credit, Federal Reserve System, Penalties, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Board amends title 12 of the Code of Federal Regulations, part 215, subpart A, as follows:

[2] These provisions appear in 12 CFR 215.5 of Regulation O, and have been adopted pursuant to section 22(g) of the Act, 12 U.S.C. 375a. The subject matter of these comments is outside the scope of the current rulemaking, but will be considered in connection with future rulemaking by the Board concerning Regulation O.

PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS OF MEMBER BANKS

1. The authority citation for part 215 is revised to read as follows:

Authority: 12 U.S.C. 248(i), 375a, 375b(7), 1817(k)(3) and 1972(2)(F)(vi), Pub. L. 102-550, 106 Stat. 3895 (1992).

Subpart A—Loans by Member Banks to Their Executive Officers, Directors, and Principal Shareholders

2. Section 215.4 is amended by adding a new paragraph (d)(3) to read as follows:

§ 215.4 General prohibitions.

* * * * *

(d) * * *

(3) *Exceptions.* The general limit specified in paragraph (d)(1) of this section does not apply to the following:

(i) Extensions of credit secured by a perfected security interest in bonds, notes, certificates of indebtedness, or Treasury bills of the United States or in other such obligations fully guaranteed as to principal and interest by the United States;

(ii) Extensions of credit to or secured by unconditional takeout commitments or guarantees of any department, agency, bureau, board, commission or establishment of the United States or any corporation wholly owned directly or indirectly by the United States;

(iii) Extensions of credit secured by a perfected security interest in a segregated deposit account in the lending bank; or

(iv) The exceptions in this paragraph (d)(3) apply only to the amount of such extensions of credit that are secured in the manner described herein.

By order of the Board of Governors of the Federal Reserve System, April 27, 1993.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-10431 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-M

---

12 CFR Part 265

[Docket No. R-0799]

Rules Regarding Delegation of Authority

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending its Rules Regarding Delegation of Authority in order to delegate to the Secretary of the Board, and to repeal with respect to the General Counsel of the Board acting with the concurrence of the Director of the Division of Banking Supervision and Regulation, the authority to approve certain transactions requiring the approval of the Board pursuant to section 5(d)(3) of the Federal Deposit Insurance Act (FDI Act). This amendment will align the Board's procedures for approving "Oakar" transactions with those procedures used to approve other types of applications involving a director interlock with a Federal Reserve Bank.

EFFECTIVE DATE: The amendments to part 265 of the Board's Rules are effective May 3, 1993.

FOR FURTHER INFORMATION CONTACT: Terence F. Browne, Senior Attorney (202/452-3707); or Timothy J. Byrne, Attorney (202/452-3565), Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunications Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Section 5(d)(3) of the FDI Act,[1] otherwise known as the "Oakar" Amendment, authorizes the merger of Savings Association Insurance Fund (SAIF) member institutions with Bank Insurance Fund (BIF) institutions, subject to certain conditions. This provision requires the prior approval of the Board to engage in an Oakar transaction when the acquiring or resulting institution is a state-chartered bank that is a member of the Federal Reserve System, or when the resulting or acquiring institution is a BIF member bank subsidiary of a bank holding company.[2]

In October 1989, the Board delegated authority to the Director of the Division of Banking Supervision and Regulation and the General Counsel to approve jointly those Oakar transactions involving failing or failed thrift institutions. The purpose of that action was to allow the Board to react quickly to emergency situations that were being resolved by the Resolution Trust Corporation and involved Oakar applications to the Board.

In early 1991, as the processing of Oakar transactions became more routine, the Board delegated authority to the Reserve Banks to approve Oakar transactions.[3] Currently, the Reserve

[1] 12 U.S.C. 1815(d)(3), as amended by the Federal Deposit Insurance Corporation Improvement Act of 1991 (Pub. L. 102-242, section 501, 105 Stat. 2236, 2388-2392 (1991)).

[2] See 12 U.S.C. 1815(d)(3)(A)(i) and (E)(i).

[3] 56 FR 8687 (1991)

Banks approve all Oakar applications except applications involving substantive issues that are considered by the Board, and applications in which a Reserve Bank has concluded that "because of unusual considerations, or for other good cause, it should not take action."[4] Because Oakar transactions have become more common, the Reserve Banks conclude that they should not take action on an Oakar application only when there is a director interlock between a Reserve Bank or branch and the applicant. In these cases, the Director of the Division of Banking Supervision and Regulation and the General Counsel jointly approve the application.

In contrast, most of the bank holding company applications involving an interlock between an applicant and a Reserve Bank or branch are approved by the Secretary of the Board.[5] In Oakar applications as well as other applications made to the Board, the applications are subject to the same level of review, and the Secretary receives a memo explaining the transactions and setting forth the recommendation of the appropriate Staff members. However, the current process for approving an Oakar application having a director interlock involves more steps than is required when the Secretary of the Board approves a bank holding company application involving a director interlock, and this Oakar approval process can be burdensome and time-consuming.

In order to align the Board's procedures for approving Oakar transactions with those procedures used to approve other types of applications involving a director interlock with a Reserve Bank, and in an effort to streamline the Oakar applications process, the Board is amending its Rules Regarding Delegation of Authority to authorize the Secretary of the Board to approve Oakar transactions. This amendment will reduce the regulatory burden associated with the Oakar application process without reducing the level of Federal Reserve System analysis of Oakar transactions.

Final Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*), the Board does not believe that these changes will have a significant adverse economic impact on a substantial number of small entities. The amendments would reduce regulatory burdens imposed by Regulation Y and the Board's Rules Regarding Delegation of Authority and have no particular adverse effect on other entities.

Effective Date

The provisions of the Administrative Procedures Act (APA) (5 U.S.C. 553) relating to notice, public participation, and deferred effective date have not been followed in connection with the adoption of these amendments because the changes to be effected are procedural in nature and do not constitute a substantive rule subject to the requirements of that section. The APA grants a specific exemption from its requirements relating to notice, public participation and the deferred effective date in these instances (12 U.S.C. 553(b)(3)(A)).

Final Paperwork Reduction Act Analysis

No collections of information pursuant to section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) are contained in these changes.

List of Subjects in 12 CFR Part 265

Authority delegations (Government agencies).

For the reasons set forth in the preamble, the Board is amending title 12 of the Code of Federal Regulations, part 265, as follows:

PART 265—RULES REGARDING DELEGATION OF AUTHORITY

1. The authority citation for part 265 is revised to read as follows:

Authority: 12 U.S.C. 248(i) and (k).

2. Section 265.5 is amended by adding paragraph (c)(3) to read as follows:

§ 265.5 Functions delegated to Secretary of the Board.

* * * * *

(c) ***

(3) *Application approval under section 5(d)(3) of the FDI Act.* To approve applications pursuant to section 5(d)(3) of the Federal Deposit Insurance Act (12 U.S.C. 1815(d)(3)), in those cases in which the appropriate Federal Reserve Bank concludes that, because of unusual considerations, or for other good cause, it should not take action.

3. In § 265.6, paragraph (c)(5) is removed.

4. In § 265.7, paragraph (c)(5) is removed, and paragraph (c)(6) is redesignated as paragraph (c)(5).

By order of the Board of Governors of the Federal Reserve System, April 28, 1993.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-10467 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-F

[4] 12 CFR 265.6(c)(5), 7(c)(5).

[5] See 12 CFR 265.5(c)(2).

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 228, 230, 239, 240 and 249

[Release Nos. 33-6996; 34-32231]

RIN 3235-AF63

Additional Small Business Initiatives

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Securities and Exchange Commission ("Commission") today adopted additional revisions to its rules and forms to facilitate financings by small business issuers under the Securities Act of 1933 and their compliance with the reporting requirements under the Securities Exchange Act of 1934. These actions, which ease the entry of small businesses into the public markets, include transitional registration forms, reporting forms, proxy statement and annual report to security holders requirements for small business issuers that have not registered more than $10 million of securities in any 12-month period (other than securities registered on Form S-8), amendments to small business issuer financial statement requirements and revisions to the information requirements of Regulation D.

Rule 254 is amended to provide that a written "test the waters" solicitation document complying with Regulation A will not constitute a "prospectus."

EFFECTIVE DATE: June 3, 1993. Issuers wishing to comply with these rule and form changes prior to the effective date may do so.

FOR FURTHER INFORMATION CONTACT: Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. With respect to the transitional registration and reporting forms, Martin Dunn (202-272-2573) or Richard Wulff (202-272-2644); and with respect to financial statement requirements, Teresa Iannaconi (202-272-2553).

SUPPLEMENTARY INFORMATION: The Commission today adopted new registration statement Form SB-1,[1] as

[1] 17 CFR 239.9.

well as amendments to Forms 1-A,[2] S-2,[3] S-4,[4] 10-SB,[5] 10-KSB[6] and 10-QSB,[7] Schedule 14A[8] and the annual report requirements of Rules 14a-3[9] and 14c-3.[10] These actions provide transitional disclosure requirements for qualifying small business issuers under the Securities Act of 1933 ("Securities Act")[11] and the Securities Exchange Act of 1934 ("Exchange Act").[12]

The Commission also adopted revisions to the financial statement requirements for small business issuers, found in Item 310[13] of Regulation S-B.[14] Amendments to Rule 254[15] of Regulation A[16] and Rule 502[17] of Regulation D[18] under the Securities Act also were adopted.

I. Executive Summary and Background

In August 1992, the Commission adopted its Small Business Initiatives to facilitate the access of small business issuers to the public markets.[19] That action revised the structure and operation of Regulation A and Rule 504[20] of Regulation D and created an integrated registration and reporting system for small business issuers.[21] Based on comments and suggestions received in response to its Small Business Initiatives, the Commission proposed additional measures to ease small business capital raising and transition from non-reporting to reporting status.[22] The Commission today is adopting a number of these additional measures in substantially the manner in which they were proposed.[23] The Commission is not adopting the changes to the Regulation D audited financial statement requirements it proposed. The Commission will explore such revisions with state securities administrators to maintain the federal-state coordination of the Uniform Limited Offering Exemption.

As adopted, new registration statement Form SB-1 permits transitional small business issuers to register securities under the Securities Act using the Regulation A model of disclosure with two years of audited financial statements. Further, as a result of the actions taken today, a small business issuer may enter the Exchange Act reporting system using a Form 10-SB consisting of Regulation A disclosure with audited financial statements. Form 10-SB requires two years of audited financial statements, except that audited statements need be provided only for the most recent fiscal year if the earlier year's audited statements are not otherwise available. Transitional small business issuers are permitted to meet their Exchange Act reporting requirements using the Regulation A model of disclosure until such time as they (1) register more than $10 million of securities in a continuous 12-month period (excluding offerings registered on Form S-8), (2) elect to graduate to a non-transitional disclosure system, or (3) are no longer small business issuers.

Rules 14a-3 and 14c-3 have been amended to require transitional small business issuers to provide to security holders only the financial statements required in their most recent Form 10-KSB. The inclusion of additional information in the annual report to security holders will not cause the issuer to be ineligible for the transitional disclosure forms.

Transitional small business issuers may also use new optional disclosure formats in Schedule 14A. Eligible small business issuers which elect not to respond to these modified disclosure requirements may continue to use the transitional disclosure forms.

Two refinements to the financial statement requirements for small business issuers are adopted. The first revision provides an automatic waiver of some or all of the requirements for audited financial statements of specified significant acquired businesses, where such financial statements are not otherwise available. The other revision permits small business issuers to proceed with initial registered offerings in the first quarter of their fiscal years on the same basis as offerings by reporting companies.

As amended, the narrative information requirements in Rule 502 of Regulation D permit eligible non-reporting issuers to provide the same kind of information as required in Part II of Form 1-A.

With respect to the Regulation A "test the waters" procedures, the Commission has adopted the proposed revision to Rule 254, which provides that a written "test the waters" document complying with Regulation A is not a prospectus.

II. Transitional Disclosure Requirements for Small Business Issuers

A. Transitional Exchange Act Registration and Reporting

In light of the favorable comment received concerning the Regulation A question-and-answer disclosure format, the Commission is allowing small business issuers to make the transition from a non-reporting to an Exchange Act reporting company using the disclosures permitted under Regulation A, so long as audited financial statements for the issuer's last two fiscal years are provided. The Exchange Act registration statement may include audited financial statements for only the most recent fiscal year, where audited financial statements for the earlier fiscal year are not otherwise available.

The transitional reporting forms are being adopted substantially as proposed. Under the proposal, however, the transitional reporting forms would not have been available to any issuer that registered under the Securities Act more than $5 million (other than pursuant to employee benefit plans or dividend reinvestment plans) in any fiscal year. This ceiling has been raised to $10 million in any continuous 12-month period in response to commenters which expressed the view that increasing the offering ceiling beyond the Regulation A ceiling would increase the utility of the transitional forms. In addition, as adopted, securities registered under dividend

[2] 17 CFR 239.90.
[3] 17 CFR 239.12.
[4] 17 CFR 239.25.
[5] 17 CFR 249.210b.
[6] 17 CFR 249.310b.
[7] 17 CFR 249.308b.
[8] 17 CFR 240.14a-101.
[9] 17 CFR 240.14a-3.
[10] 17 CFR 240.14c-3.
[11] 15 U.S.C. 77a *et seq.*
[12] 15 U.S.C. 78a *et seq.*
[13] 17 CFR 228.310.
[14] 17 CFR 228.10-702.
[15] 17 CFR 230.254.
[16] 17 CFR 230.251-263.
[17] 17 CFR 230.502.
[18] 17 CFR 230.501-508.
[19] *See* Securities Act Release No. 33-6949 (57 FR 36442) (August 13, 1992).
[20] 17 CFR 230.504.
[21] A "small business issuer" is defined as an entity: (1) With revenues of less than $25,000,000 for its most recent fiscal year; (2) which is a U.S. or Canadian issuer; (3) which is not an investment company; and (4) which is not a majority-owned subsidiary of a non-"small business issuer," provided that an issuer does not qualify if its public float (the aggregate market value of the issuer's outstanding voting securities held by non-affiliates) is $25,000,000 or more. *See* Securities Act Rule 405 (17 CFR 230.405); Exchange Act Rule 12b-2 (17 CFR 240.12b-2).
[22] *See* Securities Act Release No. 33-6950 (57 FR 36502) (August 13, 1992).
[23] The Commission proposed revisions to the definitions of "small business" and "small organization" for purposes of the Regulatory Flexibility Act (5 U.S.C. 600 *et seq.*) to incorporate the definition of small business issuer used for the small business integrated disclosure system. Amendments were proposed with respect to Securities Act Rule 157(a) (17 CFR 230.157), Exchange Act Rule 0-10(a) (17 CFR 240.0-10), and Rule 0-7 (17 CFR 260.0-7) under the Trust Indenture Act of 1939 ("Trust Indenture Act"), 15 U.S.C. 77aaa *et seq.* After these revisions were proposed, the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Pub. L. 102-366) imposed additional procedural requirements for the modification of these definitions. Accordingly, the Commission is not revising these definitions at this time.

reinvestment plans are not excluded from the calculation.[24]

Small business issuers required to file Exchange Act reports[25] may use the transitional disclosure forms until they (1) register more than $10 million under the Securities Act in any continuous 12-month period (other than securities registered on Form S-8), (2) elect to file on a non-transitional disclosure document, or (3) no longer meet the definition of small business issuer. Non-transitional disclosure documents include: (1) Securities Act registration statement forms other than Forms SB-1, S-3 (if the issuer incorporates by reference transitional Exchange Act reports), S-8 and S-4 (if the issuer uses the transitional disclosure format in that form); (2) Exchange Act periodic reporting Forms 10-K and 10-Q; (3) Exchange Act registration statement Form 10; and (4) reports or registration statements on Forms 10-KSB, 10-QSB or 10-SB that do not use the transitional disclosure document format.[26] A reporting company may not return to the transitional disclosure forms.

Instructions setting forth the disclosure that transitional small business issuers may elect have been added to Forms 10-SB, 10-KSB and 10-QSB. In addition, the cover pages of Forms 10-KSB and 10-QSB have been revised to require that a small business issuer indicate its use of the transitional disclosure alternatives in those forms.

The transitional disclosure requirements mirror the disclosure models currently included as Model A (the question-and-answer disclosure format) and Model B (the line-item disclosure format) in Form 1-A under Regulation A. These disclosure requirements have been modified where necessary to reflect their use in continuous reporting documents.

As proposed, transitional small business issuers would not have been required to provide the management's discussion and analysis of financial condition and results of operations ("MD&A") in their quarterly reports. In response to public comment, transitional small business issuers are required to update the information in their most recent Form 10-KSB which corresponds with the MD&A disclosure requirements of Regulation S-B. Specifically, the Form 10-QSB filed by a transitional small business issuer relying upon the question-and-answer format in its Form 10-KSB will be required to include updated responses to the MD&A disclosure required by Questions 47-50 in Model A of Form 1-A. The Form 10-QSB of a transitional small business issuer relying upon the line-item format in its Form 10-KSB will be required to include an updated response to the business plan disclosure required by Item 6(a)(3)(i) in Model B of Form 1-A.

B. Form SB-1

Small business issuers eligible to use the transitional disclosure provisions under the Exchange Act may register offerings of securities under the Securities Act using new Form SB-1. Form SB-1 may be used to register securities offerings of up to $10 million in any continuous 12-month period. The alternative disclosure requirements and format parallel those of Model A and Model B of Form 1-A of Regulation A. Audited financial statements for the issuer's two most recent fiscal years are required.

Form SB-1 is available to any non-reporting small business issuer or any reporting small business issuer eligible to use the transitional format in Form 10-KSB, provided—in both instances—that the issuer has not registered more than a total of $10 million of securities in the last 12-month period. In determining whether a small business issuer has not registered more than $10 million during the 12-month period, the amount being registered on the Form SB-1 would be added to previous registered offerings in that period (excluding securities registered on Form S-8).

C. Narrative Disclosure Requirements for Transitional Small Business Issuers

The basic narrative disclosure required of transitional small business issuers is the same as that currently required by Form 1-A under Regulation A. Accordingly, small business issuers eligible to use the transitional reporting scheme now have the choice of two alternative narrative disclosure formats: (1) The question-and-answer format contained in Offering Circular Model A of Form 1-A; or (2) the line-item disclosure model contained in Offering Circular Model B of Form 1-A.

Form SB-1 includes additional disclosure items necessary in registration statements under the Securities Act. The following disclosure items have been added: (1) The undertakings contained in Item 512 of Regulation S-B;[27] (2) the inside front and outside back cover page of prospectus requirements of Item 502 of Regulation S-B;[28] (3) in the question-and-answer format (Model A of Form 1-A), the selling security holders information requirements of Item 507 of Regulation S-B;[29] (4) the disclosure requirements (Items 510 and 702 of Regulation S-B) concerning the Commission's position on indemnification;[30] (5) the disclosure requirements of Item 509 of Regulation S-B regarding relationships with experts and counsel;[31] and (6) in the traditional Regulation A line-item format (Model B of Form 1-A), the disclosure requirements of Item 103 of Regulation S-B regarding legal proceedings.[32] Further, instructions have been added to Form SB-1 stating that, in lieu of the "Cover Page" requirements of Model A and Model B of Form 1-A, the information required by Item 501 of Regulation S-B[33] should be included.

D. Financial Statement Requirements for Transitional Small Business Issuers

As adopted today, small business issuers using the transitional disclosure requirements of Exchange Act Forms 10-SB and 10-KSB are required to include the same financial information required by Part F/S of Form 1-A, except that audited financial statements are required.[34] An initial registration statement on Form 10-SB is required to contain audited financial statements for the issuer's two most recent fiscal years, except that audited financial statements for only the most recent fiscal year are sufficient if audited statements for the preceding year are not otherwise available. Subsequent Form 10-KSB filings, as well as offerings registered on Form SB-1, must include audited financial statements for the two most recent fiscal years.

E. Annual Report to Security Holders and Proxy Requirements

Revisions to the rules regarding the annual report to security holders are

[24] This reflects the increased offering ceiling and the increasing use of dividend reinvestment plans to offer securities other than through the reinvestment of dividends.

[25] The requirement may arise either pursuant to section 13 (15 U.S.C. 78m) or 15(d) (15 U.S.C. 78o(d)) of the Exchange Act.

[26] Proxy and information statements by transitional small business issuers which do not rely upon the transitional disclosure formats will be considered transitional disclosure documents. Similarly, transitional small business issuers which include information in addition to the financial statements required by Rule 14a-3 or 14c-3 will be considered transitional disclosure documents.

[27] 17 CFR 228.512.

[28] 17 CFR 228.502.

[29] 17 CFR 228.507. Information regarding selling security holders is required in the line-item format in Model B of Form 1-A under Regulation A.

[30] 17 CFR 228.510 and 702.

[31] 17 CFR 228.509.

[32] 17 CFR 228.103.

[33] 17 CFR 228.501.

[34] Issuers using the transitional disclosure formats of Forms 10-SB and 10-KSB are required to furnish the information required by Item 310 of Regulation S-B.

adopted as proposed. As amended, Rule 14a–3 and Rule 14c–3 require small business issuers using the transitional reporting requirements for their most recent annual report on Form 10–KSB to provide to security holders only the financial statements contained in that Form 10–KSB. In response to public comment, notes have been added to Rules 14a–3 and 14c–3 which make clear that the inclusion of additional information, including information required of non-transitional small business issuers, in the annual report to security holders will not cause the issuer to be ineligible for the transitional disclosure forms.

The Commission also has adopted optional proxy statement disclosure formats for transitional small business issuers. These optional disclosure formats include instructions to Schedule 14A which reference the transitional disclosure forms.[35] Eligible small business issuers which elect to comply with the non-transitional Schedule 14A requirements may continue to use the transitional disclosure forms.

F. Other Securities Act Forms

As adopted, a transitional small business issuer is permitted to use the transitional disclosure requirements applicable to its Exchange Act reports for purposes of Forms S–3,[36] S–4 and S–8. In contrast to employee benefit plan offerings registered on Form S–8, registered offerings on Forms S–3 [37] and S–4 by transitional small business issuers are subject to, and included in, the calculation of the $10 million ceiling.[38] Transitional small business issuers filing a registration statement on Form S–3 may use their transitional Exchange Act reports for purposes of the historical and future incorporation by reference permitted in Form S–3. Form S–4 also has been amended to refer to the alternative disclosure formats for transitional small business issuers.

III. Small Business Integrated Disclosure System—Financial Statements

A. Amendment of Rules Applicable to Financial Statements of Significant Acquired Businesses

Registration statements, certain proxy materials and periodic reports on Form 8–K are required to include financial statements of acquired businesses for periods of one or two years based on the significance of the acquisition. Significance of an acquisition is measured by a comparison of the registrant's income and assets to the income and assets of the acquiree as well as the relationship of the acquisition price to the registrant's total assets. If the highest level of significance exceeds 10% but does not exceed 20%, one year of audited financial statements are required. If the significance exceeds 20%, two years are required.

As a result of this test, the acquisition of a business that would not be sizeable enough to require Exchange Act registration would result in the acquired company having to provide audited financial statements. For example, a small business with total assets of $25 million would be required to obtain audited financial statements of an acquiree with total assets of any amount over $2.5 million. The effort and cost of obtaining audited historical financial statements of relatively small acquisitions by small businesses is disproportionately greater than for larger businesses.

The Commission is adopting, as proposed, amendments to Item 310(c) of Regulation S–B which provide, in certain circumstances, an automatic waiver of one year of the audited financial statements otherwise required to be provided in connection with the acquisition of a significant acquired business.[39]

As amended, Item 310(c)(3) of Regulation S–B provides that, where audited financial statements are not otherwise available, audited financial statements would be automatically waived if the significance of the acquired business does not exceed 20%, and the earlier of the two years of required financial statements would be waived where significance does not exceed 40%. In either case, where unaudited financial statements are available, they would be required. Where a small business issuer relies on such an automatic waiver, the pro forma financial information included in a Form 8–K filed to report the acquisition may not be used as the basis for measuring the significance of later acquisitions as otherwise provided by Item 310(c)(5) of Regulation S–B.

Commenters on the proposal pointed out the need to address those acquisitions by small businesses experiencing marginal or break-even operations. In such cases, the net income test will result in every acquisition being significant regardless of size. Commenters suggested that, in such cases, operational significance would be better measured in terms of revenues rather than net income.

As in other circumstances, small business issuers may apply for a waiver of financial statement requirements. In light of the point raised by commenters, small business issuers that have marginal or break-even levels of net income and that can show that revenues of the acquired business do not exceed 10% of the acquiring company's revenues for the last fiscal year, upon written request, likely will be given a waiver of the requirement to provide any financial statements which would be required solely as a result of the application of the net income significance test.

B. Amendment to Rule Applicable to Age of Small Business IPO Audited Financial Statements

The Commission is adopting as proposed the amendment to Item 310(g) of Regulation S–B which governs the age of financial statements in registration statements for initial registered offerings by small business issuers. The amendment will permit small business issuers to commence an initial public offering of securities throughout the 90-day period subsequent to the end of the most recent fiscal year without providing the audited historical financial statements for that fiscal year subject to the same conditions applicable to reporting companies.[40]

[35] As Schedule 14C (17 CFR 240.14c–101) specifically references the disclosure items of Schedule 14A, these amendments will apply equally to information statements on Schedule 14C.

[36] 17 CFR 239.13.

[37] Small business issuers could use Form S–3 for the following types of offerings if the applicable transaction requirements of that form are met: (1) Primary offerings of non-convertible and asset-backed investment grade securities; (2) secondary offerings by selling security holders if securities of the same class are listed and registered on a national securities exchange or quoted on NASDAQ; and (3) securities to be offered upon the exercise of outstanding warrants or rights, pursuant to a dividend reinvestment plan, or the conversion of outstanding securities.

[38] Issuers (other than transitional small business issuers) registering securities on Form S–4 in connection with the acquisition of a transitional small business issuer may use the transitional disclosure requirements of Form SB–1 in providing the required information regarding the company to be acquired.

[39] In addition, Part F/S of Form 1–A is being amended to conform the requirements for financial statements of significant acquired businesses in Regulation A transactions.

[40] Other conditions which must be met by all registrants in order to be eligible for the extended update are: (1) All Exchange Act reports must have been filed; (2) for the most recent fiscal year for which audited financial statements are not yet available, the small business issuer reasonably and in good faith expects to report income from continuing operations before taxes; and (3) for at least one of the two fiscal years immediately preceding the most recent fiscal year, the small business issuer reported income from continuing operations before taxes.

IV. Regulation A—"Test the Waters" Document

Rule 254 has been amended as proposed to provide that, subject to specified conditions, any written "test the waters" material under the Securities Act is not a "prospectus" as defined in section 2(10)[41] of the Securities Act once it is submitted to Commission, provided that it contains the information required by Rule 254.[42] The treatment of the written test the waters document in Rule 254(e) is analogous to that provided for advertising of registered offerings pursuant to Securities Act Rule 134.[43] The anti-fraud provisions of the federal securities laws, however, continue to apply to any written "test the waters" material.[44] Also, any test the waters activity would be an "offer" as defined in section 2(3)[45] under the Securities Act.[46]

V. Revisions to Regulation D Information Requirements

The general conditions that must be met in an offering under Regulation D are set forth in Rule 502. Historically, the information required to be delivered to non-accredited investors in connection with offerings under Rules 505 or 506 depended upon the dollar amount offered. In its Small Business Initiative, however, the Commission replaced Form S–18 with Form SB–2[47] and shifted the eligibility criteria for streamlined offering documents from the amount being offered to the size of the issuer. The non-financial statement requirements of Rule 502 have been amended to reflect this revised eligibility criteria.

A. Non-financial Statement Requirements

As amended today, the non-financial statement informational requirements in Rule 502 depend upon the issuer's eligibility to use a particular registration statement form or Regulation A. The dollar amount of the particular offering is no longer determinative. Thus, non-reporting issuers conducting Regulation D offerings are required to provide the same kind of information as is required in Part I of a Securities Act registration statement form that the issuer would be entitled to use. Non-reporting issuers eligible to use Regulation A have the option of providing the same kind of information as required in Part II of Form 1–A. No substantive changes are made with respect to the non-financial statement requirements for reporting issuers, other than specifying that the disclosure contained in Form SB–1 may be provided by issuers eligible to use that form.

B. Financial Statement Requirements

The proposal to amend the Regulation D financial statement requirements has not been adopted. The Commission will continue to explore with state securities administrators what revisions would be appropriate to maintain the federal-state coordination of the Uniform Limited Offering Exemption.

VI. Summary of Final Regulatory Flexibility Analysis

The Commission has prepared a Final Regulatory Flexibility Analysis pursuant to the Regulatory Flexibility Act,[48] regarding the rules and forms adopted today. This analysis indicates that the revisions should aid small businesses in their efforts to raise capital while being consistent with the protection of investors.

The analysis notes that small businesses seeking to register their securities and become reporting issuers will benefit from the transitional disclosure alternatives in Form SB–1 and the Exchange Act reporting forms.

The analysis also notes that the new provision specifying that written "test the waters" materials complying with Regulation A are not prospectuses under section 2(10) of the Securities Act would benefit small businesses by specifying the application of the statute.

The amendments are designed to minimize costs but do not sacrifice the important concerns of investors. A copy of the Final Regulatory Flexibility Act Analysis may be obtained from Twanna M. Young, Office of Small Business Policy, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

VII. Cost-Benefit Analysis

No specific empirical data was submitted in response to the Commission's invitation to provide information on the costs and benefits of the proposed revisions. However, the vast majority of the public commenters were of the view that the proposals, if adopted, would work some cost savings to issuers that chose the new procedures; and, further, that investors would have adequate safeguards under the new forms.

VIII. Certain Other Findings

As required by section 23(a) of the Exchange Act,[49] the Commission has specifically considered the impact that these rulemaking actions would have on competition and has concluded that they would not impose a significant burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

IX. Effective Date

The rules and forms adopted today are effective June 3, 1993. Issuers wishing to comply with these rule and form changes prior to the effective date may do so.

X. Statutory Basis, Text of Proposals and Authority

The amendments to the Commission's rules and forms are being adopted pursuant to sections 2, 3(b), 6, 7, 8, 10, and 19(a) of the Securities Act and sections 12, 13, 15(d), 16(a) and 23(a) of the Exchange Act.

List of Subjects in 17 CFR Parts 228, 230, 239, 240 and 249

Reporting and recordkeeping requirements, Securities.

Text of Rule and Form Proposals

1. For the reasons set out in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 228—INTEGRATED DISCLOSURE SYSTEM FOR SMALL BUSINESS ISSUERS

The authority citation for Part 228 continues to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77jjj, 77nnn, 77sss, 78*l*, 78m, 78n, 78o, 78w, 78*ll*, 80a–8, 80a–29, 80a–30, 80a–37, 80b–11, unless otherwise noted.

---

[41] 15 U.S.C. 77(b)(10).

[42] Rule 254(b)(2) requires that the test the waters materials contain the following information (i) a statement that no money or other consideration is being solicited, and, if sent in response, will not be accepted; (ii) a statement that no sales of the securities will be made or commitment to purchase accepted until delivery of an offering circular that includes complete information about the issuer and the offering; (iii) a statement that an indication of interest made by a prospective investor involves no obligation or commitment of any kind; and (iv) identification of the chief executive officer of the issuer and a brief, general identification of the issuer's business and products.

[43] 17 CFR 230.134.

[44] Section 17(a) of the Securities Act (15 U.S.C. 77q(a)) and section 10(b) of the Exchange Act (15 U.S.C. 78j(b)).

[45] 15 U.S.C. 77b(3).

[46] The revision to Rule 254 does not affect the status of oral test the waters activity as "oral communications" for purposes of section 12(2) of the Securities Act (15 U.S.C. 77*l*(2)).

[47] 17 CFR 239.10.

[48] See 5 U.S.C. 604.

[49] 15 U.S.C. 78w(a).

2. Amend § 228.310 by revising paragraphs (c)(3)(i) and (c)(3)(ii); by removing paragraph (c)(3)(iv); by adding one sentence to the end of paragraph (c)(5); and by revising paragraph (g)(2)(i) to read as follows:

§ 228.310 (Item 310) Financial Statements.

* * * * *

(c) *Financial statements of businesses acquired or to be acquired.* * * *

(3)(i) Financial statements shall be furnished for the periods prior to the date of acquisition, for the same periods for which the small business issuer is required to furnish financial statements. The financial statements covering fiscal years shall be audited.

(ii) If none of the conditions in the definitions of significant subsidiary in paragraph (c)(2) of this Item exceeds 20% and the required audited financial statements of the acquired business are not readily available, an automatic waiver of the required audited financial statements is granted. If none of the conditions in the definitions of significant subsidiary exceeds 40% and the required audited financial statements are not readily available, an automatic waiver is granted with respect to the required audited financial statements for the fiscal year preceding the latest fiscal year. If unaudited financial statements or other financial information is available for any fiscal period for which an automatic waiver is granted, then such unaudited financial statements or other information shall be furnished.

* * * * *

(5) * * * Notwithstanding the above, if a Form 8–K (§ 249.308 of this chapter) was filed to report a significant acquisition but audited financial statements were not furnished pursuant to the automatic waiver provisions of paragraph (c)(3) of this Item, the determination of significance may not be made using the pro forma amounts for the latest fiscal year; however, upon written request from the issuer, the Commission will consider permitting the use of previously filed pro forma financial information as the basis for measurement for the significance tests.

* * * * *

(g) *Age of Financial Statements.* * * *

(2) * * *

(i) If the small business issuer is a reporting company, all reports due must have been filed;

* * * * *

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

3. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77s, 7sss, 78c, 78*l*, 78m, 78n, 78o, 78w, 78*ll*(d), 79t, 80a–8, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

By adding paragraph (e) to § 230.254 to read as follows:

§ 230.254 Solicitation of Interest Document for Use Prior to an Offering Statement.

* * * * *

(e) Written solicitation of interest materials submitted to the Commission and otherwise in compliance with this section shall not be deemed to be a prospectus as defined in section 2(10) of the Securities Act (15 U.S.C. 77b(10)).

5–6. By revising paragraphs (b)(2)(i) and (ii)(B) of § 230.502 to read as follows:

§ 230.502 General conditions to be met.

* * * * *

(b) * * *

(2) * * * (i) If the issuer is not subject to the reporting requirements of section 13 or 15(d) of the Exchange Act, at a reasonable time prior to the sale of securities the issuer shall furnish to the purchaser, to the extent material to an understanding of the issuer, its business and the securities being offered:

(A) *Non-financial statement information.* If the issuer is eligible to use Regulation A (§ 230.251–263), the same kind of information as would be required in Part II of Form 1–A (§ 239.90 of this chapter). If the issuer is not eligible to use Regulation A, the same kind of information as required in Part I of a registration statement filed under the Securities Act on the form that the issuer would be entitled to use.

(B) *Financial statement information.*—(*1*) *Offerings up to $2,000,000.* The information required in Item 310 of Regulation S–B (§ 228.310 of this chapter), except that only the issuer's balance sheet, which shall be dated within 120 days of the start of the offering, must be audited.

(*2*) *Offerings up to $7,500,000.* The financial statement information required in Form SB–2 (§ 239.10 of this chapter). If an issuer, other than a limited partnership, cannot obtain audited financial statements without unreasonable effort or expense, then only the issuer's balance sheet, which shall be dated within 120 days of the start of the offering, must be audited. If the issuer is a limited partnership and cannot obtain the required financial statements without unreasonable effort or expense, it may furnish financial statements that have been prepared on the basis of Federal income tax requirements and examined and reported on in accordance with generally accepted auditing standards by an independent public or certified accountant.

(*3*) *Offerings over $7,500,000.* The financial statement as would be required in a registration statement filed under the Act on the form that the issuer would be entitled to use. If an issuer, other than a limited partnership, cannot obtain audited financial statements without unreasonable effort or expense, then only the issuer's balance sheet, which shall be dated within 120 days of the start of the offering, must be audited. If the issuer is a limited partnership and cannot obtain the required financial statements without unreasonable effort or expense, it may furnish financial statements that have been prepared on the basis of Federal income tax requirements and examined and reported on in accordance with generally accepted auditing standards by an independent public or certified accountant.

(C) If the issuer is a foreign private issuer eligible to use Form 20–F (§ 249.220f of this chapter), the issuer shall disclose the same kind of information required to be included in a registration statement filed under the Act on the form that the issuer would be entitled to use. The financial statements need be certified only to the extent required by paragraph (b)(2)(i) (B) (*1*), (*2*) or (*3*) of this section, as appropriate.

(ii) * * *

(B) The information contained in an annual report on Form 10–K (§ 249.310 of this chapter) or 10–KSB (§ 249.310b of this chapter) under the Exchange Act or in a registration statement on Form S–1 (§ 239.11 of this chapter), SB–1 (§ 239.9 of this chapter), SB–2 (§ 239.10 of this chapter) or S–11 (§ 239.18 of this chapter) under the Act or on Form 10 (§ 249.210 of this chapter) or Form 10–SB (§ 249.210b of this chapter) under the Exchange Act, whichever filing is the most recent required to be filed.

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

The authority citation for Part 239 continues to read, in part, as follows:

* * * * *

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79m, 79n, 79q, 79t,

80a08, 80a–29, 80a–30 and 80a–37, unless otherwise noted.

* * * * *

8. Section 239.9 is added to read as follows:

§ 239.9 Form SB–1, optional form for the registration of securities to be sold to the public by certain small business issuers.

Small business issuers, as defined in Rule 405 (17 CFR 230.405 of this chapter), may use this form to register up to $10,000,000 of securities to be sold for cash, if they have not registered more than $10,000,000 in securities offerings in any continuous 12-month period, including the transaction being registered. In calculating the $10,000,000 ceiling, issuers should include all offerings which were registered under the Securities Act, other than any amounts registered on Form S–8 (§ 239.16b).

Note: The Text and Instructions of Form SB–1 will not appear in the Code of Federal Regulations.

BILLING CODE 8010–01–P

OMB APPROVAL
OMB Number: xxxx-xxxx Expires: Approval Pending Estimated average burden hours per response.. 1.0

U.S. Securities and Exchange Commission
Washington, D.C. 20549

Form SB-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

(Amendment No. ____)

_____
(Name of small business issuer in its charter)

_____	_____	_____
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

_____
(Address and telephone number of principal executive offices)

_____
(Address of principal place of business or intended principal place of business)

_____
(Name, address and telephone number of agent for service)

Approximate date of proposed sale to the public _____

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Dollar Amount to be registered	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee

The following delaying amendment is optional, but see Rule 473 before omitting it: The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Disclosure alternative used (check one): Alternative 1 ___; Alternative 2 ___

BILLING CODE 8010-01-C

General Instructions

A. Use of Form and Place of Filing

1.(a) A "small business issuer," defined in Rule 405 of the Securities Act of 1933 (the "Securities Act") may use this form to register up to $10,000,000 of securities to be sold for cash, if they have not registered more than $10,000,000 in securities offerings in any continuous 12-month period, including the transaction being registered. In calculating the $10,000,000 ceiling, issuers should include all offerings which were registered under the Securities Act, other than any amounts registered on Form S-8.

(b) A small business issuer may use this form until (1) registers more than $10 million under the Securities Act in any continuous 12-month period (other than securities registered on Form S-8), (2) elects to file on a non-transitional disclosure document (other than the proxy statement disclosure in Schedule 14A), or (3) no longer meets the definition of small business issuer. Non-transitional disclosure documents include: (1) Securities Act registration statement forms other than Forms SB-1, S-3 (if the issuer incorporates by reference transitional Exchange Act reports), S-8 and S-4 (if the issuer relies upon the transitional disclosure format in that form); (2) Exchange Act periodic reporting Forms 10-K and 10-Q; (3) Exchange Act registration statement Form 10; and (4) reports or registration statements on Forms 10-KSB, 10-QSB or 10-SB which do not use the transitional disclosure document format. A reporting company may not return to the transitional disclosure forms.

2. If the small business issuer is not a reporting company, it should file the registration statement in the regional office that is closest to its principal place of business or the Washington, DC office. However, no filing may be made in the Philadelphia regional office; small business issuers in that region should file in the Atlanta, New York or Washington, DC offices.

3. If the small business issuer is a reporting company or a holding company of a bank (see the definition of "bank" in section 12(i) of the Securities Exchange Act of 1934), it should file the registration statement in the Commission's Washington, DC headquarters.

4. Post-effective amendments should be filed with the office that declared the registration statement effective.

5. The Commission may refer processing to an office other than that where the filing was made.

B. General Requirements

1. In preparing a registration statement on this Form, reference should be made to the General Rules and Regulations under the Securities Act, particularly Regulation C which sets forth requirements for the preparation and filing of a registration statement such as paper type and size.

2. Issuers registering securities for the first time should be aware of Form SR and Rule 463 under the Securities Act concerning sales of registered securities and the use of proceeds. First-time issuers also should be aware of Exchange Act Rule 15c2-8 (§ 240.15c2-8), which requires broker-dealers to deliver a prospectus 48 hours before a sale of securities can be confirmed.

3. Issuers engaged in real estate, banking, insurance, oil and gas or mining activities should consult the Industry Guides in Item 801 of Regulation S-K (17 CFR 229.801). Real estate companies also should refer to Item 13 (Investment Policies of Registrant), Item 14 (Description of Real Estate), and Item 15 (Operating Data) of Form S-11 (17 CFR 239.18).

C. Preparation and Filing of the Registration Statement

Part I of this form, which relates to the content of certain information about the issuer, provides alternative disclosure formats. The registrant may elect either of these alternative formats.

D. Financial Statement Requirements

Regardless of the disclosure model used, all registrants shall furnish the financial statements required by Part F/S of this Form SB-1.

E. Composition of Prospectus

The information required by Part I and Part F/S of this registration statement shall comprise the prospectus.

F. Cover Page of Registration Statement

Issuers electing Alternative 1 should furnish the information required by Item 501 of Regulation S-B in lieu of the information required by Alternative 1 with respect to the cover page of the registration statement. Issuers electing Alternative 2 should furnish the information required by Item 501 of Regulation S-B in lieu of the information required by Item 1 of Alternative 2.

G. Canadian Issuer—Consent of Service

Canadian issuers eligible to use this Form should file as an exhibit to this registration statement a written irrevocable consent and power of attorney on Form F-X (§ 239.42 of this title).

Part I—Narrative Information Required in Prospectus

Alternative 1

Corporate issuers may elect to furnish the information required by Model A of Form 1-A, as well as the following information.

Item 1. Inside Front and Outside Back Cover Pages of Prospectus

Furnish the information required by Item 502 of Regulation S-B.

Item 2. Significant Parties

List the full names and business and residential addresses, as applicable, for the following persons:

(1) The issuer's directors;
(2) The issuer's officers;
(3) The issuer's general partners;
(4) Record owners of 5 percent or more of any class of the issuer's equity securities;
(5) Beneficial owners of 5 percent or more of any class of the issuer's equity securities;
(6) Promoters of the issuer;
(7) Affiliates of the issuer;
(8) Counsel to the issuer with respect to the proposed offering;
(9) Each underwriter with respect to the proposed offering;
(10) The underwriter's directors;
(11) The underwriter's officers;
(12) The underwriter's general partners; and
(13) Counsel to the underwriter.

Item 3. Relationship with Issuer of Experts Named in Registration Statement

Furnish the information required by Item 509 of Regulation S-B, if applicable.

Item 4. Selling Security Holders

Furnish the information required by Item 507 of Regulation S-B, if applicable.

Item 5. Changes in and Disagreements with Accountants

Furnish the information required by Item 304 of Regulation S-B, if applicable.

Item 6. Disclosure of Commission position on Indemnification for Securities Act Liabilities

Furnish the information required by Item 510 of Regulation S-B.

Alternative 2

Any issuer may elect to furnish the information required by Model B of Part II of Form 1-A, as well as the following information.

Item 1. Inside Front and Outside Back Cover Pages of Prospectus

Furnish the information required by Item 502 of Regulation S-B.

Item 2. Significant Parties

List the full names and business and residential addresses, as applicable, for the following persons:

(1) The issuer's directors;
(2) The issuer's officers;
(3) The issuer's general partners;
(4) Record owners of 5 percent or more of any class of the issuer's equity securities;
(5) Beneficial owners of 5 percent or more of any class of the issuer's equity securities;
(6) Promoters of the issuer;
(7) Affiliates of the issuer;
(8) Counsel to the issuer with respect to the proposed offering;
(9) Each underwriter with respect to the proposed offering;
(10) The underwriter's directors;
(11) The underwriter's officers;
(12) The underwriter's general partners; and
(13) Counsel to the underwriter.

Item 3. Relationship with Issuer of Experts Named in Registration Statement

Furnish the information required by Item 509 of Regulation S-B, if applicable.

Item 4. Legal Proceedings

Furnish the information required by Item 103 of Regulation S-B.

Item 5. Changes in and Disagreements with Accountants

Furnish the information required by Item 304 of Regulation S-B, if applicable.

Item 6. Disclosure of Commission position on Indemnification for Securities Act Liabilities

Furnish the information required by Item 510 of Regulation S-B.

Part F/S—Financial Information Required in Prospectus

Furnish the information required by Item 310 of Regulation S–B.

Part II—Information Not Required in Prospectus

Item 1. Indemnification of Directors and Officers

Furnish the information required by Item 702 of Regulation S–B.

Item 2. Other Expenses of Issuance and Distribution

Furnish the information required by Item 511 of Regulation S–B.

Item 3. Undertakings

Furnish the undertakings required by Item 512 of Regulation S–B.

Item 4. Unregistered Securities Issued or Sold Within One Year

(a) As to any unregistered securities issued by the issuer or any of its predecessors or affiliated issuers within one year prior to the filing of this Form SB–1, state:

(1) The name of such issuer;

(2) The title and amount of securities issued;

(3) The aggregate offering price or other consideration for which they were issued and the basis for computing the amount thereof;

(4) The names and identities of the persons to whom the securities were issued.

(b) As to any unregistered securities of the issuer or any of its predecessors or affiliated issuers which were sold within one year prior to the filing of this Form SB–1 by or for the account of any person who at the time was a director, officer, promoter or principal security holder of the issuer of such securities, or was an underwriter of any securities of such issuer, furnish the information specified in subsections (1) through (4) of paragraph (a)

(c) Indicate the section of the Securities Act or Commission rule or regulation relied upon for exemption from the registration requirements of such Act and state briefly the facts relied upon for such exemption.

Item 5. Index to Exhibits

(a) An index to the exhibits should be presented.

(b) Each exhibit should be listed in the exhibit index according to the number assigned to it in Part III of Form 1–A or Item 2, below.

(c) The index to exhibits should identify the location of the exhibit under the sequential page numbering system for this Form SB–1.

(d) Where exhibits are incorporated by reference, the reference shall be made in the index of exhibits.

Instructions:

1. Any document or part thereof filed with the Commission pursuant to any Act administered by the Commission may, subject to the limitations of Rule 24 of the Commission's Rules of Practice, be incorporated by reference as an exhibit to any registration statement.

2. If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the issuer shall file with the reference a statement containing the text of such modification and the date thereof.

3. Procedurally, the techniques specified in Rule 411(d) of Regulation C shall be followed.

Item 6. Description of Exhibits

As appropriate, the issuer should file as exhibits those documents required to be filed under Part III of Form 1–A. Part III of Form 1–A lists 10 exhibits. The registrant also shall file:

(11) *Opinion re legality*—An opinion of counsel as to the legality of the securities covered by the Registration Statement, indicating whether they will, when sold, be legally issued, fully paid and non-assessable, and if debt securities, whether they will be binding obligations of the issuer.

(12) *Additional exhibits*—Any additional exhibits which the issuer may wish to file, which shall be so marked as to indicate clearly the subject matters to which they refer.

(13) *Form F-X*—Canadian issuers shall file a written irrevocable consent and power of attorney on Form F-X.

Signatures

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form SB–1 and authorized this registration statement to be signed on its behalf by the undersigned, in the City of _____, State of _____, on _____, 19___

(Registrant) _____

By (Signature and Title) _____

In accordance with the requirements of the Securities Act of 1933, this registration statement was signed by the following persons in the capacities and on the dates stated.

(Signature) _____

(Title) _____

(Date) _____

Instructions for signatures.

(1) Who must sign: The small business issuer, its principal executive officer or officers, its principal financial officer, its controller or principal accounting officer and at least the majority of the board of directors or persons performing similar functions. If the issuer is a limited partnership then the general partner and a majority of its board of directors if a corporation.

(2) Beneath each signature, type or print the name of each signatory. Any person who occupies more than one of the specified positions shall indicate each capacity in which he or she signs the registration statement. See Rule 402 of Regulation C concerning manual signatures and Item 601 of Regulation S–B concerning signatures by powers of attorney.

9. Form S–2 (§ 239.12) is amended by adding Paragraph D to General Instruction II to read as follows:

Note: The text of Form S–2 will not appear in the Code of Federal Regulations.

Form S–2

* * * * *

General Instruction

* * * * *

II. Application of General Rules and Regulations

* * * * *

D. A "small business issuer," as defined in Rule 405 (17 CFR 230.405), that provided the "Information Required in Annual Report of Transitional Small Business Issuers" in its most recent annual report on Form 10–KSB is not eligible for use of this Form S–2.

10. Form S–4 (§ 239.25) is amended by adding Paragraph 4 to General Instruction D to read as follows:

Note: The text of Form S–4 will not appear in the Code of Federal Regulations.

Form S–4

* * * * *

General Instructions

* * * * *

D. Application of General Rules and Regulations

* * * * *

4. (a) Registrants and Companies to be Acquired that are eligible to use Form SB–1 may rely upon Part (b) or (c), as applicable, of this instruction in lieu of the narrative disclosure items set forth in this Form. These Registrants and Companies to be Acquired should look to Part F/S of Form SB–1 with respect to their financial statement requirements.

(b) Registrants and Companies to be Acquired which relied upon Alternative 1 in their most recent Form 10–KSB:

(i) Part 1.A.—furnish the information required by Part 1.A. of this Form;

(ii) Part I.B.—in lieu of the information required in Item 14, furnish the information required in (a) Questions 3, 4, 11, 43 and 47–50 of Model A of Form 1–A, and (b) Item 14(d) and 14(i) of this Form;

(iii) Part 1.C.—in lieu of the information required in Item 17, furnish the information required in (a) Item 17(a), 17(b)(1), 17(b)(2), 17(b)(6), 17(b)(7) and 17(b)(8) of this Form, and (b) Questions 4, 11 and 47–50 of Model A of Form 1–A;

(iv) Part 1.D.—(*1*) in lieu of providing the information required in Item 18, furnish the information required in (a) Items 18(a)(1)—18(a)(6) and (b) Questions 29–36 and 39–42 of Model A of Form 1–A; and (*2*) in lieu of providing the information required in Item 19(a), furnish the information required in (a) Items 19(a)(1)—19(a)(6) of this Form and Questions 29–36 and 39–42 of Model A of Form 1–A; (*3*) in lieu of providing the information required in Item 19(b), furnish the information required in (a) Items 19(a)(4)—19(a)(6) of this Form and Questions 29–36 and 39–42 of Model A of Form 1–A.

(v) Part II—in lieu of the exhibits required by Item 21(a) and 21(b), furnish the exhibits required in Part II of Form SB–1.

(c) Registrants and Companies to be Acquired which relied upon Alternative 2 in their most recent Form 10–KSB:

(i) Part 1.A.—furnish the information required by Part 1.A. of this Form;

(ii) Part I.B.—in lieu of the information required in Item 14, furnish the information

required in (a) Items 6 and 7 of Model B of Form 1–A, and (b) Items 14(c), (d), and (i) of this Form;

(iii) Part 1.C.—in lieu of the information required in Item 17, furnish the information required in (a) Item 17(a), 17(b)(1), 17(b)(2), 17(b)(6), 17(b)(7) and 17(b)(8) of this Form, and (b) Item 6(a)(3)(i) of Model B of Form 1–A;

(iv) Part 1.D.—(1) in lieu of providing the information required in Item 18, furnish the information required in (a) Items 18(a)(1)—18(a)(6) and (b) Items 8, 9 and 11 of Model B of Form 1–A; (2) in lieu of providing the information required in Item 19(a), furnish the information required in (a) Items 19(a)(1)—19(a)(6) of this Form and Items 8, 9 and 11 of Model B of Form 1–A; and (3) in lieu of providing the information required in Item 19(b), furnish the information required in (a) Items 19(a)(4)—19(a)(6) of this Form and Questions Items 8, 9 and 11 of Model B of Form 1–A.

(v) Part II—in lieu of the exhibits required by Item 21(a) and 21(b), furnish the exhibits required in Part II of Form SB–1.

11. Form 1–A (§ 239.90) is amended by revising paragraph (3)(c)(iv) of Part F/S to read as follows:

Note: The text of Form 1–A does not appear in the Code of Federal Regulations.

Form 1–A—Regulation A Offering Statement Under the Securities Act of 1933

* * * * *

Part II—Offering Circular

* * * * *

Part F/S

* * * * *

(3) Financial Statements of Businesses Acquired or to be Acquired.

* * * * *

(c)(i) * * *

(ii) * * *

(iii) * * *

(iv) If none of the conditions in the definitions of significant subsidiary in Rule 405 exceeds 40%, income statements of the acquired business for only the most recent fiscal year and interim period need be filed, unless such statements are readily available.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

12. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78*o*, 78p, 78s, 78w, 78x, 78*ll*(d), 79q, 9t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

13. By revising the Note following the introductory text of paragraph (b) of § 240.14a–3 to read as follows:

§ 240.14a–3 Information to be furnished to security holders.

* * * * *

(b) * * *

Note to Small Business Issuers—A "small business issuer," defined under Rule 12b–2 of the Exchange Act (§ 240.12b–2), shall refer to the disclosure items in Regulation S–B (§ 228.10—702 of this chapter) rather than Regulation S–K (§ 229.10—702 of this chapter). If there is no comparable disclosure item in Regulation S–B, a small business issuer need not provide the information requested. A small business issuer shall provide the information in Item 310(a) of Regulation S–B in lieu of the financial information required by Rule 14a–3(b)(1) (§ 240.14a–3(b)(1)). Small business issuers using the transitional small business issuers disclosure format in the filing of their most recent annual report on Form 10–KSB (§ 249.310b of this chapter) need not provide the information specified below. Rather, those small business issuers shall provide only the financial statements required to be filed in their most recent Form 10–KSB. The inclusion of additional information, including information required of non-transitional small business issuers, in the annual report to security holders will not cause the issuer to be ineligible for the transitional disclosure forms.

* * * * *

14. Amend § 240.14a–101 by adding Note G to read as follows:

§ 249.14a–101 Schedule 14A. Information required in proxy statement.

Notes: * * *

G. Special Note for Small Business Issuers

(1) Registrants and acquirees which meet the definition of "small business issuer" in Rule 12b–2 of the Exchange Act and filed their latest annual report in accordance with "Information Required in Annual Report of Transitional Small Business Issuers" in Form 10–KSB shall refer to this "Special Note for Small Business Issuers" with respect to the specified items in this Schedule. If paragraph G(2) or G(3), below, does not contain an alternative disclosure instruction, small business issuers should comply with the disclosure item in this schedule, as modified by Instruction F.

(2) Registrants and acquirees which relied upon Alternative 1 in their most recent Form 10–KSB may provide the following information (Questions numbers are in reference to Model A of Form 1–A): (a) Questions 37 and 38 instead of Item 6(d); (b) Question 43 instead of Item 7(a); (c) Questions 29–36 and 39 instead of Item 7(b); (d) Questions 40–42 instead of Item 8; (e) Questions 40–42 instead of Item 10; (e) the information required in Part F/S of Form 10–SB instead of the financial statement requirements of Items 13 or 14; (f) Questions 4, 11 and 47–50 instead of Item 13(a)(1)(3); (g) Question 3 instead of Item 14(b)(3)(i) (A) and (B); and (h) Questions 4, 11 and 47–50 instead of Item 14(b)(3)(i)(H).

(3) Registrants and acquirees which relied upon Alternative 2 in their most recent Form 10–KSB may provide the following information ("Model B" refers to Model B of Form 1–A): (a) Item 10 of Model B instead of Item 6(d) of Schedule 14A; (b) Item 8(d) of Model B instead of Item 7(a) of Schedule 14A; (c) Items 8(a)–8(c) and Item 11 of Model B instead of Item 7(b) of Schedule 14A; (d) Item 9 of Model B instead of Item 8 of Schedule 14A; (e) Item 9 of Model B instead of Item 10 of Schedule 14A; (f) the information required in Part F/S of Form 10–SB instead of the financial statement requirements of Items 13 or 14 of Schedule 14A; (g) Item 6(a)(3)(i) of Model B instead of Item 13(a)(1)(3) of Schedule 14A; (h) Items 6 and 7 of Model B instead of Item 14(b)(3)(i)(A) and (B) of Schedule 14A; and (i) Item 6(a)(3)(i) of Model B instead of Item 14(b)(3)(i)(H) of Schedule 14A.

15. By adding the following Note after paragraph (a)(2) of § 240.14c–3 to read as follows:

§ 240.14c–3 Annual Report to be Furnished Security Holders.

(a) * * *

(2) * * *

Note to Small Business Issuers—In responding to the disclosure items under paragraph (b) of Rule 14a–3, (§ 240.14a–3 of this chapter) a "small business issuer," defined under Rule 12b–2 of the Exchange Act (§ 240.12b–2), shall refer to the disclosure items in Regulation S–B (§ 228.10—702 of this chapter) rather than Regulation S–K (§ 229.10—702 of this chapter). If there is no comparable disclosure item in Regulation S–B, a small business issuer need not provide the information requested. A small business issuer shall provide the information in Item 310(a) of Regulation S–B in lieu of the financial information required by Rule 14a–3(b)(1) (§ 240.14a–3(b)(1)). Small business issuers using the transitional small business issuers disclosure format in the filing of their most recent annual report on Form 10–KSB (§ 249.310b of this chapter) need not provide the information required by paragraph (b) of Rule 14a–3. Rather, those small business issuers shall provide only the financial statements required to be filed in their most recent Form 10–KSB. The inclusion of additional information, including information required of non-transitional small business issuers, in the annual report to security holders will not cause the issuer to be ineligible for the transitional disclosure forms.

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

16. The authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a, *et seq.*, unless otherwise noted.

Note: The following forms will not appear in the Code of Federal Regulations.

17. By adding General Instruction E to Form 10–SB (§ 249.210b) to read as follows:

Form 10–SB

* * * * *

General Instructions

* * * * *

E. *Alternative Disclosure Formats.*

Small business issuers which were not previously subject to the reporting requirements of section 13 or 15(d) of the Exchange Act may elect any one of the three alternative disclosure models of Part I. Regardless of the disclosure model used, all registrants shall also complete Parts II and III, and furnish the financial statements required by Part F/S. As Alternative 1 is not a "transitional disclosure format," those small business issuers electing Alternative 1 will not be eligible for use of the transitional disclosure formats in Forms 10–KSB, 10–QSB and SB–1.

18. By removing Items 1 through 15 under "Information Required in Registration Statement" of Form 10–SB (17 CFR 249.210b).

19. By adding Part I; Part II; Part F/S and Part III after "Information Required in Registration Statement" of Form 10–SB (17 CFR 249.210b):

Form 10–SB

* * * * *

Information Required in Registration Statement

PART I

Alternative 1

Corporate issuers may elect to furnish the information required by Questions 1, 3, 4, 11, 14–20, 28–43, 45, and 47–50 of Model A of Form 1–A.

Alternative 2

Any issuer may elect to furnish the following information required by Items 6–12 of Model B of Form 1–A.

Alternative 3

Any issuer may elect to furnish the following information.

Item 1. Description of Business.

Furnish the information required by Item 101 of Regulation S–B.

Item 2. Management's Discussion and Analysis or Plan of Operation.

Furnish the information required by Item 303 of Regulation S–B.

Item 3. Description of Property.

Furnish the information required by Item 102 of Regulation S–B.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

Furnish the information required by Item 403 of Regulation S–B.

Item 5. Directors, Executive Officers, Promoters and Control Persons.

Furnish the information required by Item 401 of Regulation S–B.

Item 6. Executive Compensation.

Furnish the information required by Item 402 of Regulation S–B.

Item 7. Certain Relationships and Related Transactions.

Furnish the information required by Item 404 of Regulation S–B.

Item 8. Description of Securities.

Furnish the information required by Item 202 of Regulation S–B.

PART II

Item 1. Market Price of and Dividends on the Registrant's Common Equity and Other Shareholder Matters.

Furnish the information required by Item 201 of Regulation S–B.

Item 2. Legal Proceedings.

If the registrant uses either Alternative 2 or Alternative 3 of this form, furnish the information required by Item 103 of Regulation S–B.

Item 3. Changes in and Disagreements with Accountants.

Furnish the information required by Item 304 of Regulation S–B.

Item 4. Recent Sales of Unregistered Securities.

Furnish the information required by Item 701 of Regulation S–B.

Item 5. Indemnification of Directors and Officers.

Furnish the information required by Item 702 of Regulation S–B.

PART F/S

Furnish the information required by Item 310 of Regulation S–B. However, if audited financial statements of the registrant and its predecessors and the financial statements required to be provided for any significant business acquired or to be acquired are not otherwise available for each of the two most recent fiscal years, only the financial statements for the latest fiscal year must be audited.

PART III

Item 1. Index to Exhibits

(a) An index to the exhibits should be presented.

(b) Each exhibit should be listed in the exhibit index according to the number assigned to it in Part III of Form 1–A or Item 2, below.

(c) The index to exhibits should identify the location of the exhibit under the sequential page numbering system for this Form 10–SB.

(d) Where exhibits are incorporated by reference, the reference shall be made in the index of exhibits.

Instructions:

1. Any document or part thereof filed with the Commission pursuant to any Act administered by the Commission may, subject to the limitations of Rule 24 of the Commission's Rules of Practice, be incorporated by reference as an exhibit to any registration statement.

2. If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the issuer shall file with the reference a statement containing the text of such modification and the date thereof.

3. Procedurally, the techniques specified in Rule 12b–23 shall be followed.

Item 2. Description of Exhibits

As appropriate, the issuer should file those documents required to be filed as Exhibit Number 2, 3, 5, 6, and 7 in Part III of Form 1–A. The registrant also shall file:

(12) *Additional exhibits*—Any additional exhibits which the issuer may wish to file, which shall be so marked as to indicate clearly the subject matters to which they refer.

(13) *Form F–X*—Canadian issuers shall file a written irrevocable consent and power of attorney on Form F–X.

* * * * *

20. By adding the following at the end of the cover page of Form 10–QSB (§ 249.308b):

Form 10–QSB

* * * * *

Transitional Small Business Disclosure Format (Check one): Yes ____; No ____

* * * * *

21. Form 10–QSB (§ 249.308b) is amended by adding General Instruction H to read as follows:

* * * * *

General Instructions

* * * * *

H. In response to Item 6(a) of this Form 10–QSB, a small business issuer that is eligible to file the information required under "Information Required in Annual Report of Transitional Small Business Issuers" in its next required Form 10–KSB may include only those exhibits required by Part III of "Information Required in Annual Report of Transitional Small Business Issuers" of Form 10–KSB.

22. Form 10–QSB (§ 249.308b) is amended by adding the following instruction at the end of Item 2 of Part I—Financial Information:

* * * * *

PART I—FINANCIAL INFORMATION

* * * * *

Item 2. Management's Discussion and Analysis or Plan of Operation

* * * * *

Instructions for Transitional Small Business Issuers

(1) Those transitional small business issuers which relied upon Alternative 1 under "Information Required in Annual Report of Transitional Small Business Issuers" in their most recent Form 10–KSB may, in lieu of the disclosure required by Item 303 of Regulation S–B, update the responses to Questions 47–50 in Model A of Form 1–A. This update should provide such information as will enable the reader to assess material changes since the end of the last fiscal year and for the comparable interim period in the preceding year.

(2) Those transitional small business issuers which relied upon Alternative 2 under "Information Required in Annual Report of Transitional Small Business

Issuers" in their most recent Form 10–KSB may, in lieu of the disclosure required by Item 303 of Regulation S–B, update the response to Item 6(a)(3)(i) to Model B of Form 1–A. This update should provide such information as will enable the reader to assess material changes since the end of the last fiscal year and for the comparable interim period in the preceding year.

* * * * *

23. By adding the following at the end of the cover page of Form 10–KSB (§ 249.310b):

Form 10–KSB

* * * * *

Transitional Small Business Disclosure Format (Check one):

Yes ____; No ____

* * * * *

24. By adding General Instruction H to Form 10–KSB (§ 249.310b) to read as follows:

Form 10–KSB

* * * * *

General Instructions

* * * * *

H. *Transitional Small Business Issuers.*

(a) In lieu of the disclosure requirements set forth under Parts I, II and III, a small business issuer that has not registered more than $10,000,000 in securities offerings in any continuous 12-month period since it became subject to the reporting requirements of section 13 or 15(d) of the Exchange Act may include the information required under "Information Required in Annual Report of Transitional Small Business Issuers." In calculating the $10,000,000 ceiling, issuers should include all offerings which were registered under the Securities Act, other than any amounts registered on Form S–8.

(b) A small business issuer may provide the information set forth under "Information Required in Annual Report of Transitional Small Business Issuers" until it (1) registers more than $10 million under the Securities Act in any continuous 12-month period (other than securities registered on Form S–8), (2) elects to file on a non-transitional disclosure document (other than the proxy statement disclosure in Schedule 14A), or (3) no longer meets the definition of small business issuer. Non-transitional disclosure documents include: (1) Securities Act registration statement forms other than Forms SB–1, S–3 (if the issuer incorporates by reference transitional Exchange Act reports), S–8 and S–4 (if the issuer relies upon the transitional disclosure format in that form); (2) Exchange Act periodic reporting Forms 10–K and 10–Q; (3) Exchange Act registration statement Form 10; and (4) reports or registration statements on Forms 10–KSB, 10–QSB or 10–SB which do not use the transitional disclosure document format. A reporting company may not return to the transitional disclosure forms.

* * * * *

25. By adding Part I, Part II, Part F/S and Part III after Item 13 of Form 10–KSB (§ 249.310b) to read as follows:

Form 10–KSB

* * * * *

Item 13

* * * * *

Information Required in Annual Report of Transitional Small Business Issuers

PART I

Note: Regardless of the disclosure model used, all registrants shall furnish the financial statements required by Part F/S.

Alternative 1

Corporate issuers may elect to furnish the information required by Questions 1, 3, 4, 11, 28–43, 45, and 47–50 of Model A of Form 1–A, as well as the information in Parts II and III, below.

Alternative 2

Any issuer may elect to furnish the information required by Items 6–11 of Model B of Form 1–A, as well as the information required by Parts II and III, below.

PART II

Item 1. Market Price of and Dividends on the Registrant's Common Equity and Other Shareholder Matters

Furnish the information required by Item 201 of Regulation S–B.

Item 2. Legal Proceedings

If Alternative 2 is used, furnish the information required by Item 103 of Regulation S–B.

Item 3. Changes in and Disagreements With Accountants

Furnish the information required by Item 304 of Regulation S–B, if applicable.

Item 4. Submission of Matters to a Vote of Security Holders

If any matter was submitted during the fourth quarter of the fiscal year covered by this report to a vote of security holders, through the solicitation of proxies or otherwise, furnish the following information:

(a) The date of the meeting and whether it was an annual or special meeting.

(b) If the meeting involved the election of directors, the name of each director elected at the meeting and the name of each other director whose term of office as a director continued after the meeting.

(c) A brief description of each other matter voted upon at the meeting and the number of affirmative votes and the number of negative votes cast with respect to each such matter.

(d) A description of the terms of any settlement between the registrant and any other participant (as defined in Rule 14a–11 of Regulation A under the Act) terminating any solicitation subject to Rule 14a–11, including the cost or anticipated cost to the registrant.

Instructions to Item 4

1. If any matter has been submitted to a vote of security holders otherwise than at a meeting of such security holders, corresponding information with respect to such submission should be furnished. The solicitation of any authorization or consent (other than a proxy to vote at a shareholders' meeting) with respect to any matter shall be deemed a submission of such matter to a vote of security holders within the meaning of this item.

2. Paragraph (a) need be answered only if paragraph (b) or (c) is required to be answered.

3. Paragraph (b) need not be answered if (i) proxies for the meeting were solicited pursuant to Regulation 14A under the Act, (ii) there was no solicitation in opposition to the management's nominees as listed in the proxy statement, and (iii) all of such nominees were elected. If the registrant did not solicit proxies and the board of directors as previously reported to the Commission was re-elected in its entirety, a statement to that effect in answer to paragraph (b) will suffice as an answer thereto.

4. Paragraph (c) need not be answered as to procedural matters or as to the selection or approval of auditors.

5. If the registrant has furnished to its security holders proxy soliciting material containing the information called for by paragraph (d), the paragraph may be answered by reference to the information contained in such material.

6. If the registrant published a report containing all of the information called for by this item, the item may be answered by reference to the information in that report.

Item 5. Compliance With Section 16(a) of the Exchange Act

Furnish the information required by Item 405 of Regulation S–B.

Item 6. Reports on Form 8–K.

State whether any reports on Form 8–K were filed during the last quarter of the period covered by this report, listing the items reported, any financial statements filed and the dates of such reports.

PART F/S

Furnish the information required by Item 310(a) of Regulation S–B.

PART III

Item 1. Index to Exhibits

(a) An index to the exhibits should be presented.

(b) Each exhibit should be listed in the exhibit index according to the number assigned to it in Part III of Form 1–A or under Item 2, below.

(c) The index to exhibits should identify the location of the exhibit under the sequential page numbering system for this Form 10–KSB.

(d) Where exhibits are incorporated by reference, the reference shall be made in the index of exhibits.

Instructions:

1. Any document or part thereof filed with the Commission pursuant to any Act administered by the Commission may, subject to the limitations of Rule 24 of the Commission's Rules of Practice, be incorporated by reference as an exhibit to any registration statement.

2. If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the issuer shall file with the reference a statement containing the text of such modification and the date thereof.

3. Procedurally, the techniques specified in Rule 12b-23 shall be followed.

Item 2. Description of Exhibits

As appropriate, the issuer should file those documents required to be filed as Exhibit Number 2, 3, 5, 6, and 7 in Part III of Form 1-A. The registrant also shall file:

(12) *Additional exhibits*—Any additional exhibits which the issuer may wish to file, which shall be so marked as to indicate clearly the subject matters to which they refer.

(13) *Form F-X*—Canadian issuers shall file a written irrevocable consent and power of attorney on Form F-X.

* * * * *

By the Commission.

Dated: April 28, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93-10365 Filed 5-3-93; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 381

[Docket No. RM93-14-000]

Annual Update of Filing Fees

April 28, 1993.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of annual update of Commission filing fees.

SUMMARY: In accordance with § 381.104 of the Commission's regulations, the Commission issues this update of its filing fees. This notice provides the yearly update using data in the Commission's Payroll Utilization Reporting System to calculate the new fees. The purpose of updating is to adjust the fees on the basis of the Commission's costs, completions, and work time data for fiscal years 1987 through 1992.

EFFECTIVE DATE: June 3, 1993.

FOR FURTHER INFORMATION CONTACT: Olive J. Wallace, Office of the Executive Director, Associate Executive Director Financial Management and CFO, Federal Energy Regulatory Commission, 810 First Street, NE., suite 600, Washington, DC 20426 (202) 219-2903.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the Federal Register, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this notice will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Issued April 28, 1993.

The Federal Energy Regulatory Commission (Commission), by its designee the Executive Director,[1] is issuing this notice to update filing fees the Commission assesses for specific services and benefits provided to identifiable beneficiaries. Pursuant to § 381.104 of the Commission's regulations, the Commission is establishing updated fees on the basis of the Commission's costs, completions, and work time data for fiscal years 1987 through 1992.[2] The adjusted fees announced in this notice are effective June 3, 1993. The new fee schedule is as follows:

Fees Applicable to the Natural Gas Policy Act:	
1. Review of jurisdictional agency determinations (18 CFR 381.402)	$100
2. Petitions for rate approval pursuant to 284.123(b)(2) (18 CFR 381.403)	5,380
3. Initial or extension reports for Title III transactions (18 CFR 381.404)	110
Fees Applicable to General Activities:	
1. Petition for issuance of a declaratory order (except under Part I of the Federal Power Act) (18 CFR 381.302)	10,810
2. Review of a Department of Energy Remedial order:	
Amount in controversy	
$0-9,999 (18 CFR 381.303(b))	100
$10,000-29,999 (18 CFR 381.303(b))	600
$30,000 or more (18 CFR 381.303(a))	15,780
3. Review of a Department of Energy denial of adjustment:	
Amount in controversy	
$0-9,999 (18 CFR 381.304(b))	100
$10,000-29,999 (18 CFR 381.304(b))	600
$30,000 or more (18 CFR 381.304(a))	8,270
4. Written legal interpretations by the Office of the General Counsel (18 CFR 381.305(a))	3,100
Fees Applicable to Natural Gas Pipelines:	
1. Pipeline certificate applications pursuant to 284.224 (18 CFR 381.207(b))	1,000
Fees Applicable to Cogenerators and Small Power Producers:	
1. Certification of qualifying status as a small power production facility (18 CFR 381.505(a))	9,300
2. Certification of qualifying status as a cogeneration facility (18 CFR 381.505(a))	10,520
3. Applications for exempt wholesale generator status (18 CFR 381.801)	1,000
Fees Applicable to the Public Utility Regulatory Policies Act of 1978:	
1. 5 Megawatt exemption application (18 CFR 381.601)	21,620

[1] 18 CFR 375.313(a).

[2] The formula for updating the filing fees was revised in Order No. 548, 58 FR 2968 (January 7, 1993); III FERC Stats. & Regs. ¶ 30,960 (1993). Under the revised formula, the Commission averages six previous fiscal years' completions and work time data to determine the annual fee for a fee category.

List of Subjects in 18 CFR Part 381

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission amends part 381, chapter I, title 18, *Code of Federal Regulations*, as set forth below.

Christie McGue,

Acting Executive Director.

PART 381—FEES

1. The authority citation for part 381 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; and 49 U.S.C. 1–27.

§ 381.302 [Amended]

2. In § 381.302, paragraph (a) is amended by removing "$7,720" and inserting "$10,810" in its place.

§ 381.303 [Amended]

3. In § 381.303, paragraph (a) is amended by removing "$13,400" and inserting "$15,780" in its place.

§ 381.304 [Amended]

4. In § 381.304, paragraph (a) is amended by removing "$5,760" and inserting "$8,270" in its place.

§ 381.305 [Amended]

5. In § 381.305, paragraph (a) is amended by removing "$2,310" and inserting "$3,100" in its place.

§ 381.402 [Amended]

6. Section 381.402 is amended by removing "$85" and inserting "$100" in its place.

§ 381.403 [Amended]

7. Section 381.403 is amended by removing "$4,320" and inserting "$5,380" in its place.

§ 381.404 [Amended]

8. Section 381.404 is amended by removing "$120" and inserting "$110" in its place.

§ 381.505 [Amended]

9. In § 381.505, paragraph (a) is amended by removing "$9,100" and inserting "$9,300" in its place and by removing "$10,540" and inserting "$10,520" in its place.

§ 381.601 [Amended]

10. Section 361.601 is amended by removing "$20,650" and inserting "$21,620" in its place.

[FR Doc. 93–10421 Filed 5–3–93; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address from Pacific Molasses Co. to PM Ag Products, Inc.

EFFECTIVE DATE: May 4, 1993.

FOR FURTHER INFORMATION CONTACT: Judy M. O'Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8737.

SUPPLEMENTARY INFORMATION: Pacific Molasses Co., 333 Market St., suite 1000, San Francisco, CA 94105, has informed FDA of a change of sponsor name and address to PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430. The agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect this change. Also, the regulations are amended in 21 CFR 520.1448a(a)(2) and 520.1840(c)(3) to reflect the new drug labeler code.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Pacific Molasses Co." and by alphabetically adding a new entry for "PM Ag Products, Inc.," and in the table in paragraph (c)(2) by removing the entry for "050112" and by numerically adding a new entry for "036904" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430 ...	036904
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
036904	PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430
* * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1448a [Amended]

4. Section 520.1448a *Monensin blocks* is amended in paragraph (a)(2) by removing "050112" and adding in its place "036904".

§ 520.1840 [Amended]

5. Section 520.1840 *Poloxalene* is amended in paragraph (c)(3) by removing "050112" and adding in its place "036904".

Dated: April 23, 1993.

George A. Mitchell,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 93–10399 Filed 5–3–93; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TREASURY

Internal Revenue Service

26 CFR Parts 1 and 5c

[T.D. 8471]

RIN 1545-AQ99

Removal of Final and Temporary Regulations Relating Primarily to Provisions of Prior Law

AGENCY: Internal Revenue Service, Treasury.

ACTION: Removal of final and temporary regulations; correction.

SUMMARY: This document contain a correction to the removal of a final and temporary regulations (T.D. 8474), which were published Tuesday, April 27, 1993, (58 FR 25556). The regulations relating primarily to provisions of prior law. This action is taken in response to the Regulatory Burden Reduction Initiative.

EFFECTIVE DATE: April 27, 1993.

FOR FURTHER INFORMATION CONTACT: Paul C. Feinburg, (202) 622-3325, not a toll-free number.

SUPPLEMENTARY INFORMATION:

Background

On April 2, 1992, the Internal Revenue Service published in the Federal Register the Request for Comments on Regulatory Burden Reduction Initiative (57 FR 11277), in which the Treasury Department and the Internal Revenue Service solicited public comments on a program to—

(1) Close certain regulations projects that are no longer needed or will not be pursued in the forseeable future;

(2) Withdraw certain proposed regulations which there are no current plans to finalize; and

(3) Redesignate certain regulations as relating to prior law in light of subsequent changes to the law.

Section III of that document listed regulations identified as relating primarily to provisions of prior law. Those final and temporary regulations which did not receive any comments or which received only comments favorable to the program were removed.

The removal of the final and temporary regulations are the subject of these corrections.

Need for Correction

As published, the removal of the final and temporary regulations contains errors which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of April 27, 1993, of the removal of final and temporary regulations (T.D. 8474), which were the subject of FR Doc. 93-9694, is corrected as follows.

Paragraph 1. On page 25557, column 3, the first entry in the table, "1.305-1" is removed.

Par. 2. On page 25558, column 1, Instructional Par. 7. is corrected to read as follows:

Par. 7. Section 5c.305-1 and §§ 5c.1256-1 through 5c.1256-3 (including the authority citation immediately following each section) are removed.

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93-10412 Filed 5-3-93; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education

34 CFR Part 222

Assistance for Local Educational Agencies in Areas Affected by Federal Activities and Arrangements for Education of Children Where Local Educational Agencies Cannot Provide Suitable Free Public Education

CFR Correction

In title 34 of the Code of Federal Regulations, revised as of July 1, 1992, on page 618, in the first column, the definition of "working on Federal property" should be removed from § 222.3.

BILLING CODE 1505-01-D

34 CFR Part 222

Assistance for Local Educational Agencies in Areas Affected by Federal Activities and Arrangements for Education of Children Where Local Educational Agencies Cannot Provide Suitable Free Public Education

CFR Correction

In title 34 of the Code of Federal Regulations, revised as of July 1, 1992, on page 657 paragraph (b)(2) was inadvertently removed from § 222.102. As reinstated the text of paragraph (b)(2) reads as follows:

§222.102 How are section 2 eligibility and entitlement determined for an LEA formed by consolidation of school districts?

* * * * *

(b) * * *

(2)The LEA meets the criteria in § § 222.95 and 222.96.

BILLING CODE 1505-01-D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 92-233; RM-8078]

Radio Broadcasting Services; Campbellsville and Mannsville, KY

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 260C3 and Channel 260A at Campbellsville, Kentucky, reallots Channel 260C3 from Campbellsville, Kentucky, to Mannsville, Kentucky, and modifies the construction permit for Station WVLC(FM) to specify Channel 260C3, Mannsville, Kentucky, as the community of license, at the request of Patricia Rodgers. See 57 FR 53874, November 13, 1992. The allotment of Channel 260C3 to Mannsville, Kentucky, will provide that community with its first local aural transmission service, in accordance with § 1.420(i) of the Commission's Rules. Channel 260C3 can be allotted to Mannsville in compliance with the Commission's minimum distance separation requirements at petitioner's desired transmitter site 21.4 kilometers (13.3 miles) south, in order to avoid a short-spacing to Station WDJX(FM), Channel 259B, Louisville, Kentucky. The coordinates for Channel 260C3 at Mannsville, Kentucky, are North Latitude 37-11-00 and West Longitude 85-08-33. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 14, 1993.

FOR FURTHER INFORMATION CONTACT: Nancy J. Walls, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 92-233, adopted April 6, 1993, and released April 28, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857-3800, 1919 M Street, NW., room 246, or 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Kentucky, is amended by removing Campbellsville, Channel 260A, and adding Mannsville, Channel 260C3.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93-10407 Filed 5-3-93; 8:45 am]

BILLING CODE 6712-01-M

---

47 CFR Part 73

[MM Docket No. 92-277; RM-8112]

Radio Broadcasting Services; Broken Bow, OK

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of CarePhil Communications, substitutes Channel 291C2 for Channel 291C3 at Broken Bow, Oklahoma, and modifies Station KKBI-FM's license to specify operation on the higher class channel. See 57 FR 57410, December 4, 1992. Channel 291C2 can be allotted to Broken Bow in compliance with the Commission's minimum distance separation requirements with a site restriction of 24.8 kilometers (15.4 miles) north to accommodate petitioner's desired transmitter site, at coordinates North Latitude 34-14-45 and West Longitude 94-46-58. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 4, 1993.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 92-277, adopted April 7, 1993, and released April 28, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857-3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by removing Channel 291C3 and adding Channel 291C2 at Broken Bow.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93-10409 Filed 5-3-93; 8:45 am]

BILLING CODE 6712-01-M

---

47 CFR Part 73

[MM Docket No. 91-304; RM-7787]

Television Broadcasting Services; Albion, Lincoln and Columbus, NE

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Citadel Communications Company, Ltd., reallots Television Channel 8 from Albion to Lincoln, Nebraska, and modifies the license for Station KCAN (TV), Albion, to specify the alternate channel. In addition, the Commission allots Channel 18 to Albion. The coordinates for Channel 8 at Lincoln are 41-01-10 and 97-07-23, with a site restriction of 42.8 kilometers (26.6 miles) northwest to avoid a short-spacing to Station KCCI, Channel 8, Des Moines, Iowa, and to avoid the Kansas City freeze area. Coordinates for Channel 18 at Albion are 41-56-00 and 98-17-30, with a site restriction of 36.2 kilometers (22.5 miles) northwest to avoid short-spacing to Station KXNE, Channel 19, Norfolk, Nebraska, and unused and unapplied for Channel *21 at Albion. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 14, 1993.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 91-304, adopted April 7, 1993, and released April 28, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857-3800, 2100 M Street, NW. suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Television broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.606 [Amended]

2. Section 73.606(b), the Television Table of Allotments under Nebraska, is amended by removing Channel 8+ and adding Channel 18 at Albion, and by adding Channel 8+ at Lincoln.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93-10410 Filed 5-3-93; 8:45 am]

BILLING CODE 6712-01-M

---

47 CFR Part 73

[MM Docket No. 92-301; RM-8136]

Radio Broadcasting Services; Henderson, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Dean Broadcasting, Inc., licensee of Station KGRI-FM, Channel 260A, Henderson, Texas, substitutes Channel 260A for Channel 260C3 at Henderson and modifies Station KGRI-FM's license to specify operation on the higher powered channel. See 58 FR 04392, January 14, 1993. Channel 260C3 allotted to Henderson in compliance with the Commission's minimum distance separation requirements with a site restriction of 16.3 kilometers (10.2 miles) southwest in order to avoid a short-spacing to the reference coordinates for vacant but applied for Channel 259C2, Shreveport, Louisiana. The coordinates for Channel 260C3 are 32-01-20 and 94-52-58. With this action, this proceeding is terminated.

EFFECTIVE DATE: June 14, 1993.

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 92–301, adopted April 6, 1993, and released April 28, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas is amended by removing Channel 260A and adding Channel 260C3 at Henderson.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93–10408 Filed 5–3–93; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 91–18; Notice 2]

RIN 2127–AD87

Federal Motor Vehicle Safety Standards; Impact Protection for the Driver From the Steering Control System

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This notice amends Standard No. 203, *Impact Protection for the Driver from the Steering Control System*, to update the reference to the SAE Recommended Practice J944, from the December 1965 version to the June 1980 version. This rule is intended to clarify the positioning of the torso-shaped body block for compliance testing.

DATES: The final rule is effective on June 3, 1993. It allows optional compliance with the 1980 version until March 1, 1994. At that time, compliance with the 1965 version will no longer be allowed.

ADDRESSES: Petitions for reconsideration of the final rule should refer to the docket and notice number of this notice and be submitted to: Administrator, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Clarke B. Harper, Office of Vehicle Safety Standards NHTSA, telephone: (202) 366–2264.

SUPPLEMENTARY INFORMATION: Federal Motor Vehicle Safety Standard No. 203, *Impact Protection for the Driver from the Steering Control System*, sets performance requirements to protect the driver from steering-assembly related injuries in a crash. The standard specifies an impact test in which a block simulating the human torso strikes the steering assembly at 15 mph. The force measured on the steering column during the impact cannot exceed 2,500 pounds except for intervals whose cumulative duration is not more than 3 milliseconds.

Currently, the positioning procedure in Standard No. 203 references Society of Automotive Engineers (SAE) Recommended Practice J944, *Steering Wheel Assembly Laboratory Test Procedure*, December 1965 (SAE J944 Dec 65). This Recommended Practice specifies that the SAE 2-Dimensional manikin specified in SAE J826 "Devices for Use in Defining and Measuring Vehicle Seating Accommodation" be placed in the seat, with the seat in the full-forward position, and moved forward until the steering wheel rim contacts the abdomen of the manikin.

During compliance testing, the agency has experienced problems with this procedure because it fails to relate the steering wheel rim-manikin contact point to the position of the torso-shaped body block, nicknamed "Blak Tuffy." In November 1968, the SAE revised J944 to correct this problem (SAE J944 Nov 68). The June 1980 version, SAE J944 JUN80, is identical to SAE J944 Nov 68.

On June 6, 1991, the agency proposed to amend Standard No. 203 to use the updated SAE J944 JUN80, as this procedure clearly positions the body block reference line 0.75 inch above the Seating Reference Point (SRP) of the driver (56 FR 26046).

As the agency noted in the proposal, the fact that SAE J944 JUN80 references SRP is not expected to pose a problem even though a new definition of SRP was adopted in a final rule on August 12, 1991, (56 FR 38084). Both the new definition in 49 CFR 571.3 of the Code of Federal Regulations and the SAE definition of SRP in SAE J944 JUN80 reference SAE J826. The definition of SRP in SAE J944 JUN80 does not give the date of the version of SAE J826 which is to be used. Therefore, the agency believed that the proposal was compatible with the new definition of SRP.

The agency also noted that the new test setup might result in the Blak Tuffy dummy being aligned approximately .25 inch lower than in the old test setup. This estimate was made based on several assumptions. First, the agency assumed that the Blak Tuffy is relatively the same size as the 2–D manikin. Next, the agency assumed average occupant seat dimensions. The old test setup is conducted with the seat completely forward. The new test setup would be conducted with the seat well back, at the SRP. The agency assumed an elevation difference from the front to the back of approximately .75 inch.

Because of the .25 inch difference in alignment of the Blak Tuffy, the agency recognized that, if the proposal became a final rule, some vehicle manufacturers or steering column manufacturers might feel obligated to recertify the steering systems. It is conceivable, but the agency believed unlikely, that realignment of the test device could cause a failure requiring redesign of the steering system. The agency sought comments from manufacturers regarding the possibility of a need for redesign, and any costs this would entail.

The only other significant difference between the December 1965 and June 1980 versions of SAE J944 concerns instrumentation. The June 1980 version permits any instrumentation capable of recording the required data. The December 1965 version, currently referenced in Standard No. 203, provides detailed drawings of the load cell to be incorporated in the steering column. The agency believed the newer (1980) version is an improvement, as it allows for use of advanced electronics. In addition, as the December 1965 instrumentation would still be permitted, this difference should not impose any additional cost on manufacturers who do not wish to change their instrumentation.

Finally, the agency proposed to delete the phrase "or an approved equivalent" in the standard. This phrase was included in the initial Federal motor vehicle safety standards to make it clear that the manufacturers had flexibility in their selection of a test procedure. Since the manufacturers would retain this flexibility if the phrase were deleted, the phrase is not necessary. Although the agency must follow the test procedure specified in the standard in conducting

its compliance testing, motor vehicle manufacturers need not do so.

Comments Received

Three comments were submitted on the proposal. General Motors Corporation, Volkswagen of America, and Chrysler Corporation each supported the proposal without reservation.

Specifically, GM agreed with the agency's view that a change of .25 inch in elevation would be unlikely to cause a failure of a previously compliant design. Chrysler agreed that there would probably be little difference in the positioning of the body block in the two test procedures, and did not anticipate any need for steering system design. It approves of SAE J944 JUN80's allowance of either instrumentation. both GM and Chrysler concurred with the recommended deletion of the phrase "or an approved equivalent". VW believes the change is long overdue, and urged immediate implementation of it.

Effective Date

NHTSA believes that the rule reflects an existing practice in the industry, and that substitution of the 1980 requirement for the 1965 one will bring Standard No. 203 into accordance with industry practice. Therefore, NHTSA has determined, for good cause shown, that an effective date earlier than 180 days after issuance is in the public interest, and the amendment is effective on June 3, 1993. However, in order to insure that this amendment does not impose any burdens on any party, continued use of the 1965 procedure will be permitted as an option until March 1, 1994.

Rulemaking Analyses

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has considered the economic impact of this rule and has determined that it is not major within the meaning of E.O. 12291 or significant under Department of Transportation policies and procedures. The agency has also determined that the economic and other impacts of this rule are so minimal that a formal regulatory evaluation is not required. NHTSA believes that most manufacturers are already using the more recent version of the proposed test procedure for their compliance testing. Therefore, the agency does not anticipate any additional costs for the new compliance test procedure.

Regulatory Flexibility Act

NHTSA has also considered the impacts of this rulemaking action in relation to the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact on a substantial number of small entities. Few, if any, vehicle manufacturers are small entities within the meaning of the Regulatory Flexibility Act. Small organizations and governmental units will not be significantly affected since the amendment will not affect the purchase price of new vehicles. Accordingly, the agency has not prepared a regulatory flexibility analysis.

National Environmental Policy Act

NHTSA has also analyzed this rule for the purposes of the National Environmental Policy Act. Because the rule only updates an existing test procedure, the agency has determined that implementation of this rule will not have any significant impact on the quality of the human environment.

Executive Order 12612 (Federalism)

NHTSA has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612, and has determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This final rule does not have any retroactive effect. Under 15 U.S.C. 1392(d), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. 15 U.S.C. 1394 sets forth a procedure for judicial review of final rules establishing, amending, or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, 49 CFR part 571 is amended as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegations of authority at 49 CFR 1.50.

2. Section 571.203 is amended by redesignating S5.1 as S5.1(b) and adding a new S5.1 and S5.1(a) to read as follows:

§ 571.203 Standard No. 203; Impact protection for the driver from the steering control system.

* * * * *

S5.1 Except as herein provided, the steering control system of any vehicle to which this standard applies shall be impacted in accordance with S5.1(a). However, if any such vehicle is manufactured on or before February 28, 1994, the steering control system may be impacted in accordance with S5.1(b).

(a) When the steering control system is impacted by a body block in accordance with SAE Recommended Practice J944 JUN80 *Steering Control System—Passenger Car—Laboratory Test Procedure*, at a relative velocity of 15 miles per hour, the impact force developed on the chest of the body block transmitted to the steering control system shall not exceed 2,500 pounds, except for intervals whose cumulative duration is not more than 3 milliseconds.

* * * * *

Issued on April 28, 1993.

Howard Smolkin,

Acting Administrator.

[FR Doc. 93-10426 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-59-M

Proposed Rules

Federal Register
Vol. 58, No. 84
Tuesday, May 4, 1993

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.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 93-113, RM-8212]

Radio Broadcasting Services; Newport, OR

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Charlotte McNaughton seeking the substitution of Channel 224C2 for Channel 224C3 at Newport, Oregon, and the modification of Station KCLM's construction permit to specify operation on the higher class channel. Channel 224C2 can be allotted to Newport in compliance with the Commission's minimum distance separation requirements with a site restriction of 12.7 kilometers (7.9 miles) north to accommodate petitioner's desired transmitter site at coordinates North Latitude 44-45-22 and West Longitude 124-02-54. in accordance with § 1.420(g) of the Commission's Rules, we will not accept competing expressions of interest in use of Channel 224C2 at Newport or require the petitioner to demonstrate the availability of an additional equivalent class channel for use by such parties.

DATES: Comments must be filed on or before June 21, 1993, and reply comments on or before July 6, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. in addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Margot Polivy, Esq., Renouf & Polivy, 1532 Sixteenth Street, NW., Washington, DC 20036 (Counsel to petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rile Making, MM Docket No. 93-113, adopted April 7, 1993, and released April 28, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93-10406 Filed 5-3-93; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 58, No. 84
Tuesday, May 4, 1993

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 AGRICULTURE

Cooperative State Research Service

National Agricultural Research and Extension Users Advisory Board; Meeting

According to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463, 86 Stat. 770–776), as amended, the Office of Grants and Program Systems, Cooperative State Research Service, announces the following meeting:

Name: National Agricultural Research and Extension Users Advisory Board (hereafter referred to as the UAB).

Date: May 20–23, 1993.

Time: May 20—8:15 a.m.–8 p.m.; May 22—8:00 a.m.–10 a.m.; May 23—9:30 a.m.–12 noon.

Place: Winrock International (May 20), Route 3, Morrilton, Arkansas, Best Western (May 22), 704 West Michigan Street, Stuttgart, Arkansas, Memphis Holiday Inn Airport (May 23), 1441 East Brooks Road, Memphis, Tennessee.

Type of Meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person named below.

Purpose: To review rural economic development programs supported by the public and private sector and to write the FY 95 Priorities report.

Contact Person for Agenda and More Information: Ms. Marshall Tarkington, Executive Director, Science and Education Advisory Committees, room 432–A Administration Building, U.S. Department of Agriculture, Washington, DC 20250–2200; Telephone (202) 720–3684.

Done in Washington, DC, this 15th day of April 1993.

John Patrick Jordan,

Administrator.

[FR Doc. 93–10488 Filed 5–3–93; 8:45 am]

BILLING CODE 3410–22–M

Forest Service

Southern Region; Exemption From Appeal of the Decision To Suppress Southern Pine Beetle Infestations on the Glenwood Ranger District of the Jefferson National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice; exemption of decision from administrative appeal.

SUMMARY: Pursuant to 36 CFR 217.4(a)(11), the Regional Forester for the Southern Region has determined that good cause exists and notice is hereby given to exempt from administrative appeal the decision to suppress southern pine beetle (SPB) infestations on the Glenwood Ranger District of the Jefferson National Forest. SPB populations have increased dramatically, resulting in damage to southern yellow and white pines on approximately 50 acres in 10 areas. The primary purpose of the suppression action in these areas is to slow the spread of SPB, rehabilitate damaged areas, and rapidly remove infested merchantable trees prior to excessive loss of value due to stain and decay. Approximately 800 MBF (Thousand Board Feet) would result from this cut and remove operation. Specifically, treatments will take place in the following Compartment/Stands: 3001/04, 3003/7, 3003/05, 3008/10, 12, and 14, 3009/01, 3011/19, 3012/48, 3013/17, 3002/01, and 3018/23 of the Glenwood Ranger District.

EFFECTIVE DATE: May 4, 1993.

FOR FURTHER INFORMATION CONTACT: Questions about this exemption should be directed to Jean P. Kruglewicz, Appeals and Litigation Group Leader, Southern Region, Forest Service-USDA, 1720 Peachtree Road, NW., Atlanta, GA 30367 (404) 347–4867.

SUPPLEMENTARY INFORMATION: The purpose of the SPB suppression operations is threefold: (1) To slow the spread of this insect pest in the immediate area of the infestations, (2) rehabilitate the infested areas, and (3) to capture any value left in the dead and dying trees. Southern yellow pines are the preferred host of the SPB, but with rapidly building populations the SPB moves into nearby white pines (*Pinus strobus*). While white pines are generally less vulnerable to SPB attacks, they are at risk when mixed with, or in close proximity to, infested yellow pines. Yellow pine is not a large species component on the Glenwood Ranger District; it exists most extensively on poor dry sites on mountain ridges which are typically unsuitable for timber production. These yellow pine stands, however, provide breeding grounds for the SPB, which then infest white pine trees in the adjacent valleys that are suitable for timber production. We are concerned with both the need to remove pine sawtimber on suitable land before they lose their value and the need to slow the spread of SPB to uninfested stands with pines.

It is imperative that infested trees be removed as soon as possible to slow the spread of SPB. Adult beetles emerge in early spring and attack living pine trees. Each pair of attacking beetles construct winding S-shaped egg galleries in the inner bark, which eventually girdle and kill the tree. The beetles also introduce blue stain fungi which accelerate tree death by disrupting the water transport within the tree. In warm months, the beetle life cycle is completed in about thirty (30) days. There may be several generations yearly. This life cycle process combined with approaching warm summer temperatures results in the rapid loss of timber value due to stain and decay.

The cut and remove treatment is the most effective SPB suppression technique. This treatment would involve the removal of all infested pine trees in the stands plus a green uninfested buffer strip (approximately 100 to 200 feet). The inclusion of the buffer strip ensures the removal of freshly-attacked trees that may have been overlooked and protests the residual stand from further damage.

All ten (10) areas proposed for cut and remove treatment are located on lands identified as suitable for timber production (Management Area–7), per the approved Jefferson National Forest Land and Resource Management Plan (as amended). In the proposed treatment areas the species of pine include planted loblolly pine (*P. taeda*), Virginia pine (*P virginiana*), shortleaf pine (*P. echinata*), and pitch pine (*P. rigida*). The treatments will appear very similar to group selections, or small patch cuts, in pure pine stands and partial cuts (thinnings) in the mixed pine/hardwood stands. The largest patch cut area will be approximately 4 acres. The largest

partially cut area will be 15 acres. It is estimated that the salvage of this timber would cover approximately 50 acres in the 10 areas and yield approximately 800 MBF (thousand board feet) of dead or dying pine timber. Only areas with good access have been proposed for cut and remove treatment which should enable these areas to be logged economically. Rehabilitation practices will be disclosed in the environmental documents and may include practices such as, site preparation, slash disposal, and reforestation, depending on stand conditions and resource objectives.

The District Ranger is the responsible official. The enviromental analysis is currently being done and is near completion. The decision will likely be documented in either a Decision Memo (per the Forest Service Environmental Policy and Procedures Handbook, Section 31.2) or Decision Notice. The analysis will include methods of harvest, mitigation measures, and any post salvage rehabilitation practices. The environmental document and biological evaluation being prepared will disclose the effects of the proposed action on the environment, document public involvement, and address the issues raised by the public.

Time is of the essence for this project. It is imperative that all identified SPB infested areas be treated and the trees removed as soon as possible to slow the spread of SPB to adjacent pine trees and stands of pine trees, and expedite the removal of merchantable timber prior to warm summer temperatures which can result in the rapid loss of timber value due to stain and decay.

Dated: April 28, 1993.

Ralph F. Mumme,

Acting Deputy Regional Forester.

[FR Doc. 93-10455 Filed 5-3-93; 8:45 am]

BILLING CODE 3410-11-M

Newspapers Used for Publication of Legal Notice of Appealable Decisions for the Northern Region; ID, MT, ND, and portions of SD and Eastern WA

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by all Ranger Districts, Forests, and the Regional Office of the Northern Region to publish legal notice of all decisions subject to appeal under 36 CFR part 217 and to publish notices for public comment and notice of decision subject to the provisions proposed in 36 CFR part 215. The intended effect of this action is to inform interested members of the public which newspapers will be used to publish legal notices for public comment or decisions, thereby allowing them to receive constructive notice of a decision, to provide clear evidence of timely notice, and to achieve consistency in administering the appeals process.

DATES: Publication of legal notices in the listed newspapers will begin with decisions subject to appeal that are made on or after May 6, 1993. The list of newspapers will remain in effect until another notice is published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Stephen Solem; Regional Appeals Coordinator; Northern Region; P.O. Box 7669; Missoula, Montana 59807. Phone: (406) 329-3647.

The newspapers to be used are as follows:

Northern Regional Office

Regional Forester decisions in Montana:

The Missoulian, Missoula, Montana

Great Falls Tribune, Great Falls, Montana

The Billings Gazette, Billings, Montana

Regional Forester decisions in Northern Idaho and Eastern Washington:

The Spokesman Review, Spokane, Washington

Regional Forester decisions in North Dakota:

Bismarck Tribune, Bismarck, North Dakota

Regional Forester decisions in South Dakota:

Rapid City Journal, Rapid City, South Dakota

Beaverhead National Forest

Beaverhead Forest Supervisor, Wise River District Ranger, Wisdom District Ranger and Sheridan District Ranger decisions:

Montana Standard, Butte, Montana

Madison District Ranger Decisions:

Montana Standard, Butte, Montana

Bozeman Chronicle, Bozeman, Montana

Bitterroot National Forest

Bitterroot Forest Supervisor and District Ranger decisions:

Ravalli Republic, Hamilton, Montana

Clearwater National Forest

Clearwater Forest Supervisor and District Ranger decisions:

Lewiston Morning Tribune, Lewiston, Idaho

Custer National Forest

Custer Forest Supervisor decisions in North Dakota:

Bismarck Tribune, Bismarck, North Dakota

Custer Forest Supervisor decisions in South Dakota:

Rapid City Journal, Rapid City, South Dakota

Custer Forest Supervisor decisions in Montana:

Billings Gazette, Billings, Montana

Sheyenne District Ranger decisions:

Fargo Forum, Fargo, North Dakota

Beartooth District Ranger decisions:

Carbon County News, Red Lodge, Montana

Sioux District Ranger decisions in South Dakota:

Nation's Center News, Buffalo, South Dakota

Sioux District Ranger decisions in Montana:

Ekalaka Eagle, Ekalaka, Montana

Ashland District Ranger decisions:

Billings Gazette, Billings, Montana

Grand River District Ranger decisions:

Lemmon Leader, Lemmon, South Dakota

Medora District Ranger decisions:

Dickinson Press, Dickinson, North Dakota

McKenzie District Ranger decisions:

Bismarck Tribune, Bismarck, North Dakota

Deerlodge National Forest

Deerlodge Forest Supervisor and Ranger District decisions:

Montana Standard, Silver Bow County, Montana

Flathead National Forest

Flathead Forest Supervisor and District Ranger decisions:

The Daily Inter Lake, Kalispell, Montana Sunday Edition Only

Gallatin National Forest

Gallatin Forest Supervisor, Bozeman District Ranger, Hebgen Lake District Ranger, Livingston District Ranger, and Gardiner District Ranger decisions:

Bozeman Daily Chronicle, Bozeman, Montana

Big Timber District Ranger decisions:

Billings Gazette, Billings, Montana

Helena National Forest

Helena Forest Supervisor and District Ranger decisions:

Independent Record, Helena, Montana

Idaho Panhandle National Forests

Idaho Panhandle Forest Supervisor and District Ranger decisions:

Spokesman Review, Spokane, Washington

Kootenai National Forest

Kootenai Forest Supervisor, Rexford District Ranger, Three Rivers District Ranger, Libby District Ranger, Fisher River District Ranger decisions:

Western News, Libby, Montana

Fortine District Ranger decisions:

Tobacco Valley News, Eureka, Montana

Cabinet District Ranger decisions:

Sanders County Ledger, Thompson Falls, Montana

Lewis and Clark National Forest

Lewis and Clark Forest Supervisor and District Ranger decisions:

Great Falls Tribune, Great Falls, Montana

Lolo National Forest

Lolo Forest Supervisor, Missoula District Ranger, Ninemile District Ranger, and Seeley Lake District Ranger decisions:

Missoulian, Missoula, Montana

Plains/Thompson Falls District Ranger decisions:

Sanders County Ledger, Thompson Falls, Montana

Superior District Ranger decisions:

Mineral Independent, Plains, Montana

Nezperce National Forest

Nezperce Forest Supervisor, Salmon River District Ranger, Clearwater District Ranger, Red River District Ranger and Moose Creek District Ranger decisions:

Idaho County Free Press, Grangeville, Idaho

Dated: April 28, 1993.

Christopher D. Risbrudt,

Deputy Regional Forester.

[FR Doc. 93-10454 Filed 5-3-93; 8:45 am]

BILLING CODE 3410-11-M

California Spotted Owl—Sierran Province—Management Direction for National Forests in California

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to extend the date for submission of comments and to change the address where comments should be sent.

SUMMARY: The USDA Forest Service is extending the date for submission of written comments to July 20, 1993. The address for submission of comments is changed. Comments submitted to the address listed in the original Notice of Intent will be fully considered.

DATES: Comments concerning the scope of the analysis should be received in writing by July 20, 1993.

ADDRESSES: Send written comments to Janice Gauthier, California Spotted Owl EIS Team Leader, Land Management Planning, 2999 Fulton Avenue, Sacramento, CA 95821.

FOR FURTHER INFORMATION CONTACT: Janice Gauthier, Land Management Planning, (916) 978-4304.

SUPPLEMENTARY INFORMATION: On March 18, 1993, a Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) was published in the **Federal Register** (Vol. 58, No. 51, 14554-14555). This environmental impact statement will establish standards and guidelines for maintaining viable population of California Spotted Owls. The NOI indicated that written comments should be received by May 3, 1993. An additional 78 days has been added to encourage broad public participation.

Dated: April 29, 1993.

Mark A. Reimers,

Deputy Chief, Programs and Legislation.

[FR Doc. 93-10470 Filed 5-3-93; 8:45 am]

BILLING CODE 3410-11-M

ARCTIC RESEARCH COMMISSION

Meeting

April 23, 1993.

Notice is hereby given that the Arctic Research Commission will hold its 31st Meeting in Anchorage, AK, on May 26-27 1993. On Wednesday, May 26, a Business Session open to the public will begin at 8:30 a.m. in the MMS Conference Room, University Plaza Building, 6th Floor, 949 E. 36th Street. Agenda items include: (1) Chairman's Report; (2) Comments from agencies and organizations; (3) Status of Review of U.S. Arctic Policy; (4) Alaska Supercomputing Center; (5) Discussion of Logistics Recommendations; (6) Arctic Health Research; (7) Coordination of Federal Arctic Research; (8) Discussion of Biennial Revision, U.S. Arctic Research Plan; (9) Status of Scientific Assessment and Standards for Arctic Oil and Gas Development; (10) Discussion of Commission Tasks and Status; and (11) Other Business. An Executive Session will be held following the close of the Business Session on May 26.

On Wednesday, May 27, the Business Session open to the public will reconvene at 9 a.m. at the location above during which Coordination of Federal Arctic Research—Federal, State and International Coordination, Adherence to the Arctic Research and Policy Act will be topics of a panel discussion; and discussions of the Biennial Revision, U.S. Arctic Research Plan; Status of Scientific Assessment and Standards for Arctic Oil and Gas Development; and Commission Tasks and Status.

Any person planning to attend this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs.

Contact Person for More Information: Philip L. Johnson, Executive Director, U.S. Arctic Research Commission, 202-371-9631 or TDD 202-357-9867.

Philip L. Johnson,

Executive Director, U.S. Arctic Research Commission.

[FR Doc. 93-10444 Filed 5-3-93; 8:45 am]

BILLING CODE 7555-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

[(A-351-819), (A-427-811), (A-533-808)]

Postponement of Preliminary Determinations: Certain Stainless Steel Wire Rods From Brazil, France, and India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: May 4, 1993.

FOR FURTHER INFORMATION CONTACT: John Beck, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-3464.

Postponements

France

On April 22, 1993, Al Tech Specialty Steel Corp., Armco Stainless & Alloy Products, Carpenter Technology Corp., Republic Engineered Steels, Talley Metals Technology, Inc., and United Steelworkers of America, AFL-CIO/CLC, petitioners in this investigation, requested that the Department postpone the preliminary determination in accordance with section 733(c)(1) of the Tariff Act of 1930, as amended (the Act) (19 U.S.C 1673b(c)(1)). We find no compelling reasons to deny the request and are, accordingly, postponing the date of the preliminary determination until no later than July 28, 1993.

Brazil and India

Pursuant to section 733(c)(1)(B) of the Act, and 19 CFR 353.15(b), we determine that these investigations are "extraordinarily complicated," because

of the complexity of the issues surrounding respondent selection and the Appendix V matching criteria.

We are also required by the Act to affirmatively determine whether parties are cooperating. Regarding this issue, we have received questionnaire responses from Eletrometal SA—Metais Especiais for the Brazil investigation and Mukand, Ltd. for the India investigation.

For the reasons cited above, we determine that these investigations are extraordinarily complicated in accordance with section 733(c)(1)(B)(i)(II) of the Act, that additional time is necessary to make these preliminary determinations and that, for the purposes of extending the preliminary determinations, responding parties have cooperated. The statutory deadline for issuing these preliminary determinations is no later than July 28, 1993.

This notice is published pursuant to section 733(c)(2) of the Act and 19 CFR 353.15(d).

Dated: April 27, 1993.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 93-10498 Filed 5-3-93; 8:45 am]

BILLING CODE 3510-DS-P

[A-533-805]

Amendment of Final Determination of Sales at Less Than Fair Value: Sulfur Dyes, Including Sulfur Vat Dyes, From India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: May 4, 1993.

FOR FURTHER INFORMATION CONTACT: Kimberly Hardin, Office of Antidumping Investigations, Office of Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482-0371.

AMENDMENT TO THE FINAL DETERMINATION: We are amending the final determination of sales at less than fair value of sulfur dyes, including sulfur vat dyes, from India, to reflect the correction of a ministerial error made in the margin calculations in that determination. Although the International Trade Commission (ITC) has already issued its negative final injury determination in this investigation, we are publishing this amendment to the final determination in accordance with section 353.28(c) of the Department's regulations.

SCOPE OF INVESTIGATION: The merchandise subject to this investigation is sulfur dyes, including sulfur vat dyes. Sulfur dyes are synthetic, organic, coloring matter containing sulfur. Sulfur dyes are obtained by high temperature sulfurization of organic material containing hydroxy, nitro or amino groups, or by reaction of sulfur and/or alkaline sulfide with aromatic hydrocarbons. For purposes of this investigation, sulfur dyes include, but are not limited to, sulfur vat dyes with the following color index numbers: Vat Blue 42, 43, 44, 45, 46, 47, 49, and 50 and Reduced Vat Blue 42 and 43. Sulfur vat dyes also have the properties described above. All forms of sulfur dyes are covered, including the reduced (leuco) or oxidized state, presscake, paste, powder, concentrate, or so-called "pre-reduced, liquid ready-to-dye" forms. The sulfur dyes subject to this investigation are classifiable under subheadings 3204.15.10, 3204.15.20, 3204.15.30, 3204.15.35, 3204.15.40, 3204.15.50, 3204.19.30, 3204.19.40 and 3204.19.50 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes. Our written description of the scope of this investigation is dispositive.

CASE HISTORY: In accordance with section 735(d) of the Tariff Act of 1930, as amended (the Act), on March 1, 1993, the Department published its final determination that sulfur dyes, including sulfur vat dyes, from India were being, or were likely to be, sold in the United States at less than fair value (58 FR 11835). Subsequent to the final determination, we received allegations that the Department made ministerial errors in the margin calculations for one respondent, Atul Products, Limited (Atul).

On April 12, 1993, the Department was formally notified by the ITC that an industry in the United States is not materially injured or threatened with material injury, and the establishment of an industry in the United States is not materially retarded by reason of imports of sulfur dyes, including sulfur vat dyes, from India that are sold in the United States at less than fair value.

AMENDMENT OF FINAL DETERMINATION: On March 3, and 4, 1993, petitioner and one respondent, Atul, alleged that the Department had made a total of three ministerial errors in the final calculations performed to determine the margin found for Atul in accordance with section 353.28 of the Department's regulations. First, petitioner claimed that the Department failed to include the direct selling expenses reported in the cost of production (COP) questionnaire response in the COP calculation. Moreover, petitioner also stated that we had not included an amount for imputed inventory carrying costs. Second, petitioner claimed that in comparing COP to home market price we also failed to deduct home market commissions from the ex-factory price as indicated in a DOC memorandum dated February 17, 1993. Finally, respondent claimed that we failed to add a returnable packing charge to the net home market price for each transaction.

We disagree with petitioner regarding the direct selling expense amount used to calculate COP. We deducted discounts and rebates from the price. For purposes of the cost test, we compared this price to the COP which included all direct selling expenses except commissions. Petitioner wanted us to add direct selling expenses to COP and subtract direct selling expenses from the price. This would result in double counting. Moreover, petitioner erroneously argues that we were in error by not including imputed expenses in the COP. It is the Department's practice to include only actual expenses in COP. Accordingly, we also determine that this is not a ministerial error.

We agree with petitioner that we failed to account for commissions, as indicated in our February 17, 1993, calculation memorandum. This was a ministerial oversight, and we have made the necessary corrections (see below).

Finally, we disagree with respondent that the failure to add the returnable packing charge to the net home market price for each transaction constitutes a ministerial error. We specifically addressed this issue in comment 4 of the final determination and determine that this issue is not a ministerial error.

Accordingly, pursuant to section 735(e) of the Act and section 353.28(c) of the Department's regulations, we have corrected the ministerial error in the final determination of sales at less than fair value by accounting for home market commissions. We then compared the recalculated net home market price to Atul's COP and found that between 10 and 90 percent of Atul's home market sales had been made at below the COP over an extended period of time. Since Atul has not submitted information indicating that any of its sales below cost were at prices which would have permitted "recovery of all costs within a reasonable period of time in the normal course of trade," we were unable to conclude that the COP of such sales was recovered within a reasonable period. As a result in accordance with

section 773(b) of the Act, we disregarded the below cost sales in recalculating foreign market value.

The rate calculated for Atul at the final determination was 2.73 percent. However, 2.75 percent was the rate published in the **Federal Register** at the final determination. Based upon the above changes, the cash deposit or bonding rate for Atul is now 2.75 percent. The cash deposit or bonding rate for the "All Others" category is now 8.60 percent. The cash deposit or bonding rates for Hickson and Dadajee, Limited and Hain Limited remain unaffected by this amendment to the final determination.

DISCONTINUATION OF SUSPENSION OF LIQUIDATION: Although the aforementioned ministerial error correction affects the rates for Atul and "All Others," in accordance with section 735(c)(2) of the Act, because of the negative final determination by the ITC, we have already directed the Customs Service to terminate suspension of liquidation and release any bond or other security and refund any cash deposit required under section 733(d)(2) of the Act of all entries of sulfur dyes, including sulfur vat dyes, from India, as defined in the "Scope of Investigation" section of this notice.

This determination is published pursuant to section 735(d) of the Act (19 U.S.C. 1673d(d)) and 19 CFR 353.20.

Dated: April 28, 1993.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 93-10499 Filed 5-3-93; 8:45 am]

BILLING CODE 3510-DS-P

The University of Connecticut; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 92-151. *Applicant:* The University of Connecticut, Department of Linguistics, Storrs, CT 06269-1145. *Instrument:* Eye Position Meter, Model 6500. *Manufacturer:* Skalar Medical b.v., The Netherlands. *Intended Use:* See notice at 57 FR 54971, November 23, 1992.

Comments: None received. *Decision:* Denied. *Reasons:* To justify purchase of the foreign article, the applicant states that:

> It is our conclusion that only the two eyetrackers have the necessary sensitivity for our purposes: The DPI 1000 Eyetracker and the IRIS Eyetracker.

The IRIS (as purchased) is made abroad by Skalar and the DPI 1000 is manufactured in the U.S. by Fourward Technologies, San Jose, California. Both instruments have an accuracy to about 1 minute of arc or visual angle and are generally applicable for studies of visual tracking and reading such as the applicant intends.

The applicant further states:

> Our decision to purchase the IRIS Eyetracker was based on financial considerations. The bid from Skalar Medical was less than one-sixth the amount of the instrument made by Fourward Technologies. We had previously applied for a DPI Eyetracker as part of a Program Project Grant through Haskins Laboratories in New Haven. Although the grant was funded, our request for a DPI Eyetracker was not approved, primarily because of its expense.

Pursuant to 15 CFR 301.2(s):

> "Pertinent" specifications are those specifications necessary for the accomplishment of the specific scientific research and/or science-related educational purposes described by the applicant. Specifications or features (even if guaranteed) which afford greater convenience, satisfy personal preferences, accommodate institutional commitments or limitations, or assure lower costs of acquisition, installation, operation, servicing or maintenance are not pertinent.

Furthermore, 15 CFR 301.5(e)(7) provides, in part, as follows:

> Information provided in a resubmission that * * * contradicts or conflicts with information provided in a prior submission, shall not be considered in making the decision on an application that has been resubmitted. Accordingly, an applicant may elect to reinforce an original submission by elaborating in the resubmission on the description of the purposes contained in a prior submission and may supply additional examples, documentation and/or other clarifying detail, *but the applicant shall not introduce new purposes or other material changes* in the nature of the original application. (Emphasis supplied.)

As demonstrated above, the applicant has stated that the foreign and the domestic instruments are equivalent with respect to sensitivity and that its decision to purchase the foreign article was determined by financial considerations. We conclude that the domestic instrument was satisfactory for the applicant's needs, as evidenced by its attempt to acquire it, and that a resubmission cannot establish, without introducing impermissible new purposes, that a scientifically equivalent domestic instrument is not available. We therefore deny the application.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 93-10497 Filed 5-3-93; 8:45 am]

BILLING CODE 3510-DS-F

National Institute of Standards and Technology

Prospective Grant of Exclusive Patent License

AGENCY: National Institute of Standards and Technology, DOC.

ACTION: Notice of prospective grant of exclusive patent license.

SUMMARY: This is notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institute of Standards and Technology ("NIST"), U.S. Department of Commerce, is contemplating the grant of a field of use exclusive license in the United States to practice the invention embodied in U.S. Patent 5,172,064, titled, "Calibration System for Determining the Accuracy of Phase Modulation and Amplitude Modulation Noise Measurement Apparatus" to Techtrol Cyclonetics, Inc., having a place of business in New Cumberland, Pennsylvania. The patent rights in this invention have been assigned to the United States of America.

FOR FURTHER INFORMATION CONTACT: Bruce E. Mattson, National Institute of Standards and Technology, Technology Development and Small Business Program, Building 221, room B-256, Gaithersburg, MD 20852

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, NIST receives written evidence and argument which establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

U.S. Patent 5,172,064 relates to an apparatus and method for determining the error due to inherent PM and AM noise in a noise measurement device.

The availability of the invention for licensing was published in the **Federal Register**, Vol. 57, No. 158 (August 14, 1992). A copy of the patent may be obtained from NIST at the foregoing address.

Dated: April 28, 1993.

Raymond G. Kammer,

Acting Director.

[FR Doc. 93-10405 Filed 5-3-93; 8:45 am]

BILLING CODE 3510-13-M

CHRISTOPHER COLUMBUS QUINCENTENARY JUBILEE COMMISSION

Meeting

AGENCY: Christopher Columbus Quincentenary Jubilee Commission.

ACTION: Notice of meeting.

SUMMARY: This notice announces a forthcoming meeting of the Christopher Columbus Quincentenary Jubilee Commission, a Presidential Commission established in 1984 (Pub. L. 98-375). The meeting will be held in San Juan, Puerto Rico, and will be chaired by the Commission's Acting Chairman, Dr. William H. McNeill. This will be the Columbus Commission's final meeting.

DATES: Tuesday, May 18th, 1993, from 9 a.m. to 12 Noon, Plenary Session (Open), and from 2 p.m. to 6 p.m., Plenary Session (Open).

ADDRESSES: All meetings will be held at the Radisson Normandy Hotel, San Juan, Puerto Rico.

FOR FURTHER INFORMATION CONTACT: James F. Kuhn, Executive Director (202) 632-1992.

SUPPLEMENTARY INFORMATION: The Christopher Columbus Quicentenary Jubilee Commission will meet jointly with the Puerto Rican Quincentenary Commission during the morning Plenary Session (Open) and for the first half of the afternoon Plenary Session (Open). The Columbus Commission will meet in final session during the second half of the afternoon Plenary Session (Open).

James F. Kuhn,

Executive Director.

[FR Doc. 93-10446 Filed 5-3-93; 8:45 am]

BILLING CODE 6820-RB-M

COMMODITY FUTURES TRADING COMMISSION

Chicago Mercantile Exchange: Proposal to List Domestic Stock Index Futures and Option Contracts for Trading Through Globex

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed contract market rule change.

SUMMARY: The Chicago Mercantile Exchange (CME or Exchange) has submitted a proposal to list for trading through Globex its futures and option contracts in (1) the Standard & Poor's 500 Stock Price Index (S&P 500), (2) the MidCap 400 Stock Price Index (MidCap 400), and (3) the Russell 2000 Stock Price Index (Russell 2000). The Exchange intends to make the changes effective for all contract months shortly after Commission approval.

Acting pursuant to the authority delegated by Commission Regulation 140.96, the Director of the Division of Economic Analysis (Division) of the Commodity Futures Trading Commission (Commission) has determined that publication of the proposal is in the public interest and will assist the Commission in considering the views of interested persons.

DATES: Comments must be received on or before June 3, 1993.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Reference should be made to the CME proposal to list domestic stock index futures and option contracts for trading Globex.

FOR FURTHER INFORMATION CONTACT: Stephen A. Sherrod, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581, telephone (202) 254-7227.

SUPPLEMENTARY INFORMATION: The CME proposes to trade the subject contracts in an evening Globex session from 6:45 p.m. to 7 a.m. (Eastern Time).[1] The CME proposes Globex futures maximum price limits of 12 points in the S&P 500, 4 points in the MidCap 400, and 6 points in the Russell 2000, above or below the settlement price of the previous Regular Trading Hours (RTH) session. The proposed Globex futures price limits, equivalent to 100 points in the Dow Jones Industrial Average, are of the same magnitude as the initial price decline limits in the following RTH session. Options would be subject to a trading halt whenever Globex trading in the relevant underlying futures contract is locked limit.

The RTH close of trading in the subject domestic stock index futures contracts currently is at 4:15 p.m. The primary securities market closes its regular trading hours at 4 p.m. Under the proposed rules, the 6:45 p.m. opening of Globex trading in the subject contracts, later in the same calendar day, with the price limits specified above, would not change in the event that RTH futures trading closes locked limit or subject to a trading halt.

Copies of the proposed amendments will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, at the above address. Copies of the amended terms and conditions can be obtained through the Office of the Secretariat by mail at the same address or by telephone at (202) 254-6314.

The materials submitted by the CME in support of the proposed amendments may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR part 145 (1987)). Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the above address in accordance with CFR 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the proposed amendments should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, at the above address by the specified date.

Issued in Washington, DC on April 29, 1993.

Gerald D. Gay,

Director, Division of Economic Analysis.

[FR Doc. 93-10495 Filed 5-3-93; 8:45 am]

BILLING CODE 6351-01-M

[1] All CME contracts currently listed for trading through Globex include both an afternoon and an evening Globex trading session. However, the current proposal would not establish an afternoon Globex session in the subject contracts.

DEPARTMENT OF EDUCATION

[CFDA No.: 84.015]

National Resource Centers Program for Foreign Language and Area Studies; Inviting Applications for New Awards for Fiscal Year (FY) 1993

Purpose of Program: This program makes awards to institutions of higher education for assistance in establishing and strengthening centers of excellence for training in foreign language and area studies.

Eligible Applicants: Institutions of higher education and consortia of these institutions.

Deadline for Transmittal of Applications: June 21, 1993.

Deadline for Intergovernmental Review: August 20, 1993.

Applications Available: May 14, 1993.

Available Funds: For FY 1993, $500,000 is available for funding one or more new National Resource Centers.

Estimated Range of Awards: $150,000-$500,000.

Estimated Average Size of Awards: $250,000.

Estimated Number of Awards: 1–3.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 50 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Parts 74, 75, 77, 79, 82, 85, and 86; and (b) The regulations for this program in 34 CFR Parts 655 and 656.

Priorities

Absolute priority: Under 34 CFR 75.105(c)(3) and 34 CFR 656.23(a)(1), the Secretary gives an absolute preference to applications that meet the following priority. The Secretary funds only applications that meet this absolute priority:

Projects to establish National Resource Centers whose focus is training in African studies.

Invitational priority: Within the absolute priority specified in this notice, the Secretary is particularly interested in applications that meet the following invitational priority. However, under 34 CFR 75.105(c)(1) an application that meets this invitational priority does not receive competitive or absolute preference over other applications:

Projects proposed by historically black colleges and universities.

For Applications or Information Contact: Dr. Ann I. Schneider, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW., room 3053, ROB–3, Washington, DC 20202–5331. Telephone: (202) 708–7283.

Individuals who are hearing-impaired may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 8 p.m., Monday through Friday, Eastern time.

Program Authority: 20 U.S.C. 1122.

Dated: April 28, 1993.

Maureen A. McLaughlin,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 93–10439 Filed 5–3–93; 8:45 am]

BILLING CODE 4000–01–U

[CFDA No. 84.219]

Student Literacy Corps and Student Mentoring Corps Program

AGENCY: Department of Education.

ACTION: Notice extending the closing date for new awards under the Student Literacy Corps and Student Mentoring Corps Program for fiscal year (FY 1993).

SUMMARY: On March 16, 1993, a notice was published in the **Federal Register** (58 FR 14206) inviting applications under the Student Literacy Corps and Student Mentoring Corps Program for FY 1993. The purpose of this notice is to extend the closing date for transmittal of those applications from May 3, 1993, to May 24, 1993, to provide applicants additional time to submit applications. While the original notice stated that the project period could be up to 48 months, the instructions in the application stated that an applicant could request funding under this competition for a maximum of 24 months only. A project period for up to 48 months is correct.

FOR APPLICATIONS OR INFORMATION CONTACT: Darlene B. Collins, U.S. Department of Education, 400 Maryland Avenue, SW., room 3022, ROB–3, Washington, DC 20202–5251. Telephone: (202) 708–6128. Individuals who are hearing impaired may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 8 p.m., Monday through Friday.

Program Authority: 20 U.S.C. 1138–1138e.

Dated: April 29, 1993.

Maureen A. McLaughlin,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 93–10520 Filed 5–3–93; 8:45 am]

BILLING CODE 4000–01–U

DEPARTMENT OF ENERGY

Invention Available for License

AGENCY: Department of Energy, Office of General Counsel.

ACTION: Notice of invention available for license.

SUMMARY: The U.S. Department of Energy hereby announces that U.S. Patent No. 5,126,721, entitled "Flame Quality Monitor System for Fixed Firing Rate Oil Burners" is available for license, in accordance with 35 U.S.C. 207–209. A copy of the patent may be obtained, for a modest fee, from the U.S. Patent and Trademark Office, Washington, DC 20231.

FOR FURTHER INFORMATION CONTACT: Robert J. Marchick, Office of the Assistant General Counsel for Intellectual Property, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; Telephone (202–586–2802).

SUPPLEMENTARY INFORMATION: 35 U.S.C. 207 authorizes licensing of Government-owned inventions. Implementing regulations are contained in 37 CFR 404. 37 CFR 404.7(a)(1) authorizes exclusive licensing of Government-owned inventions under certain circumstances, provided that notice of the invention's availability for license has been announced in the **Federal Register**.

Issued in Washington, DC, on April 22, 1993.

Eric J. Fygi,

Acting General Counsel.

[FR Doc. 93–10500 Filed 5–3–93; 8:45 am]

BILLING CODE 6450–01–M

Energy Information Administration

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration.

ACTION: Notice of requests submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Pub. L. No. 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection; (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public; (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by June 3, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.)

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards, (EI-73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254-5348.

SUPPLEMENTARY INFORMATION: The first energy information collection submitted to OMB for review was:

1. Federal Energy Regulatory Commission
2. FERC-11
3. 1902-0032
4. Natural Gas Pipeline Company Monthly Statement
5. Extension
6. Recordkeeping Monthly Reporting
7. Mandatory
8. Businesses or other for-profit
9. 50 respondents
10. 12 responses
11. 5.7 hours per response
12. 3,420 hours
13. The purpose of this monthly statement is to develop statistics for use in studies investigating the reasonableness of the various revenue and cost of service items claimed in Section 7 certificates applications and Section 4 and 5 rate filings/cases.

The second information collection submitted for OMB review was:

1. Federal Energy Regulatory Commission
2. FERC-545
3. 1902-0154
4. Gas Pipeline Rates: Rate Change (Non-Formal)
5. Extension
6. On occasion
7. Mandatory
8. Businesses or other for-profit
9. 100 respondents
10. 7.57 responses
11. 225.34 hours per response
12. 170,585 hours
13. This information is required by the Commission to determine if an interstate pipeline's rate filing complies with the requirements of sections 4, 5, and 16 of the Natural Gas Act and/or Order No. 636 (Restructuring Rule issued 4/8/92 in Docket Nos. RM91-11-000 and RM87-34-065) and that the rate/charges for the transportation/sales of natural gas are just and reasonable.

Statutory Authority: Section 2(a) of the Paperwork Reduction Act of 1980 (Pub. L. No. 96-511) which amended Chapter 35 of Title 44 United States Code (See 44 U.S.C. 3506 (a) and (c)(1)).

Issued in Washington, DC, April 28, 1993.

John Gross,

Acting Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93-10501 Filed 5-3-93; 8:45 am]

BILLING CODE 6450-01-M

Energy Policy Act; Data Needs and User Requirements

AGENCY: Energy Information Administration, Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Energy Information Administration (EIA) of the Department of Energy (DOE) is soliciting public comments to facilitate its examination of data needs and user requirements in two sections of the Energy Policy Act (EPACT) of 1992 (Pub. L. 102-486): (1) Section 407, Data Acquisition Program, and (2) Section 503, Replacement Fuel Demand Estimates and Supply Information Program. Comments will aid in determining the data required, the design of resultant data collection programs, the development of replacement fuel demand estimates, and the feasibility of collecting specific types of data. Interested parties who wish to become more involved in this effort are also requested to provide suggestions as to the most efficient means for EIA to establish an ongoing process of consultation, e.g., large user meetings, **Federal Register** notices, electronic mail, small focus groups.

All written comments to this notice will be available for public inspection at the Department of Energy's (DOE) Freedom of Information Office, room 1E-190. Pursuant to the provisions of 10 CFR 1004.11 (1983), any person submitting information believed to be confidential and exempt by law from public disclosure should submit one complete copy of the document and, if possible, 10 additional copies in which the information believed to be confidential has been deleted. DOE will determine the confidential status of the information and treat it accordingly.

DATES: Comments concerning this notice should be submitted by July 6, 1993. If you anticipate that you will be submitting comments, but find it difficult to do so within the time period allowed by this notice, please advise the contact listed below of your intentions.

ADDRESSES: Comments should be submitted in writing to: Ms. Leigh Carleton, EI-632, Energy Information Administration, Department of Energy, 1000 Independence Ave., S.W., Washington, DC 20585. FAX 202-586-0018.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Ms. Leigh Carleton at the above address or by telephone on 202-586-1132.

SUPPLEMENTARY INFORMATION:

I. Background
II. EPACT Sections 407 and 503 and Selected Definitions
III. Current Actions: Request for Comments
IV. Future Actions

I. Background

EIA serves as the government's primary source of energy statistics and provides information to the Executive Branch, Congress, State and local governments, industry, and the general public. EIA's mission is to ensure that accurate, timely, and objective statistics on the Nation's energy position are available for use in public and private analysis and decision making. Under EPACT, the mission of EIA was expanded to include major new responsibilities relating to alternative transportation fuels (ATF). Under section 407, EIA is to establish a data collection program relating to the existing U.S. motor vehicle fleet. This information will be useful to persons seeking to manufacture, convert, sell, own, or operate alternative fueled vehicles or alternative fueling facilities. Additionally, under section 503, EIA is responsible for the development of annual estimates of replacement fuel demand and supply of alternative fueled vehicles.

II. Selected Definitions From EPACT Section 301 and EPACT Sections 407 and 503

Sec. 301. Definitions

For purposes of this title, title IV, and title V (unless otherwise specified)—

(2) The term *alternative fuel* means methanol, denatured ethanol, and other alcohols; mixtures containing 85 percent or more (or such other percentage, but not less than 70 percent, as determined by the Secretary, by rule, to provide for requirements relating to cold start, safety, or vehicle functions) by volume of methanol, denatured ethanol, and other alcohols with gasoline or other fuels; natural gas; liquefied petroleum gas; hydrogen; coal-derived liquid fuels; fuels (other than alcohol) derived from biological materials; electricity (including electricity from solar energy); and any other fuel the Secretary determines, by rule, is substantially not petroleum and would yield substantial energy security

benefits and substantial environmental benefits;

(14) The term *replacement fuel* means the portion of any motor fuel that is methanol, ethanol, or other alcohols, natural gas, liquefied petroleum gas, hydrogen, coal-derived liquid fuels, fuels (other than alcohol) derived from biological materials, electricity (including electricity from solar energy), ethers, or any other fuel the Secretary determines, by rule, is substantially not petroleum and would yield substantial energy security benefits and substantial environmental benefits.

Sec. 407. Data Acquisition Program

(a) Not later than one year after the date of enactment of this Act, the Secretary, through the Energy Information Administration, and in cooperation with appropriate State, regional, and local authorities, shall establish a data collection program to be conducted in at least 5 geographically and climatically diverse regions of the United States for the purpose of collecting data which would be useful to persons seeking to manufacture, convert, sell, own, or operate alternative fueled vehicles or alternative fueling facilities. Such data shall include—

(1) Identification of the number and types of motor vehicle trips made daily and miles driven per trip, including commuting, business, and recreational trips;

(2) The projections of the Secretary as to the most likely combination of alternative fueled vehicle use and other forms of transit, including rail and other forms of mass transit;

(3) Cost, performance, environmental, energy, and safety data on alternative fuels and alternative fueled vehicles; and

(4) Other appropriate demographic information and consumer preferences.

(b) The Secretary shall consult with interested parties, including other appropriate Federal agencies, manufacturers, public utilities, owners and operators of fleets of light duty motor vehicles, and State or local governmental entities, to determine the types of data to be collected and analyzed under subsection (a).

Sec. 503. Replacement Fuel Demand Estimates and Supply Information

(a) Estimates—Not later than October 1, 1993, and annually thereafter, the Secretary, in consultation with the Administrator, the Secretary of Transportation, and other appropriate State and Federal officials, shall estimate for the following calendar year—

(1) The number of each type of alternative fueled vehicle likely to be in use in the United States;

(2) The probable geographic distribution of such vehicles;

(3) The amount and distribution of each type of replacement fuel; and

(4) The greenhouse gas emissions likely to result from replacement fuel use.

(b) Information—Beginning on October 1, 1994, the Secretary shall annually require—

(1) Fuel suppliers to report to the Secretary on the amount of each type of replacement fuel that such supplier—

(A) Has supplied in the previous calendar year; and

(B) Plans to supply for the following calendar year;

(2) Supplies of alternative fueled vehicles to report to the Secretary on the number of each type of alternative fueled vehicle that such supplier—

(A) Has made available in the previous calendar year; and

(B) Plans to make available for the following calendar year; and

(3) Such fuel suppliers to provide the Secretary information necessary to determine the greenhouse gas emissions from the replacement fuels used, taking into account the entire fuel cycle.

(c) Protection of Information—Information provided to the Secretary under subsection (b) shall be subjected to applicable provisions of law protecting the confidentiality of trade secrets and business and financial information, including section 1905 of title 18, United States Code.

III. Current Actions: Request for Comments

In addition to general comments or suggestions, we are asking for the views of interested parties on the following specific questions. The questions are arranged in numeric groups (1 through 17), generally corresponding to specific items in EPACT sections 407 and 503, the texts of which are shown above in part II. We ask that respondents number their responses in the same order. This will facilitate EIA's evaluation of the comments to this notice.

Further, this notice requests that interested parties who wish to become more involved in this ongoing process provide suggestions as to the most efficient means for EIA to interact with them, e.g., large user meetings, **Federal Register** notices, electronic mail, focus groups.

Questions related to section 407

1. Section 407(a).

a. As a statistical agency, EIA generally collects and publishes data in accordance with established geographic areas, such as Census regions or Census divisions. Are these geographic areas appropriate for the collections and projections involved here? Are other types of regions more appropriate? If so, identify them and explain why.

b. Should the Clean Air Act non-attainment areas be included in the regions from which data are either collected or disseminated? (The definition of these regions is not yet stable.) Is there any specific need for EIA to conduct data collections specifically in any of these regions?

2. Section 407(a) requires that EIA establish a data collection and projection program, but does not stipulate the frequency for such a program.

a. Should these be ongoing data collection programs with small samples or a larger data collection undertaken less frequently?

b. Should data for all vehicle types (i.e., cars, light-, medium-, and heavy-duty trucks) be collected with equal frequency, or should data for some vehicle types be collected more frequently than for others?

c. At what level of detail are AFV projections needed (e.g., are separate projections needed for various types of electric vehicles ranging from battery technology vehicles to various types of electric hybrid vehicles)?

d. Considering the possible seasonal variability of trip data for different sectors, regions, and vehicle types, is it necessary to collect data on trips for a full year or would a shorter time period be sufficient?

3. Since the government already collects limited data on residential, nonresidential, and business motor vehicles, including cars, light-, medium-, and heavy-duty trucks, and buses, EIA is investigating the following data systems with respect to their usefulness in developing the data collection needs of Section 407(a):

The Residential Transportation Energy Consumption Survey (EIA),

The Nationwide Personal Transportation Survey (Department of Transportation),

Census of Transportation: Truck Inventory and Use Survey (Census Bureau), and

Nationwide Truck Activity Survey (Formerly the Nationwide Truck Activity & Commodity Survey) (Department of Transportation & Census Bureau).

EIA is interested in obtaining information about other motor vehicle surveys, data collections, sampling frames, and/or marketing surveys which

could be utilized in the development of the data collection system, or as a component of the system. Also, EIA is interested in opinions concerning how well these other systems serve, or how they could best be adapted to serve, the data needs of this section.

4. Section 407(a)(1).

a. What is the appropriate definition of "trip"? Is origin/destination, mileage, and purpose sufficient, or is more detail required on the component parts of an individual trip? For instance, are commuting patterns required for residential vehicles versus nonresidential vehicles?

b. Area different levels of trip detail necessary for different types of motor vehicles?

c. Is different or more detailed information on trip patterns necessary for dual fueled vehicles?

d. Are different kinds of information required for fleet vehicles versus businesses with single vehicles?

e. What level of accuracy is required for the trip data (i.e., is it necessary to obtain detailed information from trip logs, or are best guess estimates sufficient)?

f. Is there a need to link fuel consumption information to various types of trips?

g. Is information on fuel consumption and expenditures necessary for all types of vehicles by consuming sectors, e.g., business, households, government?

h. Should data on government vehicles collected elsewhere be included in the data collection system?

5. Section 407(a)(2).

a. What information is available on regional historical trends in mass transit use or on projections of mass transit developments by local governments or regional planning commissions?

b. (1) Are EIA's current plans to make projections for the Nation and the nine Census divisions sufficient? (2) Should such projections be made more detailed? If not, should they be less detailed?

c. What is the appropriate periodicity of such a data collection and projection program: annual, biennial, triennial, or some other period?

6. Section 407(a)(3).

a. What cost data need to be collected: initial construction cost, initial purchase price and price certainty, tax implications associated with ATF and AFV, road taxes, routine operational costs, routine and unusual maintenance costs, aspects and characteristics which deal with rebates, availability of parts, resale/residual/salvage value, warranties, insurance, cost of time lost due to ATF or AFV use, and lifetime cost to the purchaser?

b. (1) What performance data need to be collected: miles per unit cost of the fuel, engine, drive train and battery lifetimes, emissions, acceleration in traffic, power when climbing hills, ease of starting, and/or travel range? (2) How is performance to be measured and reported? (3) Should the term "performance" refer to the technical and economic aspects of an AFV, including reliability, maintainability, duration of engine life, changes in emissions over time and use, fuel handling, and safety of all aspects of the AFV and ATF and their associated infrastructures? (4) Should calibration of technical performance be included?

c. (1) Which environmental data need to be collected: noxious or annoying smells, criteria pollutant and greenhouse gas emissions, emissions into water and onto the ground, and/or effects on the environment from routine construction and unusual occurrences? (2) How far back in the fuel cycle are environmental data needed? (3) Which specific environmental data are to be included?

d. What safety data need to be collected: toxic or hazardous materials associated with ATF and AFV, accident reports, and/or fuel distribution constraints (e.g., fuel trucks traveling through tunnels)?

e. What energy data need to be collected: Btu per refueling, resources needed to assure uninterrupted fuel supplies, total Btu required to construct each AFV, and/or offsets to petroleum-based energy resources?

f. EIA's responsibility in Section 407(a)(3) is to establish a data collection program for existing U.S. motor vehicles using alternative fuels. Should the information requirement of this section be limited to vehicle fleets, or should the requirements extend to those alternative fueled and privately owned vehicles to be used for personal travel, commuting, or recreational travel as in Section 503(a)(1)?

g. Since Section 407(a)(2) requires the projections to represent the most likely combination of AFV use and other forms of transit, including rail and other forms of mass transit, should the baseline data for the projections include the collection of rail and other mass transit data according to the requirements of Section 407(a)(3)?

7. Section 407(a)(4).

a. Please provide information on individuals and organizations who have undertaken research and data collections with respect to consumer preferences for different types and attributes of motor vehicles.

b. Do consumer preference data need to be linked to the trip information, or is it acceptable for the data to be obtained independently?

c. Is it sufficient to obtain the consumer preference information from limited groups of individuals through marketing type surveys or focus groups; or, is it necessary to obtain the data through statistical surveys?

d. What specific consumer preference data are needed for each type of motor vehicle?

e. What specific demographic data are needed for each type of motor vehicle owner or fleet owner or operator?

8. EIA needs to know more about the nonresidential vehicle fleet population. Little uniform, comprehensive data are available on the organization, descriptive characteristics, and operating practices of this "critical" population and the vehicles it encompasses. Because much of the initial penetration of ATF and AFV is envisioned to occur within fleets, it is important to understand the characteristics of vehicle fleets and how they will affect the use of AFV and their fuel sources. We would like to obtain information or suggestions on the following:

a. Whether data related to fleets are, in fact, a consideration for interested individuals;

b. Data sets that may exist on fleets of business vehicles;

c. The feasibility of utilizing state vehicle registration data to identify "fleets" of business vehicles;

d. Problems and issues related to identifying "central fueling capability" of fleets of vehicles from State vehicular registration data or other data sources;

e. Information and advice from companies, associations, governments, or individuals with vehicle fleets about the legal registration of the vehicles, their respective operating territories, and garaging locations;

f. Availability of insurance data for identifying fleets of vehicles; and

g. Whether the data collection system should include information on fleets of rental cars; and if so, are the data presently available?

9. Information or comments are requested on the relationship between the data to be collected in section 407(a)(1), (3), and (4) and the projections to be made in item (2) of section 407(a) are also sought.

10. Section 407(b).

a. Who are the interested parties other than those explicitly set forth in section 407(b)?

b. What is the most efficient means of interacting with interested parties: large user meetings, **Federal Register** notices, newsletters, electronic mail, small focus group meetings, or other means?

Questions Related to Section 503

11. Section 503(a)(1).

a. Specific ways to identify and classify AFV types used for distinctly different functions,

b. Specific ways to identify and enumerate off-the-road AFV,

c. Specific ways to identify and enumerate vehicles which have been converted from petroleum-based fuels to replacement fuels, and

d. Specific ways to identify and enumerate permanently out-of-service AFV.

12. Section 503(a)(2).

a. As a statistical agency, the EIA generally collects and publishes data in accordance with established geographic areas such as Census regions or Census divisions. Are these geographic areas appropriate for the collections and projections or are other regions required? If other regions are required, what are they?

b. Should the data collection(s) have the capability of providing national level estimates; or are regional data collections sufficient for potential data users?

13. Section 503(a)(3).

a. Can you identify specific ways to estimate the quantities of replacement fuels used for transportation (especially as the fuels may have other uses)?

b. (1) Should the regions specified for Section 503(a)(2) be the same as for section 503(a)(3)? (2) Should these regions be consistent with the regions used for section 407?

c. Should the data collection(s) have the capability of providing national level estimates; or are regional data collections sufficient for potential data users?

d. Should "replacement fuels" in this section be interpreted as applying equally to all fuels defined in section 301(14)?

14. Section 503(a)(4).

a. Which greenhouse gas emissions should be estimated?

b. Should the resulting emissions include the associated net displacement of the fossil fuel emissions?

c. In what units of measurement should these emissions be reported (e.g., grams per vehicle mile)?

15. Section 503(b)(1).

a. Do fuel suppliers possess these data?

b. Can you provide specific ways to identify fuels which have been consumed by vehicles with a fuel-switching capability?

16. Section 503(b)(2).

a. Specific ways to identify the suppliers of AFV,

b. Specific ways to identify AFV which have been converted from petroleum-based fuels to replacement fuels, and

c. Specific ways to identify AFV which are retired from use.

17. Section 503(b)(3).

a. Do fuel suppliers possess data on these gases?

b. Should some of the data requirements be addressed to the vehicle suppliers?

c. Are estimates of selected greenhouse gas emissions sufficient for interested parties?

d. (1) Should the entire fuel cycle include just the combustion cycle, or should it begin where fuel supplies and raw materials are mined? (2) Does the entire fuel cycle for biofuels include emissions from fertilizers and fuel used in producing the biofuels? (3) Should the fuel processing, distribution, storage, and handling stages be considered?

IV. Future Actions

After EIA has carefully evaluated responses to this notice, it will then lay out a sequence of steps that it proposes to follow regarding this ongoing effort. These steps will be published in a subsequent **Federal Register** notice. Topics will be added, revised, or deleted as EIA, in consultation with interested parties, further defines its data needs and user requirements.

Currently envisioned activities included developing a mailing list of interested parties, preparing for meetings with interested parties, developing a set of alternative data collection strategies for review by the interested parties, and evaluating surveys and special studies that could provide relevant data or be used as a host vehicle for collecting data for Section 407. Where existing data collections are to be used, meetings will be held with the data collectors concerning the potential of adding items to existing data collection programs or changing their methodology to better meet user needs. Where new data collections are to be established, a series of pretests will be undertaken, to examine possible survey procedures and questionnaire formats. Based upon comments provided by interested users and respondents, EIA will develop a data acquisition program, test survey procedures and questionnaires, revising them as necessary, prior to implementation.

Comments (excluding those comments DOE determines are confidential) submitted in response to this notice may be included in future requests for approval by the Office of Management and Budget of resultant information collections and will become a matter of public record.

Statutory Authorities: Section 2(a) of the Paperwork Reduction Act of 1980, (Pub. L. 96–511,) which amended chapter 35 of title 44 United States Code (44 U.S.C. 3506(a)).

Issued in Washington, DC, April 28, 1993.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–10502 Filed 5–3–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. QF87–59–007]

Panther Creek Partners; Amendment to Filing

April 28, 1993.

On April 23, 1993, Panther Creek Partners tendered for filing a supplement to its filing in this docket.

The supplement pertains to the ownership structure, contractual and technical aspects of its small power production facility. No determination has been made that the submittal constitutes a complete filing.

Any person desiring to be heard or objecting to the granting of qualifying status should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed by May 17, 1993, and must be served on the applicant. 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.

Lois D. Cashell,

Secretary.

[FR Doc. 93–10415 Filed 5–3–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–307–000]

El Paso Natural Gas Co.; Request Under Blanket Authorization

April 28, 1993.

Take notice that on April 20, 1993, El Paso Natural Gas Company (El Paso), Post Office Box 1492, El Paso, Texas, 79978, filed a request for authorization at Docket No. CP93–307–000, pursuant

to §§ 157.205 and 157.216(b) of the Commission's Regulations under the Natural Gas Act, to abandon a 14.6 mile segment of pipeline, three delivery taps, and the related service, all as more fully set forth in the request for authorization on file with the Commission and open for public inspection.

The request for authorization states that by order issued May 31, 1946, at Docket No. G–655 the Commission granted El Paso authorization to construct and operate, among other thing, its Fullerton Line, El Paso avers that subsequent to construction of the Fullerton Line, El Paso installed the A.J. Blevins, H.O. Sims, and SOHOI Oil Co. Taps on that pipeline. El Paso received authority to continue to the sale of gas for resale and the operation of these taps at Docket No. CP69–23–000.

El Paso notes a 14.6 mile portion of the Fullerton Line, is essentially a "dead leg" in El Paso's interstate system; it was utilized to transport only 27 Mcf in the aggregate from January through February, 1992, to the A.J. Blevins Tap (Domestic end-user), and only 180 Mcf in the aggregate from January through March, 1992 to the H.O. Sims Tap (domestic end-user). No deliveries have been made to SOHIO Oil Co. Tap since 1978. El Paso provides no other interstate transmission services on this segment of the Fullerton Line. As a result, El Paso believes that the continued operation and maintenance of this portion of the Fullerton Line is no longer in the public interest and proposed to abandon this 14.6 mile segment.

El Paso states that based on the alternative service arrangements made by the end-user customers served by the A.J. Blevins and H.O. Sims Taps, and the lack of a gas service requirement at the SOHIO Oil Co. Tap, these three (3) tap facilities and the 14.6 mile segment of the Fullerton Line are no longer required and should be abandoned from natural gas service.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–10416 Filed 5–3–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER93–563–000]

Massachusetts Electric Co.; Filing

April 23, 1993.

Take notice that on April 14, 1993, Massachusetts Electric Company (MECo) tendered for filing a Notice of Partial Termination for the Service Agreement for Borderline Sales, dated July 9, 1992, between MECo and Western Massachusetts Electric Company.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before May 7, 1993. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–10419 Filed 5–3–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–304–000]

Northern Natural Gas Co.; Application

April 28, 1993.

Take notice that on April 16, 1993, Northern Natural Gas Company, (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP93–304–000, an application pursuant to section 7(b) of the Natural Gas Act and part 157 of the Commission's Regulations thereunder (18 CFR 157.7 and 157.18), for permission and approval to abandon seven compressor units in Roger Mills County, Oklahoma and Carson County, Texas all as more fully set forth in its application which is on file with the Commission and open to public inspection.

It is stated that Northern proposes to abandon the following facilities:

1. The Roger Mills County #2 Compressor Station consisting of one 3,750 HP turbine compressor which was installed in 1986 pursuant to Northern's blanket certificate approved by order issued September 1, 1982 in Docket No. CP82–401. Northern maintains that as volumes produced from various fields have declined due to depletion of field reservoirs and the associated lower wellhead pressures, thus reducing the throughput at this station from 270 MMCf/d to 40 MMCf/d.

2. The Skellytown Compressor Station consisting of six compressor unity. It is maintained that three units were installed in 1931, one unit installed in 1936, one unit installed in 1943, certificated by an order issued on April 6, 1943 in docket No. G–280, and one unit installed in 1944 pursuant to an order issued on October 26, 1943, in Docket No. G–465. It is asserted that gas volumes produced from these fields have declined due to a normal process of depletion without any new wells connected, thus reducing throughput of this station from 40 MMCf/d at peak production to 9.1 MMCf/d currently.

Northern also maintains that these units proposed to be abandoned have not been utilized for some time because compression has not been needed to maintain deliveries. Northern believes that the abandonment of these units would not result in abandonment of service to any of Northern's existing customers or producers, nor would the proposed abandonment adversely affect capacity since this compression is no longer needed to receive the remaining supply available.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 19, 1993, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (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 motion 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 Energy Regulatory Commission by sections 7 and 15 of the NGA and the Commission's Rules of Practice and

Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion 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 Northern to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 93-10418 Filed 5-3-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER93-572-000]

Northern States Power Co. (MN), Northern States Power Co. (WI), Filing

April 23, 1993.

Take notice that on April 16, 1993, Northern States Power Company (Minnesota) and Northern States Power Company (Wisconsin) (jointly "NSP Companies") tendered for filing certain Transmission Service Agreements entered into by the NSP Companies pursuant to the NSP Companies FERC Electric Tariff Original Volume No. 1.

The NSP Companies request acceptance for filing of one standard form Transmission Service Agreements under the Original Tariff with Interstate Power Company effective May 1, 1993. The NSP Companies request acceptance for filing of a standard form Transmission Service Agreements under the Settlement Tariff with Wisconsin Public Service Corporation effective April 19, 1993. The NSP Companies request any waiver necessary to allow the agreements to be accepted for filing on the dates requested.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before May 7, 1993. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-10420 Filed 5-3-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP93-308-000]

Texas Eastern Transmission Corp.; Application

April 28, 1993.

Take notice that on April 21, 1993, Texas Eastern Transmission Corporation (Texas Eastern) P.O. Box 1642, Houston, Texas 77251-1642, filed in Docket No. CP93-308-000 pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon a firm sales service and an interruptible sales service for Arkansas Louisiana Gas Company (Arkla) under Texas Eastern's Rate Schedules SGS-B and I-B, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Texas Eastern indicates that the transportation services are no longer desired by the relative parties and that the termination of the respective services would relieve both parties from the contractual obligations of such agreements.

Texas Eastern also contends that there will be no abandonment of facilities nor will the abandonment of the service proposed herein result in any abandonment of service to its other customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 19, 1993, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) 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 motion 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 Energy Regulatory 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 or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion 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 Texas Eastern to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 93-10417 Filed 5-3-93; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4651-6]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before June 3, 1993.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 260-2740.

SUPPLEMENTARY INFORMATION:

Office of Air and Radiation

Title: Lead Additive Report for Refineries and Importers; Lead Additive Report for Manufacturing Facility or Site (EPA ICR #232.06; OMB #2060-0066). This ICR requests renewal of the existing clearance.

Abstract: Gasoline refineries and importers must submit quarterly reports to EPA on their lead usage and gasoline production. Lead additive manufacturers must report to EPA their quarterly sales of lead to refineries. EPA

uses the information to verify compliance with regulations which, for health reasons, limit lead content in gasoline.

Burden Statement: Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information.

Respondents: Refineries, gasoline importers, and lead additive manufacturers.

Estimated Number of Respondents: 448.

Estimated Total Annual Burden on Respondents: 986 hours.

Frequency of Collection: Quarterly.

Send comments regarding the burden estimate, or any other aspect of this information collection, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223Y), 401 M Street SW., Washington, DC 20460

and

Troy Hillier, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20530.

Dated: April 28, 1993.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 93-10477 Filed 5-3-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4625-9]

Transfer of Data to Contractors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intended transfer of confidential business information to contractors.

SUMMARY: EPA intends to transfer confidential business information (CBI) collected from the pulp, paper, and paperboard manufacturing industry to two contractors. Transfer of the information will allow the contractors to assist EPA in developing regulations under the Clean Water Act and the Clean Air Act for the pulp, paper, and paperboard manufacturing industry. The information being transferred was collected under authority of section 308 of the Clean Water Act, section 114 of the Clean Air Act, and section 3007 of the Resource Conservation and Recovery Act. Interested persons may submit comments on this intended transfer of information to the address shown below.

DATES: Comments on the transfer of data are due May 14, 1993.

ADDRESSES: Comments may be sent to Marion Thompson, Engineering and Analysis Division (WH-552), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Marion Thompson, Engineering and Analysis Division (WH-552), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 260-7117.

SUPPLEMENTARY INFORMATION: EPA has previously transferred to a subcontractor, Eastern Research Group of Arlington, Massachusetts, information, including confidential business information (CBI), concerning the pulp, paper, and paperboard industry. The information was collected under authority of section 308 of the Clean Water Act, section 114 of the Clean Air Act, and section 3007 of the Resource Conservation and Recovery Act.

The information transferred includes questionnaire data requested by EPA in 1990 and provided in 1990, 1991, 1992, and 1993. The transferred data includes economic and financial information about the companies that EPA will analyze during development of revised regulations. EPA collected information on assets, liabilities, revenues, and expenses. EPA also collected information about individual product categories, including production quantities, shipments, and values. Many companies claimed that their responses should be considered confidential business information.

EPA determined that this transfer was necessary to enable the subcontractor to perform its work under EPA Contract No. 68-C0-0080 and to assist EPA in developing economic impact analyses that support effluent limitations guidelines and standards and maximum achievable control technology standards for the pulp, paper, and paperboard industry. Notice to this effect was provided in the **Federal Register** on February 5, 1993 (58 FR 7225). That subcontract expired at the end of February 1993.

Today, EPA is giving notice that it has entered into an additional contract, No. 68-C3-0302, with Eastern Research Group, Inc. of Arlington, Massachusetts, to assist EPA in developing economic impact analysis. Eastern Research Group will provide support for economic analysis and for questionnaire data analysis. EPA intends to maintain Eastern Research Group's access to information, including CBI, that has already been transferred. EPA also intends to transfer to Eastern Research Group information to be collected in the future to support the economic analysis for the regulations of the pulp, paper, and paperboard industry.

EPA also previously transferred to another contractor, Tetra Tech, Inc., of Fairfax, Virginia, information, including confidential business information, concerning the pulp, paper, and paperboard industry. The information transferred to Tetra Tech includes pollutant discharge and self-monitoring data. Many companies claimed that this information, which was provided in questionnaires, should be considered confidential business information. The information transferred also includes identification of companies by their locations and by confidential identification codes that link discharge data and compliance cost estimates.

EPA determined that this transfer was necessary to enable the contractor to perform its work under EPA Contract Nos. 68-C9-0013 and 68-C1-0008 and to assist EPA in developing environmental assessments and regulatory impact analyses that support effluent limitations guidelines and standards and maximum achievable control technology standards for the pulp, paper, and paperboard industry. Notice to this effect was provided to the affected companies at the time the information was collected. The previously-noticed contract expired in February 1993.

Today, EPA is giving notice that it has entered into an additional contract, No. 68-C3-0303, with Tetra Tech, Inc. of Fairfax, Virginia to assist EPA in developing environmental assessments and regulatory impact analyses. EPA intends to maintain Tetra Tech's access to information, including CBI, that has already been transferred. EPA also intends to transfer to Tetra Tech information to be collected in the future to support the environmental assessment and regulatory impact analysis for the regulations of the pulp, paper, and paperboard industry.

Today, EPA also give notice of its intent to transfer confidential business information concerning the pulp, paper, and paperboard industry to another contractor. EPA has entered into a contract, No. 68-C0-0080, with Abt Associates, Inc., of Cambridge, Massachusetts, and Abt Associates, Inc. has entered into an additional contract with its subcontractor RCG/Hagler, Bailly of Boulder, Colorado to assist EPA in developing a benefits assessment and a regulatory impact analysis. EPA has determined that transfer of confidential business information to RCG/Hagler, Bailly is necessary to

enable the subcontractor to perform its work under Contract No. 68–C0–0080. The information to be transferred includes identification of companies by their locations and by confidential identification coeds to link discharge data and compliance costs estimates. Further, to the extent that Abt Associates, Inc. must review information, including CBI, to perform their work as prime contractor, EPA intends to transfer information, including CBI, to Abt Associates, Inc.

In accordance with 40 CFR part 2, subpart B, the previously collected information and information that may be collected in the future to support development of regulations for the pulp, paper, and paperboard industry will be transferred to Eastern Research Group and to Tetra Tech. The contractors are given access only to the data that they need to perform their assignments under their contracts. EPA has determined that these transfers are necessary to enable the contractors to perform their work under EPA Contract Nos. 68–C3–0302, 68–C3–0303, and 68–C0–0080.

Dated: April 27, 1993.

James Hanlon,

Acting Director, Office of Science and Technology.

[FR Doc. 93–10424 Filed 5–3–93; 8:45 am]

BILLING CODE 6560–50–P

[FRL–4651–5]

Kentucky: Adequacy Determination of State/Tribal Municipal Solid Waste Permit Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of tentative determination to fully approve the adequacy of the Commonwealth of Kentucky's municipal solid waste permitting program, public hearing and public comment period.

SUMMARY: Section 4005(c)(1)(B) of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984, requires States to develop and implement permit programs to ensure that municipal solid waste landfills (MSWLFs) which may receive hazardous household waste or small quantity generator waste will comply with the revised Federal MSWLF Criteria (40 CFR part 258). RCRA section 4005(c)(1)(C) requires the Environmental Protection Agency (EPA) to determine whether States have adequate "permit" programs for MSWLFs, but does not mandate issuance of a rule for such determinations. EPA has drafted and is in the process of proposing a State/Tribal Implementation Rule (STIR) that will provide procedures by which EPA will approve, or partially approve, State/Tribal landfill permit programs. The Agency intends to approve adequate State/Tribal MSWLF permit programs as applications are submitted. Thus, these approvals are not dependent on final promulgation of the STIR. Prior to promulgation of STIR, adequacy determinations will be made based on the statutory authorities and requirements. In addition, States/Tribes may use the draft STIR as an aid in interpreting these requirements. The Agency believes that early approvals have an important benefit. Approved State/Tribe permit programs provide for interaction between the State/Tribe and the owner/operator regarding site-specific permit conditions. Only those owners/operators located in State/Tribes with approved permit programs can use the site-specific flexibility provided by part 258 to the extent the State/Tribal permit program allows such flexibility. EPA notes that regardless of the approval status of a State/Tribe and the permit status of any facility, the federal landfill criteria will apply to all permitted and unpermitted MSWLF facilities.

Kentucky has applied for a determination of adequacy under section 4005 of RCRA. The EPA Region IV has reviewed Kentucky's MSWLF application and has made a tentative determination that Kentucky's MSWLF permit program meets the requirements for full program approval and ensures compliance with the revised MSWLF Criteria. Kentucky's application for program adequacy determination is available from EPA Region IV and the State for public review and comment. Although RCRA does not require EPA to hold a public hearing on a determination to approve any State/Tribe's MSWLF program, the Region has scheduled a public hearing on this determination on the date given below in the **DATES** section.

DATES: All comments on Kentucky's application for a determination of adequacy must be received by the close of the public hearing which will be held on June 24, 1993, at 7:30 p.m., at the Capital Plaza Tower, Ground Floor Auditorium, 500 Mero Street, Frankfort, Kentucky. The State will participate in the public hearing held by the EPA.

ADDRESSES: Copies of Kentucky's application for adequacy determination are available during the hours of 8 a.m. to 5 p.m. at the following addresses for inspection and copying: Kentucky Department of Environmental Protection, Fort Boone Plaza, 14 Reilly Road, Frankfort, Kentucky 40601, Attn: Ms. Caroline P. Haight, telephone 502–564–6716; and U.S. EPA Region IV Library, 345 Courtland Street NE., Atlanta, Georgia, 30365, Attn: Ms. Priscilla Pride, telephone 404–347–4216. Written comments should be submitted to Ms. Patricia S. Zweig, mail code 4WD–RCRA, EPA Region IV, Office of Solid Waste, 345 Courtland Street NE., Atlanta, Georgia.

FOR FURTHER INFORMATION CONTACT: EPA Region IV, 345 Courtland Street NE., Atlanta, Georgia 30365, Attn: Ms. Patricia S. Zweig, mail code 4WD-RCRA, telephone 404–347–2091.

SUPPLEMENTARY INFORMATION:

A. Background

On October 9, 1991, EPA promulgated revised Criteria for MSWLFs (40 CFR part 258). Subtitle D of RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), requires States to develop permitting programs to ensure that MSWLFs comply with the Federal Criteria under part 258. Subtitle D also requires in section 4005 that EPA determine the adequacy of State municipal solid waste landfill permit programs to ensure that facilities comply with the revised Federal Criteria. To fulfill this requirement, the Agency has drafted and is in the process of proposing a State/Tribal Implementation Rule (STIR). The rule will specify the requirements which State/Tribal programs must satisfy to be determined adequate.

The EPA intends to approve State/Tribal MSWLF permit programs prior to the promulgation of STIR. EPA interprets the requirements for States or Tribes to develop "adequate" programs for permits or other forms of prior approval to impose several minimum requirements. First, each State/Tribe must have enforceable standards for new and existing MSWLFs that are technically comparable to EPA's revised MSWLF criteria. Next, the State/Tribe must have the authority to issue a permit or other notice of prior approval to all new and existing MSWLFs in its jurisdiction. The State/Tribe also must provide for public participation in permit issuance and enforcement as required in section 7004(b) of RCRA. Finally, EPA believes that the State/Tribe must show that it has sufficient compliance monitoring and enforcement authorities to take specific action against any owner or operator that fails to comply with an approved MSWLF program.

The EPA Region IV will determine whether a State/Tribe has submitted an "Adequate" program based on the interpretation outlined above. EPA plans to provide more specific criteria for this evaluation when it proposes the State/Tribal Implementation Rule. EPA expects States/Tribes to meet all of these requirements for all elements of a MSWLF program before it gives full approval to a MSWLF program.

B. State of Kentucky

On February 14, 1992, the EPA, Region IV received Kentucky's final MSWLF permit program application for adequacy determination. Region IV reviewed the final application and submitted comments to Kentucky. Kentucky addressed EPA's comments and submitted a revised final application for adequacy determination on February 12, 1993. Region IV has reviewed Kentucky's revised application and has tentatively determined that all portions of Kentucky's Subtitle D program meet all the requirements necessary to qualify for full program approval and ensures compliance with the revised Federal Criteria.

The public may submit written comments on EPA's tentative determination until June 24, 1993, the date of the public hearing. Copies of Kentucky's application are available for inspection and copying at the location indicated in the **ADDRESSES** section of this notice. Comments may be submitted as transcribed from the discussion of the hearing or in writing at the time of the hearing.

Kentucky will be using alternative, but equally effective methods, to ensure that provisions which are technically comparable to the revised federal criteria are being applied in Kentucky. To ensure compliance with all of the revised Federal Criteria, Kentucky will implement the following areas of its MSWLF permit program through enforceable permit conditions.

1. Kentucky will require as a permit condition that the owner/operator of all MSWLFs will include in its detection monitoring program, the full list of Appendix I constituents as specified in 40 CFR 258.54(a). This permit condition will be effective on or before October 9, 1993. Kentucky will use the criteria as specified in 40 CFR 258.53(g) for determining the adequacy of statistical methods. Kentucky will include the statistical methods criteria in the permit application for all MSWLFs effective on or before October 9, 1993.

2. Kentucky will include as a permit condition, effective on or before October 9, 1993, the requirement that all MSWLFs must meet the performance standard for the final cover criteria as specified in § 258.60(a)(1).

3. Kentucky will include as a permit condition, effective on or before October 9, 1993, the requirements of 40 CFR 258.73, that all MSWLFs required to implement a corrective action program will provide financial assurance for any necessary corrective action. Under the authority of Kentucky House Bill 839, the state has the ability to utilize and enforce any of the financial assurance mechanisms promulgated pursuant to 40 CFR 258.73.

Full approval for Kentucky's MSWLF permit program is based in part upon the implementation of the above mentioned permit conditions on or before October 9, 1993. The implementation of the permit conditions will ensure compliance with the revised Federal Criteria.

EPA will consider all public comments received on its tentative determination during the public comment period and during the public hearing. Issues raised by those comments may be the basis for a determination of inadequacy for Kentucky's program. EPA will make a final decision on whether or not to approve Kentucky's program by August 1, 1993 and will give notice of it in the **Federal Register**. The notice will include a summary of the reasons for the final determination and a response to all major comments.

Section 4005(a) of RCRA provides that citizens may use the citizen suit provisions of section 7002 of RCRA to enforce the Federal MSWLF criteria in 40 CFR part 258 independent of any State/Tribal enforcement program. As EPA explained in the preamble to the final MSWLF criteria, EPA expects that any owner or operator complying with provisions in a State/Tribal program approved by EPA should be considered to be in compliance with the Federal Criteria. See 56 FR 50978, 50995 (October 9, 1991).

Compliance with Executive Order 12291

The Office of Management and Budget has exempted this notice from the requirements of Section 3 of Executive Order 12291.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant economic impact on a substantial number of small entities. It does not impose any new burdens on small entities. This notice, therefore, does not require a regulatory flexibility analysis.

Authority: This notice is issued under the authority of section 4005 of the Solid Waste Disposal Act as amended; 42 U.S.C. 6946.

Dated: April 26, 1993.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 93-10478 Filed 5-3-93; 8:45 am]

BILLING CODE 6560-50-P-M

[OPPTS-59964; FRL-4585-1]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of November 11, 1984, (49 FR 46066) (40 CFR 723.250), EPA published a rule which granted a limited exemption from certain PMN requirements for certain types of polymers. Notices for such polymers are reviewed by EPA within 21 days of receipt. This notice announces receipt of 14 such PMN(s) and provides a summary of each.

DATES: Close of review periods:

Y 93-80, 93-81, 93-82, 93-83, 93-84, 93-85, 93-86, 93-87, April 14, 1993.

Y 93-88, 93-89, 93-90, April 18, 1993.

Y 93-91, 93-92, 93-93, April 20, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, rm. E-545, 401 M St., SW., Washington, DC, 20460 (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office, ETG-102 at the above address between 8 a.m. and noon and 1

p.m. and 4 p.m., Monday through Friday, excluding legal holidays.

Y 93-80

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-81

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-82

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-83

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-84

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-85

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-86

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automotive coatings. Prod. range: Confidential.

Y 93-87

Manufacturer. Confidential.
Chemical. (G) Amine salt of styrene acrylic copolymer.
Use/Production. (S) Pigment dispersing resin for automative coatings. Prod. range: Confidential.

Y 93-88

Manufacturer. Confidential.
Chemical. (G) Polyether/polyester urethane.
Use/Production. (G) Used in coatings for textiles applied by industrial manufactures. Prod. range: Confidential.

Y 93-89

Manufacturer. Confidential.
Chemical. (G) Soya-castor alkyl polymer.
Use/Production. (S) Used for a copolymer alkyd used in air-dry baking finishes. Prod. range: Confidential.

Y 93-90

Manufacturer. Confidential.
Chemical. (G) Polyester resin.
Use/Production. (S) Manufacture of powder goods. Prod. range: Confidential.

Y 93-91

Manufacturer. Confidential.
Chemical. (G) Unsaturated polyester polymer.
Use/Production. (S) Molding resin. Prod. range: Confidential.

Y 93-92

Importer. Toyobo America Inc..
Chemical. (G) Aromatic copolymer with 5-sulfo 1,3-benzenedicarboxylic acid monosodium salt and 2,2-dimethyl-3-hydroxypropyl-2,2-dimethyl-3-hydroxypropionate.
Use/Production. (S) Ink binder. Prod. range: Confidential.

Y 93-93

Manufacturer. Confidential.
Chemical. (G) Polyurethane polyol.
Use/Production. (G) Coating additive open, nondispersive use. Prod. range: Confidential.

Dated: April 21, 1993.

Frank V. Caesar,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 93-10479 Filed 5-3-93; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL MARITIME COMMISSION

Deppe/Lykes Reciprocal Space Charter and Coordinated Sailing et al.; Agreements Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 232-011253-002.
Title: Deppe/Lykes Reciprocal Space Charter and Coordinated Sailing Agreement
Parties:
Deppe Linie GmbH & Co.
Lykes Bros. Steamship Co., Inc.
Synopsis: The proposed amendment expands the geographic scope of the Agreement to include east coast Mexican ports. The parties have requested a shortened review period.

Agreement No.: 224-200763.
Title: Port of New York and New Jersey/American President Lines.
Parties:
The Port of New York and New Jersey ("Port")
American President Lines, Ltd. ("APL")
Synopsis: The Agreement provides that the Port will pay APL a container incentive of $20.00 for each import container and $40.00 for each export container moved through the Port's marine terminals during calendar year 1993, provided each container is shipped by rail to or from points more than 260 miles from the port.

Agreement No.: 224-200764.
Title: Port of New York and New Jersey/Sea-Land Service, Inc.
Parties:
The Port of New York and New Jersey ("Port")
Sea-Land Service, Inc. ("Sea-Land")
Synopsis: The Agreement provides that the Port will pay Sea-Land a container incentive of $20.00 for each import container and $40.00 for each export container moved through the Port's marine terminals during calendar year 1993, provided each container is shipped by rail to or from points more than 260 miles from the port.

Agreement No.: 224-200765.
Title: Port of New York and New Jersey/Nedlloyd Lines USA, Corp.
Parties:
The Port of New York and New Jersey ("Port")
Nedlloyd Lines USA, Corp. ("Nedlloyd")
Synopsis: The Agreement provides that the Port will pay Nedlloyd a container incentive of $20.00 for each import container and $40.00 for each

export container moved through the Port's marine terminals during calendar year 1993, provided each container is shipped by rail to or from points more than 260 miles from the port.

Dated: April 28, 1993.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93-10398 Filed 5-3-93; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of February 2-3, 1993

In accordance with § 271.5 of its rules regarding availability of information, there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on February 2-3, 1993.[1] The Directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting indicates that economic activity rose appreciably further in the fourth quarter. Total nonfarm payroll employment registered another small increase in December, and the civilian unemployment rate remained at 7.3 percent. Industrial production posted solid gains over the closing months of the year. Retail sales were up substantially in the fourth quarter, and residential construction activity increased sharply. Indicators of business fixed investment suggest a notable gain in recent months, particularly for producers' durable equipment. The nominal U.S. merchandise trade deficit narrowed slightly in October-November from its average rate in the third quarter. Recent data on wages and prices have been mixed but they continue to suggest on balance a trend toward lower inflation.

Interest rates have declined somewhat since the Committee meeting on December 22. In foreign exchange markets, the trade-weighted value of the dollar in terms of the other G-10 currencies rose on balance over the intermeeting period.

M2 appears to have contracted in December and January, after expanding at a moderate pace over the course of previous months; M3 is estimated to have declined appreciably in both months. From the fourth quarter of 1991 to the fourth quarter of 1992, both M2 and M3 grew at rates somewhat below the lower ends of the Committee's annual ranges for 1992. Total domestic nonfinancialdebt appears to have expanded at the lower end of the Committee's monitoring range for the year.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee at this meeting established ranges for growth of M2 and M3 of 2 to 6 percent and 1/2 to 4-1/2 percent respectively, measured from the fourth quarter of 1992 to the fourth quarter of 1993. The Committee expects that developments contributing to unusual velocity increases are likely to persist during the year. The monitoring range for growth of total domestic nonfinancial debt was set at 4-1/2 to 8-1/2 percent for the year. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks to maintain the existing degree of pressure on reserve positions. In the context of the Committee's long-run objectives for price stability and sustainable economic growth, and giving careful consideration to economic, financial, and monetary developments, slightly greater reserve restraint or slightly lesser reserve restraint would be acceptable in the intermeeting period. The contemplated reserve conditions are expected to the consistent with little change in M2 and M3 over the period from January to March.

By order of the Federal Open Market Committee, April 16,1993.

Normand Bernard,

Deputy Secretary, Federal Open Market Committee.

[FR Doc. 93-10434 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-F

[1] Copies of the Record of policy actions of the Committee for the meeting of February 2-3, 1993, are available upon request to The Board of Governors of the Federal Reserve System, Washington, DC 20551.

Federal Open Market Committee; Procedural Instructions With Respect to Foreign Currency Operations

Amended February 2, 1993.

In conducting operations pursuant to the authorization and direction of the Federal Open Market Committee as set forth in the Authorization for Foreign Currency Operations and the Foreign Currency Directive, the Federal Reserve Bank of New York, through the Manager of the System Open Market Account ("Manager"), shall be guided by the following procedural understandings with respect to consultations and clearance with the Committee, the Foreign Currency Subcommittee, and the Chairman of the Committee. All operations undertaken pursuant to such clearances shall be reported promptly to the Committee.

1. The Manager shall clear with the Subcommittee (or with the Chairman, if the Chairman believes that consultation with the Subcommittee is not feasible in the time available):

A. Any operation that would result in a change in the System's overall open position in foreign currencies exceeding $300 million on any day or $600 million since the most recent regular meeting of the Committee.

B. Any operation that would result in a change on any day in the System's net position in a single foreign currency exceeding $150 million, or $300 million when the operation is associated with repayment of swap drawings.

C. Any operation that might generate a substantial volume of trading in a particular currency by the System, even though the change in net position in that currency might be less than the limits specified in 1B.

D. Any swap drawing proposed by a foreign bank not exceeding the larger of (i) $200 million or (ii) 15 percent of the size of the swap arrangement.

2. The Manager shall clear with the Committee (or with the Subcommittee, if the Subcommittee believes that consultation with the full Committee is not feasible in the time available, or with the Chairman, if the Chairman believes that consultation with the Subcommittee is not feasible in the time available):

A. Any operation that would result in a change in the System's overall open position in foreign currencies exceeding $1.5 billion since the most recent regular meeting of the Committee.

B. Any swap drawing proposed by a foreign bank exceeding the larger of (i) $200 million or (ii) 15 percent of the size of the swap arrangement.

3. The Manager shall also consult with the Subcommittee or the Chairman about proposed swap drawings by the System, and about any operations that are not of a routine character.

Normand Bernard,

Deputy Secretary, Federal Open Market Committee.

[FR Doc. 93-10437 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-P

Federal Open Market Committee; Authorization for Foreign Currency Operations; Amended February 2, 1993

1. The Federal Open Market Committee authorizes and directs the Federal Reserve Bank of New York, for System Open Market Account, to the extent necessary to carry out the Committee's foreign currency directive and express authorizations by the Committee pursuant thereto, and in conformity with such procedural instructions as the Committee may issue from time to time:

A. To purchase and sell the following foreign currencies in the form of cable transfers through spot or forward transactions on the open market at home and abroad, including transactions with the U.S. Treasury, with the U.S.

Exchange Stabilization Fund established by Section 10 of the Gold Reserve Act of 1934, with foreign monetary authorities, with the Bank for International Settlements, and with other international financial institutions:

Austrian schillings
Belgian francs
Canadian dollars
Danish kroner
Pounds sterling
French francs
German marks
Italian lire
Japanese yen
Mexican pesos
Netherlands guilders
Norwegian kroner
Swedish kronor
Swiss francs

B. To hold balances of, and to have outstanding forward contracts to receive or to deliver, the foreign currencies listed in paragraph A above.

C. To draw foreign currencies and to permit foreign banks to draw dollars under the reciprocal currency arrangements listed in paragraph 2 below, provided that drawings by either party to any such arrangement shall be fully liquidated within 12 months after any amount outstanding at that time was first drawn, unless the Committee, because of exceptional circumstances, specifically authorizes a delay.

D. To maintain an overall open position in all foreign currencies not exceeding $25.0 billion. For this purpose, the overall open position in all foreign currencies is defined as the sum (disregarding signs) of net positions in individual currencies. The net position in a single foreign currency is defined as holdings of balances in that currency, plus outstanding contracts for future receipt, minus outstanding contracts for future delivery of that currency, i.e., as the sum of these elements with due regard to sign.

2. The Federal Open Market Committee directs the Federal Reserve Bank of New York to maintain reciprocal currency arrangements ("swap" arrangements) for the System Open Market Account for periods up to a maximum of 12 months with the following foreign banks, which are among those designated by the Board of Governors of the Federal Reserve System under Section 214.5 of Regulation N, Relations with Foreign Banks and Bankers, and with the approval of the Committee to renew such arrangements on maturity:

Foreign bank	Amount of arrangement (millions of dollars equivalent)
Austrian National Bank	250
National Bank of Belgium	1,000
Bank of Canada	2,000
National Bank of Denmark	250
Bank of England	3,000
Bank of France	2,000
German Federal Bank	6,000
Bank of Italy	3,000
Bank of Japan	5,000
Bank of Mexico	700
Netherlands Bank	500
Bank of Norway	250
Bank of Sweden	300
Swiss National Bank	4,000
Bank for International Settlements:	
Dollars against Swiss francs	600
Dollars against authorized European currencies other than Swiss francs	1,250

Any changes in the terms of existing swap arrangements, and the proposed terms of any new arrangements that may be authorized, shall be referred for review and approval to the Committee.

3. All transactions in foreign currencies undertaken under paragraph I(A) above shall, unless otherwise expressly authorized by the Committee, be at prevailing market rates. For the purpose of providing an investment return on System holdings of foreign currencies, or for the purpose of adjusting interest rates paid or received in connection with swap drawings, transactions with foreign central banks may be undertaken at non-market exchange rates.

4. It shall be the normal practice to arrange with foreign central banks for the coordination of foreign currency transactions. In making operating arrangements with foreign central banks on System holdings of foreign currencies, the Federal Reserve Bank of New York shall not commit itself to maintain any specific balance, unless authorized by the Federal Open Market Committee. Any agreements or understandings concerning the administration of the accounts maintained by the Federal Reserve Bank of New York with the foreign banks designated by the Board of Governors under Section 214.5 of Regulation N shall be referred for review and approval to the Committee.

5. Foreign currency holdings shall be invested insofar as practicable, considering needs for minimum working balances. Such investments shall be in liquid form, and generally have no more than 12 months remaining to maturity. When appropriate in connection with arrangements to provide investment facilities for foreign currency holdings, U.S. Government securities may be purchased from foreign central banks under agreements for repurchase of such securities within 30 calendar days.

6. All operations undertaken pursuant to the preceding paragraphs shall be reported promptly to the Foreign Currency Subcommittee and the Committee. The Foreign Currency Subcommittee consists of the Chairman and Vice Chairman of the Committee, the Vice Chairman of the Board of Governors, and such other member of the Board as the Chairman may designate (or in the absence of members of the Board serving on the Subcommittee, other Board Members designated by the Chairman as alternates, and in the absence of the Vice Chairman of the Committee, his alternate). Meetings of the Subcommittee shall be called at the request of any member, or at the request of the Manager of the System Open Market Account, for the purposes of reviewing recent or contemplated operations and of consulting with the Manager on other matters relating to his responsibilities. At the request of any member of the Subcommittee, questions arising from such reviews and consultations shall be referred for determination to the Federal Open Market Committee.

7. The Chairman is authorized:

A. With the approval of the Committee, to enter into any needed agreement or understanding with the Secretary of the Treasury about the division of responsibility for foreign currency operations between the System and the Treasury;

B. To keep the Secretary of the Treasury fully advised concerning System foreign currency operations, and to consult with the Secretary on policy matters relating to foreign currency operations;

C. From time to time, to transmit appropriate reports and information to the National Advisory Council on International Monetary and Financial Policies.

8. Staff officers of the Committee are authorized to transmit pertinent information on System foreign currency operations to appropriate officials of the Treasury Department.

9. All Federal Reserve Banks shall participate in the foreign currency operations for System Account in accordance with paragraph 3 G(1) of the Board of Governors' Statement of Procedure with Respect to Foreign

Relationships of Federal Reserve Banks dated January 1, 1944.

Normand Bernard,

Deputy Secretary, Federal Open Market Committee.

[FR Doc. 93-10436 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-P

Federal Open Market Committee; Procedures for Allocation of Securities in the System Open Market Account (As Last Amended April 17, 1975, Effective May 1, 1975)

1. Securities in the System Open Market Account shall be reallocated at least once each year as determined by the Board's Division of Reserve Bank Operations and Payment Systems and the Manager of the System Open Market Account for the purpose of settling Interdistrict clearings and approximately equalizing for each Federal Reserve Bank the ratio of gold certificate holdings to Federal Reserve notes outstanding.

2. Until the next reallocation, the Account shall be apportioned on the basis of the ratios determined in Paragraph 1.

3. Profits and losses on the sale of securities from the Account shall be allocated on the day of delivery of the securities sold on the basis of each Bank's current holdings at the opening of business on that day.

Normand Bernard,

Deputy Secretary, Federal Open Market Committee.

[FR Doc. 93-10435 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-P

Caisse Nationale de Credit Agricole S.A., Paris, France; Application to Engage in Nonbanking Activities

Caisse Nationale de Credit Agricole S.A., Paris, France (Applicant), has applied pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) (BHC Act) and § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)) to engage *de novo* through a wholly owned subsidiary, Credit Agricole Futures, Inc., Chicago, Illinois (Company), a futures commission merchant registered under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), in executing and clearing, clearing without executing, executing and clearing through the use of omnibus trading accounts, and providing investment advisory services with regard to futures contracts and options on futures contracts in the following commodities on the following exchanges: Cocoa, Coffee "C", and Sugar #11 on the Coffee, Sugar & Cocoa Exchange; Corn, Soybeans, Soybean Meal, Soybean Oil, and Wheat on the Chicago Board of Trade; Soybeans on the MidAmerica Commodity Exchange; Hard Red Winter Wheat on the Kansas City Board of Trade; and Crude Oil, Heating Oil, Natural Gas (futures contracts only), and Unleaded Regular Gasoline on the New York Mercantile Exchange. Applicant also proposes to provide, through Company, custodial and other incidental services to mutual funds offered to non-U.S. residents outside the United States with respect to all types of futures contracts and options on futures contracts. Applicant proposes to conduct these activities throughout the United States and the world.

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with Board approval, engage in any activity which the Board, after due notice and opportunity for hearing, has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto. This statutory test requires that two separate tests be met for an activity to be permissible for a bank holding company. First, the Board must determine that the activity is, as a general matter, closely related to banking. Second, the Board must find in a particular case that the performance of the activity by the applicant bank holding company may reasonably be expected to produce public benefits that outweigh possible adverse effects.

A particular activity may be found to meet the "closely related to banking" test if it is demonstrated that banks have generally provided the proposed activity, that banks generally provide services that are operationally or functionally similar to the proposed activity so as to equip them particularly well to provide the proposed activity, or that banks generally provide services that are so integrally related to the proposed activity as to require their provision in a specialized form. *National Courier Ass'n* v. *Board of Governors*, 516 F.2d 1229, 1237 (D.C. Cir. 1975). In addition, the Board may consider any other basis that may demonstrate that the activity has a reasonable or close relationship to banking or managing or controlling banks. Board Statement Regarding Regulation Y, 49 FR 806 (1984).

Applicant believes that the proposed activities are closely related to banking or managing or controlling banks. The Board previously has approved, by regulation and order, acting as a futures commission merchant in the execution and clearance on major commodity exchanges of futures contracts and options on futures contracts in financial commodities, such as gold and silver bullion and coins, foreign exchange, government securities, certificates of deposit and money market instruments that banks may buy and sell for their own accounts, and stock and bond indices, as well as providing related investment advice. See 12 CFR 225.25(b)(18), (19); *Republic New York Corporation*, 63 Federal Reserve Bulletin 951 (1977); *The Sanwa Bank, Limited*, 74 Federal Reserve Bulletin 578 (1988); *The Long-Term Credit Bank of Japan, Limited*, 74 Federal Reserve Bulletin 573 (1988). The Board also previously has approved, by order, the provision of investment advice with respect to trading futures and options on futures in non-financial commodities, such as agricultural and energy commodities. See Swiss Bank Corporation, 77 Federal Reserve Bulletin 126 (1991). Further, the Board has approved providing custodial services to investment companies. See 12 CFR 225.125(i).

The Board has not previously approved the proposed activities with respect to acting as an FCM in executing, clearing, and brokering futures contracts and options on futures contracts in non-financial commodities. Applicant asserts that the proposed activities are essentially identical to activities previously approved by the Board. In this regard, Applicant believes that the execution and clearance of futures and options on futures in financial and non-financial commodities is functionally indistinguishable. Furthermore, Applicant states that the volatility of non-financial futures and options is not materially different than that for financial futures and options. Applicant also believes that Company's extensive experience in trading futures and options on futures in financial commodities makes it particularly well suited to engage in the proposed activities in non-financial commodities.

In order to satisfy the proper incident to banking test, section 4(c)(8) of the BHC Act requires the Board to find that the performance of the activities by Company can reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices. Applicant believes that the proposed activities will benefit the public by promoting competition. Applicant also believes that approval of

this application will allow Company to provide a wider range of services and added convenience to its customers, and to offer its customers securities not otherwise available for purchase in the United States. Applicant believes that the proposed activities will not result in any unsound banking practices or other adverse effects.

In publishing the proposal for comment, the Board does not take a position on issues raised by the proposal. Notice of the proposal is published solely to seek the views of interested persons on the issues presented by the application and does not represent a determination by the Board that the proposal meets, or is likely to meet, the standards of the BHC Act.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, not later than May 31, 1993. Any request for a hearing on this application must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of Chicago.

Board of Governors of the Federal Reserve System, April 28, 1993.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-10468 Filed 5-3-93; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL TRADE COMMISSION

[File No. 922 3017]

Nature's Cleanser, Inc., et al.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

In the matter of Nature's Cleanser, Inc., a corporation, and Donald Douglas-Torry, individually and as an officer of said corporation.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, a California-based corporation, that markets herbal products, and its officer from making the alleged false claims, and would require them to offer full refunds to all consumers who purchased the products. The respondents also would be required to have competent and reliable scientific evidence to substantiate any future claims regarding the performance, benefits or effectiveness of any food, drug or device they sell.

DATES: Comments must be received on or before July 6, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th Street and Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Linda Badger, San Francisco Regional Office, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 744–7920.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

The Federal Trade Commission, having initiated an investigation of certain acts and practices of Nature's Cleanser, Inc. and Donald Douglas-Torry ("respondents"), and it now appearing that proposed respondents are willing to enter into an agreement containing an order to cease and desist from the acts and practices being investigated,

It is hereby agreed By and between respondents, by their duly authorized officers and their attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent Nature's Cleanser, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois. The principal place of business of this corporation is located at 345 North Maple Drive, Suite 385, Beverly Hills, California 90210.

2. Proposed respondent Donald Douglas-Torry is an officer of the corporate respondent. He formulates, directs, and controls the acts and practices of the corporate respondent, including the acts and practices alleged in this order. His principal office and place of business is the same as that of the corporate respondent.

3. Proposed respondents admit all the jurisdictional facts set forth in the attached draft complaint.

4. Proposed respondents waive:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

d. All claims under the Equal Access to Justice Act, 5 U.S.C. 504.

5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the attached draft complaint, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the attached draft complaint, or that the facts alleged in the draft complaint, other than the jurisdictional facts, are true.

7. This agreement contemplates that if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (a) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order to cease and desist in disposition of the proceeding and (b) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and

decision containing the agreed-to order to proposed respondents' address as stated in this agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

8. Proposed respondents have read the attached draft complaint and the following order. Proposed respondents understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

Definitions

For the purposes of this order, the following definitions shall apply:

A. The term "Nature's Cleanser" means the herbal formulae known as "Weight Controlled Longevity Formula," and "Nature's Cleanser Bowel Management Formula," as marketed by Nature's Cleanser, Inc.

B. The term "Lady's Comfort" means the herbal formula known as "Lady's Comfort PMS/Menopause Formula," as marketed by Nature's Cleanser, Inc.

I

It is ordered That respondent Nature's Cleanser, Inc., a corporation, its successors and assigns, and its officers, and respondent Donald Douglas-Torry, 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 advertising, promotion, offering for sale, sale or distribution of Nature's Cleanser, or any product containing substantially similar ingredients, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that:

A. Such product can be taken in any dosage without causing adverse health effects;
B. Such product does not contain a laxative;
C. Such product contains an appetite suppressant;
D. Such product is effective in weight control;
E. Such product is effective in weight loss; or
F. Such product is effective in weight loss or weight control without a decrease in caloric intake.

II

It is further ordered That respondent Nature's Cleanser, Inc., a corporation, its successors and assigns, and its officers, and respondent Donald Douglas-Torry, 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 advertising, promotion, offering for sale, sale or distribution of Lady's Comfort, or any product containing substantially similar ingredients, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that such product, or any ingredient of such product:

A. Replaces hormones in the human body;
B. Is an effective alternative to synthetic hormones;
C. Prolongs a woman's period of fertility; or
D. Helps remove cellulite or prevents the formation of new cellulite.

III

It is further ordered That respondent Nature's Cleaner, Inc., a corporation, its successors and assigns, and its officers, and respondent Donald Douglas-Torry, 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 advertising, promotion, offering for sale, sale or distribution of any food, drug, or device, as those terms are defined in section 15 of the FTC Act, 15 U.S.C. 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, regarding the performance, benefits, efficacy or lack of adverse effects of any such product, unless at the time of making such representation respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. for purpose of this Order, "competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

Provided That, with respect to any drug products, if the Food and Drug Administration promulgates any final standard that establishes conditions under which such product is safe and effective under the Food, Drug and Cosmetic Act, then in lieu of the above, respondents may rely upon scientific evidence that fully conforms to such final standard as a reasonable basis for said representation.

IV

It is further ordered That respondents are jointly and severally liable for consumer redress to those consumers who purchased Nature's Cleaner or Lady's Comfort from respondents no later than May 25, 1992 (hereinafter referred to as "eligible consumers"), and shall within five (5) days from the date of service of this Order, mail Exhibit 1, attached hereto, via first class mail, offering a full refund to each eligible consumer. No information other than that contained in Exhibit 1 shall be included or added, nor shall any other material be transmitted therewith. The outside of the envelope transmitting Exhibit 1 shall prominently and conspicuously display the words "REFUND OFFER ENCLOSED." If, within forty-five (45) days from the date of service of this Order, an eligible consumer requests a refund by returning the letter referenced in Exhibit 1, or by otherwise communicating to respondents via mail, telephone, or in any other manner his or her request for a refund, respondents shall send a check for the full refund to the eligible consumer within sixty (60) days from the date of service of this Order. Respondents shall pay all costs associated with administering this consumer redress, including, but not limited to, first class postage. If for any reason, an eligible consumer does not communicate his or her request for a refund within forty-five (45) days from the date of service of this Order, then, in lieu of making direct consumer redress, the purchase amount attributed to the eligible consumer shall be paid by respondents to the United States Treasury within sixty (60) days from the date of service of this Order. Furthermore, if for any reason, a copy of Exhibit 1 sent to any eligible consumer is returned to respondents as undeliverable, the purchase amount attributed to the eligible consumer shall be paid by respondents to the United States Treasury within sixty (60) days from the date of service of this Order.

All payments to the United States Treasury shall be by certified or cashiers check made payable to the Treasurer of the United States, and delivered to: The Office of Consumer Litigation, Civil Division, U.S. Department of Justice, Washington, DC 20530 for appropriate disposition. The respondents, or their successors and assigns, shall for a period of three (3) years from the date this Order becomes final, maintain and make available upon request to the Federal Trade Commission for inspection and copying all records necessary to show compliance with this provision, including, but not limited to, the relevant customer lists, copies of Exhibit 1 sent to consumers, and evidence of payments made to eligible consumers or to the United States Treasury. No portion of the payment herein described shall be deemed a payment of any fine, penalty, or punitive assessment.

V

It is further ordered That for five (5) years after the last date of dissemination of any representation covered by this Order, respondents, or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements, promotional materials, documents, or other materials relating to such representation;
B. All materials that were relied upon in disseminating such representation; and
C. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

VI

It is further ordered That respondents shall 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 this Order.

VII

It is further ordered That the individual respondent shall, for a period of five (5) years after the date of service of this Order upon him, promptly notify the Commission, in writing, of his discontinuance of his present business or employment and of his affiliation with a new business or employment. For each such new affiliation, the notice shall include the name and address of the new business or employment, a statement of the nature of the new business or employment, and a description of respondent's duties and responsibilities in connection with the new business or employment.

VIII

It is further ordered That respondents shall, within ten (10) days from the date of service of this Order upon them, distribute a copy of this Order to any individual or entity who is involved in the preparation and placement of advertisements or promotional materials, or communicates with customers or prospective customers regarding the efficacy of any product covered by this Order.

IX

It is further ordered That, for five (5) years from the date of issuance of this Order, the corporate respondent, its successors and assigns, and the individual respondent, shall cause a copy of Exhibit 2 to be distributed to each purchaser for resale of any product covered by this Order, to each managerial employee of respondents, and to each salesperson of respondents' products, whether they are independent sales agents or employees of respondents.

X

It is further ordered That respondents shall, within sixty (60) days from the date of service of this Order upon them, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

Exhibit 1

Date
Customer Name
Customer Address

Dear Mr./Ms./Mrs.: Our records indicate that you have purchased our Nature's Cleanser or Lady's Comfort herbal products. The Federal Trade Commission challenged as inaccurate or unsubstantiated the following advertising claims for these products:

1. that Nature's Cleanser is effective in weight loss or control, or contains an appetite suppressant,
2. that Nature's Cleanser does not contain ingredients with laxative properties,
3. that Nature's Cleanser will have no adverse health effects regardless of how much is consumed,
4. that Lady's Comfort prolongs fertility, is a substitute for hormones, or helps remove or prevent the formation of cellulite.
5. that Lady's Comfort relieves menstrual cramps and other discomforts associated with the menstrual cycle or relieves discomfort associated with menopause.

Nature's Cleanser denies the Federal Trade Commission's charges. But to settle the case, we have entered into an agreement with the FTC which does not admit of any liability on our part. We will send refunds to anyone who was not fully satisfied with the product.

Our records indicate product purchases of $ _____. If you wish a refund, please fill in the form below and return it to us in the enclosed stamped envelope. You do not need to return the product or a proof of purchase to receive a refund. We must receive your refund request by [date 45 days from service of the Order]. You should receive your refund by [date 70 days from service of the Order]. If you have any questions, please call us at [corporate respondent's phone number].

Sincerely,

Donald Douglas-Torry,

President.

Please check one of the following:

_____Please send my refund.
_____I am a satisfied customer and do not wish a refund.

Customer's signature

Exhibit 2

Pursuant to a consent agreement with the Federal Trade Commission and in addition to other company policies regarding medical claims, it is a company policy that neither the company nor its distributors shall represent as to the following products, or one with substantially similar ingredients:

1. That Nature's Cleanser is effective in weight loss or control, or contains an appetite suppressant,
2. That Nature's Cleanser does not contain ingredients with laxative properties,
3. That Nature's Cleanser will have no adverse health effects regardless of how much is consumed,
4. That Lady's Comfort prolongs fertility, is a substitute for hormones, or helps remove or prevent the formation of cellulite.

Neither the company nor its distributors will make representations for products if they have no competent and reliable scientific basis for the representations.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondents Nature's Cleanser, Inc., an Illinois corporation, and Donald Douglas-Torry, individually and as an officer of the corporation.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days,

the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns two products, named "Nature's Cleanser" and "Lady's Comfort," sold by Nature's Cleanser, Inc. ("the company"). The Nature's Cleanser product consists of herbal tablets sold for their laxative and weight loss effects. The Commission's complaint charges that respondents' advertising contained false representations that Nature's Cleanser is not a laxative; that Nature's Cleanser is an effective, safe method of weight control or reduction, and that the product contains an appetite suppressant. Specifically, the complaint alleges that respondents falsely represented that:

(1) Nature's Cleanser can be taken in any dosage without causing adverse health effects,

(2) Nature's Cleanser does not contain a laxative,

(3) Nature's Cleanser contains an appetite suppressant,

(4) Nature's Cleanser is effective in weight control,

(5) Nature's Cleanser is effective in weight loss, and

(6) Nature's Cleanser is effective in weight loss or weight control without a decrease in caloric intake.

The Lady's Comfort product consists of herbal tablets sold for relief from various women's conditions. The Commission's complaint charges that respondents' advertising contained false representations that Lady's Comfort is a hormone substitute, prolongs fertility or removes cellulite. Moreover, the Commission's complaint charges that advertisements indicating that Lady's Comfort will aid those suffering from discomfort due to the menstrual cycle or menopause are unsubstantiated. Specifically, the complaint alleges that respondents falsely represented that Lady's Comfort:

(1) Replaces hormones in the human body,

(2) Is an effective alternative to synthetic hormones,

(3) Prolongs a woman's period of fertility, and

(4) Helps remove cellulite and prevents the formation of new cellulite.

Moreover, the complaint alleges that respondents lacked substantiation for claims that Lady's Comfort:

(1) Relieves menstrual cramps and other discomfort associated with the menstrual cycle, and

(2) Relieves discomfort associated with menopause.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondents from engaging in similar acts and practices in the future. Parts I and II of the proposed order would prohibit the company from making any of the false claims delineated above for Nature's Cleanser, Lady's Comfort, or any products with substantially similar ingredients.

Part III of the proposed order includes broad fencing-in relief, requiring the respondents to cease and desist from making any representation regarding the performance, benefits, efficacy or lack of adverse effects of any food, drug or device, unless they possess and rely upon competent and reliable scientific evidence that substantiates the representation. This provision also includes a "safe harbor," allowing the respondents to rely on final standards promulgated by the Food and Drug Administration to substantiate representations they make regarding any drug products.

Part IV of the proposed order is a consumer redress provision requiring the company to notify purchasers of the Nature's Cleanser and/or Lady's Comfort products of the Commission's allegations and to offer these purchasers full refunds.

The proposed order also requires the respondents to maintain materials relied upon to substantiate claims covered by the order, to distribute copies of the order to individuals or entities involved in the preparation or placement of the company's advertisements, to distribute a summary of the terms of the order to the company's salespeople, managers and distributors, to notify the Commission of any changes in corporate structure that might affect compliance with the order, to notify the Commission of certain changes in the business or employment of the named individual respondent, and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 93–10496 Filed 5–3–93; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89F–0395]

E.I. Du Pont De Nemours and Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 9B4170) proposing that the food additive regulations be amended to provide for the safe use of *N,N'*-dioleoylethylenediamine as a release agent in films made of ethylene-vinyl acetate copolymers and certain ionomeric resins for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 10, 1989 (54 FR 41505), FDA announced that a food additive petition (FAP 9B4170) had been filed by E.I. du Pont de Nemours and Co., Chestnut Run Plaza, P.O. Box 80715, Wilmington, DE 19880–0715 (formerly 1007 Market St., Wilmington, DE 19898). This petition proposed that § 178.3860 *Release agents* (21 CFR 178.3860) be amended to provide for the safe use of *N,N'*-dioleoylethylenediamine as a release agent in films made of ethylene-vinyl acetate copolymers complying with § 177.1350 (21 CFR 177.1350) and certain ionomeric resins (polymers of ethylene and methacrylic acid and their partial metal salts) complying with § 177.1330 (21 CFR 177.1330) for use in contact with food. E.I. du Pont de Nemours and Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–10400 Filed 5–3–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93M–0135]

Ciba Vision Corp.; Premarket Approval of Ciba Vision Disinfecting Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CIBA Vision Corp., Duluth, GA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the CIBA Vision® Disinfecting Solution. The device is to be manufactured under an agreement with Pilkington Visioncare (formerly Sola Barnes Hind), Sunnyvale, CA, which has authorized CIBA Vision Corp. to incorporate information contained in its approved premarket approval application and related supplements for the BARNES HIND® SOFTMATE® Disinfecting Solution. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 24, 1993, of the approval of the application.

DATES: Petitions for administrative review by June 3, 1993.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Debra Y. Lewis, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1080.

SUPPLEMENTARY INFORMATION: On August 3, 1992, CIBA Vision Corporation, Duluth, GA, submitted to CDRH an application for premarket approval of the CIBA Vision® Disinfecting Solution. The CIBA Vision® Disinfecting Solution is indicated for use to rinse, disinfect, and store soft (hydrophilic) contact lenses. The application includes authorization from Pilkington Visioncare, Sunnyvale, CA 94086-5200, to incorporate information contained in its approved premarket approval application and related supplements for BARNES HIND® SOFTMATE® Disinfecting Solution.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On March 24, 1993, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH. A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 3, 1993, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 21, 1993.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 93-10401 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Medical Imaging Drugs Advisory Committee

Date, time, and place. May 27 and 28, 1993, 8 a.m., Parklawn Bldg., 5600 Fishers Lane, conference rooms D and E, Rockville, MD.

Type of meeting and contact person. Open committee discussion, May 27, 1993, 8 a.m. to 5 p.m.; open public hearing, May 28, 1993, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion; 9 a.m. to 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 2 p.m.; Leander Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 13, 1993, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On May 27, 1993, the committee will discuss

new drug applications (NDA's) for Tc-99m Bicisate, (Neurolite) NDA 20–256, the DuPont Merck Pharmaceutical Co., a diagnostic radiopharmaceutical for use in single photon emission computed tomography (SPECT); Iopromide Injection, (Ultravist) NDA 20–220, Berlex Laboratories Inc., a non-ionic x-ray contrast agent; and on May 28, 1993, Indium-111 Pentetreotide (Octreoscan) NDA 20–314, Mallinckrodt Medical Inc., a diagnostic radiopharmaceutical for use in gamma scintigraphy and SPECT.

Closed committee deliberations. On May 28, 1993, the committee will review trade secret or confidential commercial information. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative session to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 27, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–10460 Filed 5–3–93; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Science Board to the Food and Drug Administration

Date, time, and place. May 24, 1993, 10:40 a.m. and May 25, 1993, 9 a.m., Sheraton Crystal City Hotel, 1800 Jefferson Davis Hwy., Arlington, VA.

Type of meeting and contact person. Open committee discussion, May 24, 1993, 10:40 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; open committee discussion, May 25, 1993, 9 a.m. to 4:15 p.m.; open public hearing, 4:15 p.m. to 5:15 p.m., unless public participation does not last that long; Sheryl A. Rosenthal, Office of the Senior Advisor for Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5839.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations should notify the contact person before May 14, 1993, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The board will receive a general orientation about FDA and an overview of the existing scientific research at the agency. An introduction to the operations of the Center for Food Safety and Applied Nutrition, the National Center for Toxicological Research, and the Center for Devices and Radiological Health will also be presented.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting. This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 27, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–10462 Filed 5–3–93; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Industry Exchange Meeting on the Foreign Drug Inspection Program; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA), Office of Small Business, Scientific and Trade Affairs, Office of Regulatory Affairs/Pacific Region, Center for Drug Evaluation and Research, and Office of Health Affairs are cosponsoring an industry exchange meeting. The foreign drug inspection program will be discussed.

DATES: The industry exchange meeting will be held on Thursday, May 20, 1993, 7:45 a.m. to 5 p.m.

ADDRESSES: The industry exchange meeting will be held at the San Francisco Airport Hilton, San Francisco International Airport, San Francisco, CA.

FOR FURTHER INFORMATION CONTACT: Jeanne White or Sharon Schneider, Food and Drug Administration, Office of Small Business, Scientific and Trade Affairs (HF–50), 5600 Fishers Lane, Rockville, MD 20857, 301–443–6776 or Mark Roh, Food and Drug Administration, Small Business Representative, Pacific Region, Federal Office Bldg., rm. 526, United Nations Plaza, San Francisco, CA 94102, 415–556–2263. Those persons interested in attending this meeting should fax their registration to 415–556–2822, including name, firm name, address, and telephone number. There is no

registration fee for this meeting, but advance registration is required.

SUPPLEMENTARY INFORMATION: FDA is sponsoring the second Commissioner of Food and Drugs' industry exchange meeting on the foreign drug inspection program. FDA speakers will provide current information on the foreign drug inspection program and will be available for question and answer sessions to address issues and concerns on the part of the regulated industry.

Dated: April 28, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-10461 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-93-3557; FR-3412-N-03]

Revised Notice of Funding Availability (NOFA) for the Urban Revitalization Demonstration; Revision To Extend Application Deadline Date for Eligible Applicants

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, Department of Housing and Urban Development (HUD, or the Department).

ACTION: Extension of Deadline Date; Notice of funding availability for the Urban Revitalization Demonstration Program.

SUMMARY: In response to discussions with a number of interest groups and public housing agencies (PHAs), the Department has decided to extend the application submission date for the Notice of Funding Availability originally published on January 5, 1993, entitled Funding Availability (NOFA) for Urban Revitalization Demonstration, and republished on March 29, 1993, entitled Revised Notice of Funding Availability (NOFA) for the Urban Revitalization Demonstration—Revised Procedures to Reduce Burdens on Applicants, from May 5, 1993 to May 26, 1993. This revised NOFA only modifies specific dates related to the submission of applications, submission of certifications, and the date related to the final funding decisions. All other requirements and clarifications set forth in the March 29, 1993 republication of the original NOFA remain in place except for the items outlined under the "background" section below.

BACKGROUND: This modification addresses the following areas:

1. The March 29, 1993 revised NOFA required that applications be submitted no later than 4 p.m. e.s.t. on May 5, 1993. Because the statute allows for an expanded period of time for application submission and, in recognition of concerns expressed by PHAs, the application submission deadline is being extended to no later than 4 p.m. e.s.t. on May 26, 1993.

2. If the required certification by the Mayor allowing replacement housing (if applicable) cannot be submitted by May 26, 1993, this certification may be submitted separately, but not later than 4 p.m. e.s.t. on August 25, 1993.

3. The Department intends to select grantees by August 26, 1993 and announcements will be made shortly thereafter.

Dated: April 29, 1993.

Michael B. Janis,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 93-10526 Filed 5-3-93; 8:45 am]

BILLING CODE 4210-33-M

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. N-93-3618; FR-3509-N-01]

Mortgagee Review Board Administrative Actions

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice describes the cause and description of recent administrative actions taken by HUD's Mortgagee Review Board against named HUD-approved mortgagees.

FOR FURTHER INFORMATION CONTACT: William Heyman, Director, Office of Lender Activities and Land Sales Registration, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708-1824. The Telecommunications Device for the Deaf (TDD) number is (202) 708-4594. (These are not toll-free numbers)

SUPPLEMENTARY INFORMATION: Section 202(c)(5) of the National Housing Act (added by section 142 of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235, approved December 15, 1989)) requires that HUD "publish in the **Federal Register** a description of and the cause for administrative action against a HUD-approved mortgagee" by the Department's Mortgagee Review Board. In conformity with the requirements of section 202(c)(5), this document gives notice of administrative actions that have been taken by the Mortgagee Review Board from January 1, 1993 through March 31, 1993.

1. Sound Mortgage, Inc., Seattle, Washington

Action: Proposed withdrawal of HUD mortgagee approval.

Cause: A HUD monitoring review which cited the company for violations of HUD-FHA requirements in the origination of a HUD-FHA insured mortgage. The company failed to assure that the mortgagor made the minimum required investment in the property, and failed to conduct a property inspection.

2. Hallmark Mortgage Services, Inc., Tampa, Florida

Action: Proposed withdrawal of HUD mortgagee approval.

Cause: A HUD monitoring review citing violations of HUD-FHA program requirements that included: Permitting the use of a "straw buyer" in a HUD-FHA insured mortgage transaction; failure to maintain a Quality Control Plan that complies with HUD-FHA requirements; signing the HUD-54113 underwriter/mortgagee certifications in blank; failure to maintain the Home Mortgage Disclosure Act (HMDA) 1990 and 1991 loan application, origination and purchase portfolio register and failure to submit the 1990 data to HUD; and failure to maintain complete loan origination files in compliance with HUD-FHA requirements.

3. Gill Savings Association, San Antonio, Texas

Action: Withdrawal of HUD mortgagee approval.

Cause: Failure to comply with the terms and conditions of an Indemnification Agreement with HUD that required indemnification for HUD's claim losses totalling $280,408.

4. Chemical Mortgage Company, Columbus, Ohio

Action: Settlement Agreement that provides for corrective action and compliance with the Department's section 235 mortgage servicing requirements.

Cause: A HUD monitoring review which cited the company for noncompliance with the Department's section 235 mortgage servicing requirements, including: Failure properly to refund underpaid assistance to mortgagors, due to commingling of subsidy and escrow funds; improper billing of HUD for mortgage subsidies;

failure to timely perform retroactive reviews when mortgagor income increased; billing both HUD and mortgagors for escrow shortages; improper billing for mortgage subsidies on loans insured before 1976; failure to make timely disclosure of escrow account balances to mortgagors; improper practices concerning overpaid assistance; and failure to update status codes on the HUD Single Family Default Monitoring System Report in a timely manner.

5. Kadilac Mortgage Bankers, Ltd., Great Neck, New York

Action: Settlement Agreement that includes indemnification to the Department in the amount of $149,019 for HUD's claim loss in connection with an improperly originated mortgage; agreement not to submit future claims in connection with four improperly originated mortgages; and payment to the Department the sum of $25,000 in lieu of a civil money penalty.

Cause: A HUD monitoring review that cited violations of HUD–FHA program requirements including: Failure to verify the adequacy and source of mortgagors' assets, false gift letter; overinsured mortgage; and payment of a referral fee.

6. Sovereign Mortgage Corporation, Marietta, Georgia

Action: Proposed withdrawal of HUD mortgagee approval.

Cause: A HUD monitoring review that cited violations of HUD–FHA program requirements including: Failure to comply with reporting requirements under the Home Mortgage Disclosure Act; failure to implement and maintain a Quality Control Plan; allowing false documentation to be submitted to HUD; failure to ensure that mortgagors made the minimum required investment; submitting loans involving "straw buyers" to HUD; failure to conduct face-to-face interviews with mortgagors; charging a mortgagor undisclosed discount points; overcharging interim interest to mortgagors; failure to verify the source of funds; and completing the lender's certification on HUD Form 92900 prior to the mortgagor's certification.

7. Goldpost Mortgage Corporation, Rochester, New York

Action: Settlement agreement that provides for payment to the Department of $75,000 in connection with five improperly originated mortgages.

Cause: A HUD monitoring review citing violations of HUD–FHA program requirements. The company submitted mortgages for HUD–FHA insurance endorsement which exceeded maximum permissible mortgage amounts.

8. Mortgage Systems, Inc., Las Vegas, Nevada

Action: Probation and proposed civil money penalty in the amount of $10,000.

Cause: A HUD monitoring review that cited violations of HUD–FHA program requirements including: Failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act; failure to implement an adequate Quality Control Plan; failure to timely submit closed loans to HUD for endorsement; failure to maintain complete mortgage origination files and documents; failure properly to remit One-Time Mortgage Insurance Premiums (OTMIPs); and reporting incorrect loan closing dates to HUD, resulting in underpayment of the OTMIP interest and late charges.

9. Venture Financial Services, Inc., Mesa, Arizona

Action: Proposed Settlement agreement that would include indemnification or buydown of an overinsured mortgage, and compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that cited violations of HUD–FHA program requirements including: Failure to assure that a mortgagor made the minimum required investment in a HUD–FHA insured mortgage; failure to implement an adequate Quality Control Plan; and failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA).

10. Sunland Mortgage, Inc., Cerritos, California

Action: Proposed Settlement agreement that provides for indemnification to HUD for its claim loss of $13,329 in connection with one improperly originated mortgage, and compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that cited violations of HUD–FHA program requirements that included: Improper origination of a HUD–FHA insured mortgage; failure to maintain an adequate Quality Control Plan; failure to perform a face-to-face interview with a mortgagor; failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA); and noncompliance with document-retention requirements.

11. First Countywide Mortgage Corporation, Hialeah, Florida

Action: Proposed Settlement agreement that would include indemnification for any claim losses sustained by the Department in connection with two improperly originated mortgages.

Cause: A HUD monitoring review that cited violations of HUD–FHA requirements including: Improper loan origination practices; inadequate Quality Control Plan; and failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA).

12. Mortgage Concepts, Inc., Orange, California

Action: Proposed Settlement agreement that would include indemnification to the Department for any claim loss in connection with one improperly originated mortgage, and noncompliance with HUD–FHA requirements.

Cause: A HUD monitoring review that disclosed violations of HUD–FHA requirements including: Failure to maintain and implement an adequate Quality Control Plan; failure to comply with reporting requirements under the Home Mortgage Disclosure Act (HMDA); failure to comply with the principal activity requirements for HUD–FHA approved loan correspondents; and improperly originating one HUD–FHA insured mortgage.

13. Miltex Mortgage, Inc., Austin, Texas

Action: Proposed Settlement agreement that would provide for indemnification to the Department in the amount of $7,868 for its claim loss in connection with an improperly originated mortgage, and compliance with HUD–FHA requirements.

Cause: A HUD monitoring review that disclosed violations of HUD–FHA program requirements including: Improperly originating one HUD–FHA insured mortgage; failure to implement and maintain an adequate Quality Control Plan; and failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA).

14. Central Wyoming Mortgage, Casper, Wyoming

Action: Letter of Reprimand.

Cause: A HUD monitoring review that cited violations of HUD–FHA program requirements including: Failure to maintain an adequate Quality Control Plan; failure to comply with HUD–FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA); failure to close and fund loans in the company's own name; and failure to maintain complete loan documents.

15. Mortgagees That Failed To Comply With HUD–FHA Reporting Requirements Under the Home Mortgage Disclosure Act (HMDA) and/or Quality Control Plan Requirements

Action: Letters of Reprimand.

Cause: HUD monitoring reviews that disclosed violations by the following mortgagees of the Department's reporting requirements under HMDA, or failure to comply with the Department's requirements for a Quality Control Plan, or both:

Mortgagees Issued a Letter of Reprimand for Failure To Meet HMDA Reporting Requirements and To Maintain an Adequate Loan Origination Quality Control Plan

Kentshire, Inc., Dayton, Ohio; David Mortgage, Inc., d/b/a Barnacle Mortgage Co., Cincinnati, Ohio; Treasure Coast Mortgage Corp., Sebring, Florida; National First Lenders Corp., Knoxville, Tennessee; Triangle East Mortgage Corp., Rocky Mount, North Carolina; Alliance Mortgage Corp., Hillside, Illinois; Martin & Associates, Inc., Columbus, Ohio; Bankers Financial Group, Inc., Dallas, Texas; Choice Mortgage, Inc., Richardson, Texas; Prime Lending, Inc., Dallas, Texas; Mortgage One Corp., Columbia, South Carolina; Greater Houston Financial Services, Houston, Texas; Nation's Bankers' Mortgage, Inc., Houston, Texas; AmeriFirst Investment Co., Overland Park, Kansas; Savage Mortgage Co., Houston, Texas; CMC Mortgage Corp., Wichita, Kansas; Mid-State Mortgage Co., Gladstone, Missouri; Charter Mortgage Corp., Overland Park, Kansas; Progressive Mortgage Corp., Houston, Texas; Citizens Mortgage Co., Joplin, Missouri; Advance Mortgage Corp., Overland Park, Kansas; McGuire Mortgage Co., Prairie Village, Kansas; and American Financial Mortgage Corp., Atlanta, Georgia.

Mortgagees Issued a Letter of Reprimand for Failure To Report HMDA Data Only

Mortgage Market, Inc., Metaire, Louisiana; Diversified Home Mortgage, Colorado Springs, Colorado; Mortgage Broker Financial Corp., Boulder, Colorado; Stanley Financial Services, Inc., Colorado Springs, Colorado; Fidelity Mortgage Co., Grand Junction, Colorado; First Republic Mortgage Corp., Dayton, Ohio; First Western Funding Corp., Greeley, Colorado; Omega Mortgage Corp., Fort Collins, Colorado; Midwest Home Mortgage Corp., Longmont, Colorado; Unlimited Mortgage Services, Worthington, Ohio; Renaissance Mortgage Corp., Houston, Texas; International Mortgage Corp., Overland Park, Kansas; First American Mortgage Corp., Prairie Village, Kansas; Heritage Mortgage Co., St. Joseph, Missouri; and Mortgages Unlimited, Inc., Liberal, Kansas.

16. Leader Mortgage Company, Overland Park, Kansas

Action: Letter of Reprimand.

Cause: HUD monitoring review that cited the company for failure to maintain an adequate Quality Control Plan.

Dated: April 22, 1993.

James E. Schoenberger,

Associate General Deputy Assistant Secretary.

[FR Doc. 93–10453 Filed 5–3–93; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Aquatic Nuisance Special Task Force Meeting

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Aquatic Nuisance Species Task Force. A number of subjects will be discussed during the Task Force meeting, including: The proposed Ruffe Control Program, the draft Intentional Introductions Policy Review, an update on the ballast water regulations for the Great Lakes, the Aquatic Nuisance Species Program, an update on activities of the Great Lakes Panel on Nonindigenous Species, and announcement of upcoming events.

DATES: The Aquatic Nuisance Species Task Force will meet from 9 a.m. to 3 p.m. on Thursday, May 20, 1993.

ADDRESSES: The Aquatic Nuisance Species Task Force meeting will be held at the Main Interior Building, room 8068 (North Penthouse), 1849 C Street NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sharon Gross, Aquatic Nuisance Species Task Force Coordinator, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Arlington, Virginia 22203 at (703) 358–1718.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Aquatic Nuisance Species Task Force established under the authority of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101–646, 104 Stat. 4761, 16 U.S.C. 4701 *et seq.*, November 29, 1990). Minutes of the meetings will be maintained by the Coordinator, Aquatic Nuisance Species Task Force, room 840, 4401 North Fairfax Drive, Arlington, Virginia 22203 and will be available for public inspection during regular business hours, Monday through Friday within 30 days following the meeting.

Dated: April 27, 1993.

Gary Edwards,

Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 93–10397 Filed 5–3–93; 8:45 am]

BILLING CODE 4310–55–M

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before April 24, 1993. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013–7127. Written comments should be submitted by May 19, 1993.

Beth L. Savage,

Acting Chief of Registration, National Register.

GEORGIA

Bulloch County

Stewart Stores, Jct. of Railroad and Grady Sts., Portal, 93000430

HAWAII

Hawaii County

Kamehameha Hall, 1162 Kalanianaole Ave., Hilo, 93000426

MICHIGAN

Alger County

Mikulich General Store, Jct. of Co. Rts. 1 and 44, Limestone Township, Traunik, 93000428

Ionia County

Belding, Alvah N., Memorial Library, 302 E. Main St., Belding, 93000427

Wayne County

Christ Church Chapel, 61 Grosse Pointe Rd., Grosse Pointe Farms, 93000424

Grosse Pointe High School, 11 Grosse Pointe Blvd., Grosse Pointe Farms, 93000429

RHODE ISLAND

Kent County

West Winds, 300 Wakefield St., West Warwick, 93000425

VERMONT

Windham County

Parker Hill Rural Historic District, Parker Hill and Lower Parker Hill Rds., Rockingham, 93000431

In order to assist in its preservation, the commenting period for the following property has been waived:

INDIANA

Jefferson County

Oakdale School, Morgan Rd., Jefferson Proving Ground, Madison vicinity 93000432

[FR Doc. 93-10469 Filed 5-3-93; 8:45 am]

BILLING CODE 4310-70-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Registration

By notice dated March 15, 1993, and published in the **Federal Register** on March 22, 1993, (58 FR 15378), Ganes Chemical, Inc., Industrial Park Road, Pennsville, New Jersey 08070, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations, § 1301.54(e), the Director, Office of Diversion Control hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: April 27, 1993.

Gene R. Haislip,

Director, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93-10413 Filed 5-3-93; 8:45 am]

BILLING CODE 4410-09-M

Importation of Controlled Substances; Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1311.42 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on March 29, 1993, Radian Corporation, 8501 Mopac Blvd., P.O. Box 201088, Austin, Texas 78720, made application to the Drug Enforcement Administration to be registered as an importer of Dextropropoyphene, bulk (non-dosage forms) (9273) a basic class of controlled substance in Schedule II. The firm plans to import deuterated material not currently available in the United States for manufacturing an exempt product.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed to the Director, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than June 3, 1993.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Director, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: April 27, 1993.

Gene R. Haislip,

Director, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93-10414 Filed 5-3-93; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Employment and Training Administration

Chevron Petroleum Technology Co. (CPTC) (A Division of Chevron U.S.A. Inc.), et al.; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In the Matter of Chevron Exploration & Production Services Co., Various Department and Divisions in the Following States:

TA-W-27,344 Exploration & Production Department, Houston, TX,
TA-W-27,345 Technical Services Department, Houston, TX,
TA-W-27,346 Eastern Support Division, New Orleans, LA
TA-W-27,346A Eastern Support Division, LA except New Orleans,
TA-W-27,347 Western Support Division, San Ramon, CA,
TA-W-27,347A Western Support Division, CA except San Ramon,
TA-W-27,347B Western Support Division, TX,
TA-W-27,347C Western Support Division, CO; Chevron Oil Field Research Co.,
TA-W-27,853 La Habra, CA,
TA-W-27,853A TX

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued Notices of Certification applicable to all workers of the subject firms on July 22, 1992 and on November 30, 1992. The Notices were published in the **Federal Register** on August 4, 1992 (57 FR 34308) and December 15, 1992 (57 FR 59356), respectively.

The Department is amending the subject certification to reflect a new name change effective December 31, 1992. Because of a reorganization, workers of the above firms are now employees of the Chevron Petroleum Technology Company (CPTC), a division of Chevron, U.S.A. Inc.

Accordingly, the Department is amending the certifications to reflect the name change.

The amended notice applicable to TA-W-27,344; TA-W-27,345; TA-W-27,346; TA-W-27,346A; TA-W-27,347; TA-W-27,347A-C, and TA-W-27,853 and TA-W-27,853A, respectively, is hereby issued as follows.

All workers of Chevron Exploration and Production Services Company, (Chevron Petroleum Technology Company, a division of Chevron, U.S.A. Inc.) Houston, Texas and operating in the following States: Texas, Louisiana, California and Colorado who became totally or partially separated from employment on or after May 28, 1991 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974." and

"All workers of Chevron Oil Field Research Company, (Chevron Petroleum

Technology Company, a division of Chevron, U.S.A. Inc.) La Habra, California and the State of Texas who became totally or partially separated from employment on or after September 14, 1991 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 27th day of April 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93-10484 Filed 5-3-93; 8:45 am]

BILLING CODE 4510-30-M

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period of April 1993.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-28,307; Hurlock Sportswear, Hurlock, MD

TA-W-28,172; Semiconductor Specialties Corp., Kane, PA

TA-W-28,081; Lodge & Shipley, Inc., Cincinnati, OH

TA-W-28,435; Unocal Molycorp, York, PA

TA-W-28,333; Struthers Wells Corp., Warren, PA

In the following cases, the investigation revealed that the criteria for eligibility has not been met for the reasons specified.

TA-W-28,312; Berrong Enterprises Limited, Houston, TX

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-28,379; H & G Services, Williston, ND

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-28,277; BP Performance Polymers, Inc., Hackettstown, NJ

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-28,491; KAI, Bay City, MI

Increased imports did not contribute importantly to worker separations at the firm.

TA-W-28,375; Parker Pen USA, Limited, Janesville, WI

Increased imports did not contribute importantly to worker separations at the firm.

TA-W-28,187; Coastal Oil, Inc., Oklahoma City, OK

The investigation revealed that criterion (1) and criterion (2) have not been met. A significant number or proportion of the workers did not become totally or partially separated as required for certification. Sales or production did not decline during the relevant period as required for certification.

TA-W-28,304; Pennzoil Exploration & Production Co, West Neola, UT

The investigation revealed that criterion (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

Affirmative Determinations

TA-W-28,437; C & M Sportswear, Newark, NJ

A certification was issued covering all workers separated on or after January 6, 1992.

TA-W-28,522; Jane & Linda Sportswear, Inc., Lebanon, KY

A certification was issued covering all workers producing ladies' pants and skirts separated on or after March 24, 1992.

TA-W-28,438; Portland General Electric Co., Trojan Nuclear Plant, Rainier, OR

A certification was issued covering all workers producing electric power separated on or after February 23, 1992.

TA-W-28,438A; Portland General Electric Co., Portland, OR

A certification was issued covering all workers of Portland General Electric Co., Portland, OR and PGE Non-Nuclear Division producting electric power separated on or after February 23, 1992.

TA-W-28,383; Dale Electronics, Inc., El Paso, TX

A certification was issued covering all workers producing thermistors separated on or after February 26, 1993.

TA-W-28,479; OMC Trade Winds, Manawa, WI

A certification was issued covering all workers producing remote controls and electronics for outboard motors separated on or after December 1, 1992.

TA-W-28,258; Texas, Inc., Exploration & Production Technology Dept., Houston, TX

A certification was issued covering all workers separated on or after January 12, 1992.

TA-W-28,346; Technical Services for Electronics, Inc., (AKA TSE, Inc, Fairfax, MN

A certification was issued covering all workers separated on or after January 25, 1992.

TA-W-28,267; Mecon Manufacturing, Inc., Caribou, ME

A certification was issued covering all workers producing Automobile circuit breakers separated on or after January 20, 1992.

TA-W-28,418; ASARCO—Troy Unit, Troy, MT

A certification was issued covering all workers separated on or after February 18, 1992.

TA-W-28,386 Chalk Line, Inc., West Point, GA

A certification was issued covering all workers producing undecorated outerwear separated on or after February 18, 1992.

TA-W-28,232; Binns Machinery Products, Cincinnati, OH

A certification was issued covering all workers separated on or after January 1, 1992.

TA-W-28,228; Geneva Steel, Provo, UT

A certification was issued covering all workers separated on or after January 5, 1992.

TA-W-28,514; Simon Petroleum Technology Corp, Houston, TX

A certification was issued covering all workers separated on or after March 23, 1992.

TA-W-28,245; Abex/NWL Aerospace Oxnard, CA

A certification was issued covering all workers producing servo valves and hydraulic pumps on or after January 15, 1992.

TA-W-28,354; Melville Knitwear Co., Inc., Monroe, NC

A certification was issued covering all workers producing ladies' sweaters separated on or after February 9, 1992.

TA-W-28,354; Melville Knitwear Co., Inc., Waxhaw, NC

A certification was issued covering all workers producing ladies' sweaters separated on or after February 9, 1992.

I hereby certify that the aforementioned determinations were issued during the month of April 1993. Copies of these determinations are available for inspection in room C-4318, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: April 27, 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93-10481 Filed 5-3-93; 8:45 am]

BILLING CODE 4510-30-M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than May 14, 1993.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than May 14, 1993.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 19th day of April, 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition No.	Articles produced
Syntron, Inc (Wkrs)	Houston, TX	04/19/93	04/10/93	28,561	Acoustic transducers.
Rogue Valley Printed Circuits (Wkrs)	Medford, OR	04/19/93	04/05/93	28,562	Printed circuit boards.
Moore-Clark Co. (Wkrs)	LaConner, WA	04/19/93	04/01/93	28,563	Fish feed.
Sooner Pipe & Supply Co (Wkrs)	Tulsa, OK	04/19/93	04/06/93	28,564	Sells oilfield equipment and supplies.
Moench Tanning Co (Wkrs)	Gowanda, NY	04/19/93	04/05/93	28,565	Leather.
Southwestern Energy Production Co (Wkrs).	Oklahoma City, OK	04/19/93	03/29/93	28,566	Crude oil and natural gas.
Simpson Paper Co, Humboldt Pulp (Wkrs).	Eureka, CA	04/19/93	03/31/93	28,567	Softwood pulp.
Plummer Precision Optics (Wkrs)	Pennsburg, PA	04/19/93	04/07/93	28,568	Optical components.
I.T.T. Avionics (IAM)	Clifton, NJ	04/19/93	01/29/93	28,569	Radar jamming systems.
IRI International Corp (Co)	Pampa, TX	04/19/93	04/06/93	28,570	Melts and forges steel bars and billets.
G and L Machine (Wkrs)	South Paris, ME	04/19/93	03/31/93	28,571	Machining of parts.
G.E.O., Inc (Wkrs)	Casper, WY	04/19/93	03/15/93	28,572	Provides geological data.
FMR Grinding Wheel Co., Inc (USWU)	West Haven, CT	04/19/93	03/30/93	28,573	Grinding wheels.
Camco Products & Service (Co)	Anchorage, AK	04/19/93	04/08/93	28,574	Service oil and gas wells.
AAI/Microflite Simulation (Wkrs)	Binghamton, NY	04/19/93	04/01/93	28,575	Flight simulators and training devices.
IBM Corp (Wkrs)	Buffalo, NY	04/19/93	04/05/93	28,576	Service, support center.
Pratt & Whitney Aircraft (IAMAW)	East Hartford, CT	04/19/93	04/07/93	28,577	Commercial and military aircraft engines.
Pratt & Whitney Aircraft (IAMAW)	North Haven, CT	04/19/93	04/07/93	28,578	Commercial and military aircraft engines.
Pratt & Whitney Aircraft (IAMAW)	Rocky Hill, CT	04/19/93	04/07/93	28,579	Commercial and military aircraft engines.
Pratt & Whitney Aircraft (IAMAW)	Middletown, CT	04/19/93	04/07/93	28,580	Commercial and military aircraft engines.
Pratt & Whitney Aircraft (IAMAW)	Cheshire, CT	04/19/93	04/07/93	28,581	Commercial and military aircraft engines.
Pratt & Whitney Aircraft (IAMAW)	Southington, CT	04/19/93	04/07/93	28,582	Commercial and military aircraft engines.

[FR Doc. 93-10482 Filed 5-3-93; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-27,997]

Texaco Exploration & Production, Inc., Eastern E & P Region, New Orleans, LA; Revised Determination on Reopening

On April 20, 1993, the Department, at the request of the petitioners, reopened its investigation for workers and former workers of the subject firm. The initial investigation resulted in a negative determination on January 15, 1993 because the "contributed importantly" test of the Group Eligibility Requirements of the Trade Act was not met. The denial notice was published in the **Federal Register** on March 9, 1993 (58 FR 13092).

The investigation findings show that the predominant portion of the crude oil produced by Texaco's Eastern E & P Region is sold internally.

The findings also show that the production of both crude oil and natural gas at New Orleans decreased in 1991 compared to 1990 and in the first 10 months of 1992 compared to the same period in 1991. Significant worker separations began in 1992.

Findings on reopening show increased company imports of crude oil in 1991 compared to 1990 and in the first 10 months of 1992 compared to the same period in 1991.

Conclusion

After careful consideration of the new facts obtained on reopening, it is concluded that increased imports of articles like or directly competitive with the crude oil produced by the Eastern E & P Region of Texaco Exploration and Production, Inc., in New Orleans, Louisiana contributed importantly to the decline in production and to the total or partial separation of workers at the subject plant. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

All workers and former workers of the Eastern E & P Region of Texaco Exploration & Production, Inc., in New Orleans, Louisiana who became totally or partially separated from employment on or after July 1, 1992, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 22d day of April 1993.

Stephen A. Wandner,

Deputy Director, Office of Legislation and Actuarial Service, Unemployment Insurance Service.

[FR Doc. 93-10483 Filed 5-3-93; 8:45 am]

BILLING CODE 4510-30-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Council on the Arts; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the National Council on the Arts will be held on May 14, 1993 from 9 a.m.-5:30 p.m. and May 15 from 8:30 a.m.-4:30 p.m. in room M-09 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

Portions of this meeting will be open to the public on May 14 from 9: a.m.-5:30 p.m. and May 15 from 9:30 a.m.-4:30 p.m. The topics for discussion will include opening remarks; Congressional update; preliminary discussion of FY 95 Budget; Cultural Diversity Task Force update; and Program Review and/or Guidelines and/or Application Review for the Arts in Education, Challenge/Advancement, Dance, Design Arts, Expansions Arts, Folk Arts, International, Literature, Local Arts Agencies, Media Arts, Museum, Music, Planning and Research, Opera-Musical Theater, Presenting & Commissioning, Special Constituencies, State & Regional, Theater, and Visual Arts Programs.

The remaining portion of this meeting on May 15 from 8:30 a.m.-9:15 a.m. is for the purpose of reviewing nominations for the National Medal of Arts. In accordance with the determination of the Chairman of November 24, 1992, this session will be closed to the public pursuant to subsections (6) and 9(B) of section 552b of title 5, United States Code.

Also, if in the course of application review it becomes necessary for the Council to discuss non-public financial information about individuals, such as salary information, submitted with grant applications, the Council will go into closed session for that limited purpose only pursuant to subsection (c)(4) of section 552b of title 5, United States Code. Such closure would be in accordance with the determination of the Chairman of November 24, 1992.

Any interested persons may attend, as observers, Council discussions and reviews which are open to the public.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682-5532, TTY 202/682-5496, at seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, national Endowment for the Arts, Washington, DC 20506, or call (202) 682-5439.

Dated: April 27, 1993.

Yvonne M. Sabine,

Director, Panel Operations, National Endowment for the Arts.

[FR Doc. 93-10443 Filed 5-3-93; 8:45 am]

BILLING CODE 7537-01-M

Dance Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Dance Advisory Panel (Choreographers' Fellowships Prescreening Section) to the National Council on the Arts will meet on June 9-10, 1993 from 9 a.m.-8 p.m. and June 11 from 9 a.m.-4 p.m. in room M-07 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

This meeting is for the purpose of application evaluation, under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the Agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, this session will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682-5439.

Dated: April 26, 1993.

Yvonne M. Sabine,

Director, Panel Operations, National Endowment for the Arts.

[FR Doc. 93-10445 Filed 5-3-93; 8:45 am]

BILLING CODE 7537-01-M

Dance Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Dance Advisory Panel (Choreographers' Fellowships Section) to the National Council on the Arts will be held on June 14-15, 1993 from 9 a.m.-8:30 p.m., June 16 from 9 a.m., June 17 from 9 a.m.-9 p.m., 8:30 p.m. and June 18 from 9 a.m.-6 p.m. in room M-09 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington DC 20506

A portion of this meeting will be open to the public on June 18 from 3 p.m.-6 p.m. The topic will be policy discussion.

The remaining portions of this meeting on June 14-15 from 9 a.m.-8:30 p.m., June 16 from 9 a.m.-9 p.m., June 17 from 9 a.m.-8:30 p.m., and June 18 from 9 a.m.-3 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels

which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington DC 20506, 202/682-5532, TTY 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington DC 20506, or call (202) 682-5439.

Dated: April 26, 1993.

Yvonne M. Sabine,

Director, Panel Operations, National Endowment for the Arts.

[FR Doc. 93-10449 Filed 5-3-93; 8:45 am]

BILLING CODE 7537-01-M

Folk Arts Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Folk Arts Advisory Panel (Folk Arts Organizations/State Arts Apprenticeships Programs Section) to the National Council on the Arts will be held on June 8-9, 1993 from 9 a.m.-9:30 p.m., June 10 from 9 a.m.-6:30 p.m., and June 11 from 9 a.m.-4 p.m. in room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

A portion of this meeting will be open to the public on June 9 from 12:30 p.m.-2:30 p.m. The topic will be policy discussion.

The remaining portions of this meeting on June 8 from 9 a.m.-9:30 p.m., June 9 from 9 a.m.-12:30 p.m. and 2:30 p.m.-9:30 p.m., June 10 from 9 a.m.-6:30 p.m., and June 11 from 9 a.m.-4 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of November 24, 1992, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682-5532, TTY 202/682-5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682-5439.

Dated: April 26, 1993.

Yvonne M. Sabine,

Director, Panel Operations, National Endowment for the Arts.

[FR Doc. 93-10448 Filed 5-3-93; 8:45 am]

BILLING CODE 7537-01-M

NATIONAL SCIENCE FOUNDATION

Committee of Visitors of the Advisory Committee for Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting.

Date and Time: May 19-21, 1993; 8:30 a.m. to 5 p.m.

Place: Room 500B, 1110 Vermont Avenue, NW., Washington, DC.

Type of Meeting: Closed.

Contact Person: Dr. Conrad A. Istock, Program Director/Cluster Leader, Systematic and Population Biology Cluster, National Science Foundation, 1800 G. St. NW., Washington, DC 20550. Telephone: (202) 357-9728.

Purpose of Meeting: To carry out Committee of Visitors (COV) review, including examination of decisions on proposals, reviewer comments, and other privileged materials.

Agenda: To provide oversight review of the Systematic Biology and Population Biology Programs.

Reason for Closing: The meeting is closed to the public because the Committee is reviewing proposal actions that will include privileged intellectual property and personal information that could harm individuals if they were disclosed. If discussions were open to the public, these matters that are exempt under 5 U.S.C. 552b(c) (4) and (6) of the G Government in the Sunshine Act would be improperly disclosed.

Dated: April 29, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93-10464 Filed 5-3-93; 8:45 am]

BILLING CODE 7555-01-M

Special Emphasis Panel in International Programs; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in International Programs.

Date and Time: May 12, 1993; 8:30 a.m. to 5 p.m.

Place: Room 500-C, 1110 Vermont Avenue, NW., Washington, DC.

Type of Meeting: Closed.

Contact Person: Myra McAuliffe, Program Specialist, Division of International Programs, room V-501, National Science Foundation, 1800 G St. NW., Washington, DC 20550. Telephone: (202) 653-5862.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Japan Center for Global Partnership (CGP) Medium and Long-Term Visits for Individual Research Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Reason for Late Notice: Difficulty in making meeting arrangements.

Dated: April 29, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93-10463 Filed 5-3-93; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

Abnormal Occurrence Report; Section 208 Report Submitted to the Congress

Notice is hereby given that pursuant to the requirements of section 208 of the Energy Reorganization Act of 1974, as amended, the Nuclear Regulatory Commission (NRC) has published and issued another periodic report to Congress on abnormal occurrences (NUREG-0090, Vol. 15, No. 4).

Under the Energy Reorganization Act of 1974, which created the NRC, an abnormal occurrence is defined as "an unscheduled incident or event that the Commission (NRC) determines is

significant from the standpoint of public health or safety." The NRC has made a determination that events involving an actual loss or significant reduction in the degree of protection against radioactive properties of source, special nuclear, and by-product material are abnormal occurrences.

The report to Congress is for the fourth calendar quarter of 1992. The report identifies the occurrences or events that the Commission determined to be significant and reportable; the remedial actions that were undertaken are also described.

There were two abnormal occurrences at nuclear power plants. Six abnormal occurrences involving medical misadministration (all therapeutic) at NRC-licensed facilities are discussed in this report. No abnormal occurrences were reported by NRC's Agreement States. The report also contains information updating previously reported abnormal occurrences.

A copy of the report is available for inspection or copying for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555, or at any of the nuclear power plant Local Public Document Rooms throughout the country.

Copies of NUREG–0090, Vol. 15, No. 4 (or any of the previous reports in this series), may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013–7082. A year's subscription to the NUREG–0090 series publication, which consists of four issues, is also available.

Copies of the report may also be purchased from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

Dated at Rockville, MD this 28th day of April 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–10456 Filed 5–3–93; 8:45 am]

BILLING CODE 7590–01–M

First Meeting of the CONTAIN Peer Review Committee

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The CONTAIN Peer Review Committee will meet to review the technical adequacy of the CONTAIN code.

DATES: May 24–27, 1993.

TIME: 8:30 a.m. each day.

ADDRESS: Sandia National Laboratory, Albuquerque, New Mexico, May 24–25, Building 980, room 95 (meeting location), May 26–27, Building 823, room 2279 (meeting location).

FOR FURTHER INFORMATION CONTACT: A. Notafrancesco, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492–3537.

SUPPLEMENTARY INFORMATION: The objective of this effort is to organize and conduct a peer review of the CONTAIN code, light water reactor version. The peer review is to provide an independent assessment of the modeling capabilities and limitations, and adequacy of the CONTAIN code. The results of the peer review are to be documented in a summary report that describes the results of the independent assessment by the peer review participants and the technical acceptability of the code.

A peer review committee has been organized using recognized experts from the national laboratories, universities, CONTAIN user community and independent contractors. Meetings are held to discuss and evaluate the applicability and state of validation of the various CONTAIN phenomenological models. The meeting scheduled for May 24–27, 1993, is the first meeting of the CONTAIN Peer Review Committee. The Committee will (1) review the Committee charter, (2) review the code design objectives and targeted applications, (3) select a process for conducting the review, (4) identify and select a standard for determining technical adequacy, and (5) receive briefings from the code development staff about the integrated code and the detailed models in the code.

Dated at Rockville, Maryland, this 26th day of April, 1991.

Editorial Note: This document was received at the Office of the Federal Register on April 29, 1993.

For the U.S. Nuclear Regulatory Commission.

Farouk Eltawila,

Chief, Accident Evaluation Branch, Division of Systems Research, Office of Nuclear Regulatory Research.

[FR Doc. 93–10465 Filed 5–3–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 999–0001; License No. 2467–3128; EA 92–203]

Order Modifying Order Imposing Civil Monetary Penalty

In the Matter of Capital Materials Testing, Inc. Ballston Spa, New York 12020.

I

Capital Materials Testing, Inc. (Licensee) is the holder of a Byproduct Material License issued by the State of New York which authorizes the Licensee to use byproduct materials in industrial radiography and replacement of sources in accordance with the conditions specified therein. On October 6–7, 1992, the New York State Licensee was working at a field site in Pittsfield, Massachusetts under NRC jurisdiction subject to the reciprocity requirements set forth in 10 CFR 150.20.

II

An NRC inspection of the Licensee's activities was conducted on October 6–7, 1992. The results of the inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated November 20, 1992. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice in a letter, dated December 9, 1992. In its response, the Licensee did not deny the violations, but requested remission of the civil penalty.

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff determined that the violations occurred as stated and that the penalty proposed for Violation I designated in the Notice should be imposed. Accordingly, NRC issued an Order Imposing a Civil Monetary Penalty to the licensee on February 3, 1993. The licensee responded in a letter dated February 24, 1993 and requested a hearing. In correspondence dated February 26, 1993 and March 13, 1993, the NRC confirmed telephone conversations between Mr. Stanley Liebert, Licensee President, and NRC representatives in which the Licensee requested delay in processing of the Licensee's February 24, 1993 hearing request until after NRC reviewed additional information the Licensee was to submit for consideration. On March 25, 1993, the Licensee submitted the additional information. The information specified the corrective actions taken by the Licensee following the October 6–7, 1992 NRC inspection and provided financial information to support the Licensee's assertion concerning its ability to pay.

III

Upon review of the facts of this case, including the information submitted in the licensee's March 25, 1993 letter, I find that the Licensee's prompt and extensive corrective actions support a $2,500 reduction of the $7,500 civil penalty imposed in the February 3, 1993 Order, based on mitigation consistent with the NRC Enforcement Policy.

IV

In view of the foregoing, and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *it is hereby ordered that:* The NRC February 3, 1993 Order Imposing a Civil Monetary Penalty in the amount of $7,500 be modified to the amount of $5,000.

V

The Licensee may request that the NRC proceed with the Licensee's February 24, 1993 request for a hearing within 10 days of the date of this Order. If the Licensee requests that the NRC proceed with its hearing request, the Commission will issue an Order designating the time and place of the hearing. If the Licensee does not request the NRC to proceed with its request for hearing within 10 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If full payment has not been made by this time, or if either arrangements for payment over time are not completed by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests proceeding with a hearing as provided above, the issue to be considered at such hearing shall be whether, on the basis of Violation I, admitted by the Licensee, this Order should be sustained.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 26th day of April 1993.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

[FR Doc. 93–10458 Filed 5–3–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–482]

Wolf Creek Nuclear Operating Corp.; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–42, issued to Wolf Creek Nuclear Operating Corporation (the licensee), for operation of the Wolf Creek Generating Station (WCGS) located in Coffey County, Kansas.

The proposed amendment would revise the WCGS operating license and technical specifications (TS) to increase the rated core power level from the present specification 3411 megawatts thermal (MWt) to a specification of 3565 MWt, thereby allowing the plant to operate at a nuclear steam supply system power of 3579 MWt. The revisions would also allow the licensee to implement a proposed hot leg temperature (T_{HOT}) reduction program that would extend the range of T_{HOT} down 15 degrees fahrenheit from the current design value of 618.2 degrees fahrenheit. The licensee intends to operate with a 5 degree fahrenheit reduction in T_{HOT}. the proposed amendment would change: (1) The definition of rated thermal power in Section 1.25 of the TS, (2) the overtemperature delta T and overpower delta T setpoint parameters in Table 2.2–1, "Reactor Trip System Instrumentation Trip Setpoints," and (3) the indicated reactor coolant system T_{avg} limit in Table 3.2–1, "DNB Parameters," and in Section 3/4.2.5 of the Bases.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By June 3, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document rooms located at the Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these

requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Suzanne C. Black, Director, Project Directorate IV–2: Petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

If a request for a hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 59.92.

For further details with respect to this action, see the application for amendment dated January 5, 1993, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC 20555, and at the local public document rooms located at the Emporia State University, Williams Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621.

Dated at Rockville, Maryland, this 26 day of April 1993.

For the Nuclear Regulatory Commission.

Suzanne C. Black,

Director, Project Directorate IV–2, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 93–10457 Filed 5–3–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 030–01244; License No. 06–00819–03; EA 93–016]

Confirmatory Order Modifying License (Effective Immediately)

In the Matter of Yale-New Haven Hospital New Haven, Connecticut.

I

Yale-New Haven Hospital (Licensee), New Haven, Connecticut, is the holder of Byproduct/Source Material License No. 06–00819–03 (License), issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR parts 30 and 33. The License authorizes the Licensee to perform diagnostic and therapeutic procedures with the radioactive material as well as research. This is a broad scope license. The License was most recently renewed on August 13, 1985, and was due to expire on August 31, 1990 but was extended by the NRC pending staff action on the Licensee's renewal request and is considered to be in timely renewal.

II

Between December 3, 1992, and January 27, 1993, the NRC performed two inspections of licensed activities at the Licensee's facility. The inspections were conducted to review two incidents involving therapeutic misadministrations and a failure to control licensed material that occurred between November 30 and December 1, 1992, and on January 21, 1993, which are described in detail in a Notice of Violation and Proposed Imposition of Civil Penalties issued concurrently on this date. During the inspections, five violations of NRC requirements were identified.

The violations associated with the first incident included: (1) The failure to perform a survey of patient linens prior to removing them from the patient's room as required; (2) the failure to maintain security and control of licensed material; (3) the existence of radiation levels above the regulatory limit in unrestricted areas; and (4) the failure to implement written procedures and policies to ensure that brachytherapy administrations were done in accordance with the written directive as required under the Licensee's Quality Management (QM) program. One violation of the Licensee's QM program was identified with regard to the second incident in that the administering physician failed to verify that the treatment site for a brachytherapy treatment using a High Dose Rate afterloader device was in accordance with the written directive and treatment plan.

There violations are of significant concern because in the first incident, a failure to perform a required survey resulted in the failure to maintain control of a radioactive source and could have resulted in misuse of the material by, and created a potential for an unnecessary excessive exposure to, members of the public. Secondly, the failure to: (1) Implement QM procedures that would identify if a brachytherapy source were not properly implanted or inadequately secured against accidental removal and (2) follow QM procedures requiring that the treatment site be confirmed with the written directive and treatment plan prior to administering the treatment dose directly contributed to misadministrations to two patients.

III

The violations are particularly disturbing to the NRC since the Licensee possesses a large broad scope license which places a significant responsibility on the Radiation Safety Committee (RSC), as well as the Radiation Safety Officer (RSO), to ensure that licensed activities are conducted safely and in accordance with NRC requirements. Although the NRC issued a Notice of Violation and Proposed Civil Penalty to the Licensee on August 3, 1989, for the improper disposal of a radioactive source resulting from inadequate control of licensed material, as well as a Severity Level III Notice of Violation to the Licensee on April 15, 1992, for other violations of NRC requirements associated with use of brachytherapy sources, sufficient management attention has not been provided to improve the radiation safety program, as evidenced by the recent findings.

The Licensee's failure to maintain sufficient control of radioactive materials raises significant questions regarding the adequacy of oversight of

activities at its facility, as well as the ability of the Licensee to assure that activities at that facility are conducted safely and in accordance with requirements. Accordingly, without additional requirements, there is a substantial question as to whether licensed activities will be adequately controlled at the Licensee's facility.

IV

In a letter to the NRC, dated February 10, 1992, the Licensee committed to: (1) Retain the services of an independent expert to perform an assessment of the radiation safety program, (2) make available to NRC the final assessment report, and (3) provide to NRC quarterly reports on the Licensee's progress in implementing the recommendations developed as a result of the assessment. During a telephone conversation on February 22, 1993, between Ravinder Nath, Ph. D., of the Licensee's staff and Mr. James Dwyer of the NRC Region I staff, the Licensee committed to retaining the services of an independent expert in order to perform an assessment of the radiation safety program that will include the program areas described in Section V of this Order. In view of the concerns set forth in Section III of this Order, I have concluded that these additional actions are needed to increase and improve management attention to licensed activities so as to assure that these activities are conducted safely and in accordance with NRC requirements. Specifically, I have determined that the public health and safety require that Licensee No. 06–00819–03 be modified to confirm the Licensee's commitment to: (1) The performance of an independent assessment of the Licensee's radiation safety program, and, in particular, the management of that program, and (2) development and implementation of an improvement program to correct the deficiencies identified by the assessment. The Licensee consented to the issuance of this Confirmatory Order during the February 22, 1993 telephone call referenced above. Pursuant to 10 CFR 2.202, based on the significance of the violations described above, and on the licensee's consent to the Order, I have also determined that the public health and safety require that this Order be immediately effective.

V

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR parts 30 and 33, *it is hereby ordered*, Effective immediately, that License No. 06–00819–03 is modified as follows:

A. The Licensee shall retain the services of an expert, independent of the Licensee's staff, with extensive experience in the management and implementation of a broad scope radiation safety program to perform an assessment of the Licensee's radiation safety program and provide recommendations for a performance improvement program. Within 30 days from the date of this Order, the Licensee shall submit to the Regional Administrator, NRC Region I, for approval, the name and qualifications of the expert.

B. Within 120 days of NRC approval of the expert selection as described above, the assessment shall be completed, and a copy of the assessment report, including the expert's recommendations for an improvement plan, shall be submitted to the NRC within the following 15 days. The assessment of the Licensee's radiation safety program shall include, but not be limited to, a review of:

1. The Licensee's organization, and assigned responsibilities and authorities within that organization;

2. The Licensee's program for training and retraining individuals working with NRC-licensed materials, in NRC regulations, in the conditions of the License, in the licensee's QM program, and in safe practices for using licensed material;

3. The Licensee's methods of approving individuals for the use of licensed materials and developing procedures for the safe use of licensed materials;

4. The Licensee's program for training and qualifying all individuals involved in managing, supervising, inspecting and auditing licensed activities;

5. The Licensee's program of surveillance and audits to determine compliance by individual users of licensed materials with NRC regulations, the conditions of the NRC Licenses, the Licensee's QM program, and the Licensee's own procedures for the safe use of radioactive materials;

6. The adequacy of the existing staffing within the radiation safety department, to ensure that the items set forth in Section V.B.5 of this Order are adequately performed; and,

7. The Licensee's management of the radiation safety program, including the function of the Radiation Safety Committee and its methods of monitoring the program to ensure that problems are identified and promptly corrected.

C. Within 30 days of the Licensee's receipt of the assessment report, the Licensee shall submit a performance improvement plan to the Regional Administrator, NRC Region I, describing the methods of implementing the recommendations of the assessment report, or providing justification for alternate or no corrective action if any specific recommendations are not adopted. This plan shall include:

1. Action items completed or to be performed;

2. Schedules for, or dates of, completion of each specific action item; and

3. A system for monitoring and tracking the status and completion of the action items.

D. During implementation of the consultant's assessment, as well as the subsequent performance improvement plan, the Licensee shall provide written quarterly status reports to the NRC Region I office concerning the findings of the assessment, the development of the improvement plan, and the implementation of the plan, until such time as all items in the performance improvement plan have been implemented. Upon completion of all action items, a final report shall be submitted to the Regional Administrator, NRC Region I.

The Regional Administrator, NRC Region I, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

VI

Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be

whether this Confirmatory Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), any person adversely affected by this Order other than the Licensee, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section V above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 26th day of April 1993.

Hugh L. Thompson,

Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support.

[FR Doc. 93-10459 Filed 5-3-93; 8:45 am]

BILLING CODE 7590-01-M

PHYSICIAN PAYMENT REVIEW COMMISSION

Requests for Letters of Intent and Notice for Cooperative Agreements and Grants for Fiscal Year 1993

AGENCY: Physician Payment Review Commission.

ACTION: Notice.

The Physician Payment Review Commission is soliciting letters of intent for the development of research and analysis proposals in support of its ongoing work to advise Congress on issues specified in its legislative mandate. The Commission is looking to researchers to propose methodologies and databases that can make significant contributions to its deliberations in a number of policy areas. This notice describes the application procedures, general policy considerations, and criteria to be used in reviewing applications for the Commission's cooperative agreements and grants. This will be a two-stage process. First, all interested applicants must submit a letter of intent. Based upon the criteria discussed below, the Commission will select researchers to submit full proposals.

Background on the Commission

The Physician Payment Review Commission was established in 1986 (Pub. L. 99-272) to advise the U.S. Congress on physician payment policy under Part B of the Medicare program. The 13-member Commission is comprised of physicians, health economists, health services research experts, and individuals representing the perspectives of Medicare beneficiaries, private payers, nurses, and others expert in the field of health policy. Supporting the Commission is an multidisciplinary staff with skills in research, policy analysis, and administration.

In 1990, the Commission's legislative mandate was substantially expanded to include topics in addition to Medicare physician payment. Its responsibilities now include consideration of a broader set of interrelated policies affecting the financing, quality, and delivery of health services. These include access to care for residents of underserved areas, including those covered by Medicaid, medical malpractice reform, development of information and tools to improve quality and contain costs, cost containment under health system reform, financing of graduate medical education, and ensuring competency of physicians.

The Commission submits an annual report to the Congress on March 31. It also submits a series of reports in May making recommendations on Medicare Volume Performance Standards, monitoring access to care and the financial liability of Medicare beneficiaries, and commenting on the President's budget.

Priority Areas for Cooperative Agreements and Grant Funding

The Commission invites proposals on the following topics:

(1) *Use of tools to improve medical practice.* The Commission is interested in learning about the uses of tools to improve medical practice—such as profiling, protocols, and practice guidelines—by physician organizations, health plans, and in practice settings. It would like to known about the extent to which these entities are actively working with physicians (both to involve them in developing tools and to feed back information to them) and innovative ways in which these tools are being used. It is interested in examining whether and how groups that have ongoing relationships with physicians are providing them with information or engaging in activities to foster more cost-effective delivery of medical services.

(2) *Use of physicians and other health professionals in HMOs and multispecialty group practices.* For its work on both health system reform and graduate medical education, the Commission would like to learn more about the staffing experiences of group and staff model HMOs and multispecialty group practices. The types of issues studied should address include how these organizations use physicians and nonphysician practitioners, how work is allocated among primary care physicians and specialists, the impact of their hiring practices on the market for primary and specialty care physicians, how much retraining they find necessary for new staff, and their role in graduate medical education.

(3) *Effects of changes in payment policy for assistants-at-surgery.* In recent years, payments to assistants-at-surgery were reduced from 20 percent to 16 percent of the principal surgeon's payment and procedures with physicians billing as an assistant-at-surgery less than 5 percent of the time nationwide were excluded from payment. In addition, policies such as overvalued procedures and implementation of the Medicare Fee Schedule have reduced payments further by reducing the payment rates for surgery that payment to assistants is tied to. The result of these policies was to reduce aggregate payment to assistants-at-surgery by more than half. The Commission is interested in studies that would assess the impact of these payment policies on the pattern of use of assistants and the implications of any changes for patient care.

(4) *Certification of physicians to perform procedures.* The Commission will be taking up issues related to physician competency and credentialing in the coming year. As part of that work, it needs information on how hospitals and professional organizations certify physicians to perform certain procedures. It is interested in both the performance measures applied and the process used to determine competence for credentialing purposes.

(5) *Bundling of physicians' services for payment purposes.* Medicare and private payers have long used a bundled payment for major surgery that includes at least a defined range of pre- and postoperative evaluation and management services as well as the operation. The Commission is interested in research on options for additional bundling of related services performed by a single physician (for example, combining payment for certain diagnostic tests with payment for procedures or visits).

The Commission will also consider proposed studies related to bundling services in which multiple physicians are involved. It has a particular interest in a study of trauma services that would analyze the services provided by critical care and trauma specialists, review current methods of payment for trauma services, develop options for paying for these services, and consider whether there is a need for financial incentives to encourage the use of these specialists in the care of medicare beneficiaries. (this study would have to be completed by December 31, 1993.)

(6) *Delivering care to inner city populations.* To support its work on improving access to care for underserved populations, the Commission would like to learn from existing successful programs. The type of study it has in mind would: (1) Develop criteria for determining program success, (2) using those criteria, identify successful programs, (3) define the characteristics of these programs that have contributed to their success and determine whether there are common elements among successful programs that distinguish them from weak programs, and (4) assess which elements that increase the chances for success can be influenced through policy measures.

(7) *Risk measurement.* The Commission is interested in research to explore approaches to risk measurement that would be applicable to applying risk adjustments to the premiums paid to plans by an employer or a local health board. In particular, the Commission is interested in risk measures based on demographic data or health status (as opposed to those based on prior utilization). The Commission is specifically interested in identifying databases that could be used for testing the ability of such risk adjusters to predict average utilization for groups of enrollees.

(8) *Managed care and physicians.* The Commission, as part of its work on health system reform, is interested in the types of arrangements that managed-care plans, especially IPAs, PPOs, and point-of-service plans, make with physicians. It is interested in exploratory research to address several questions: (1) How do managed-care plans select physicians for their networks and remove physicians from networks; (2) how do they pay their primary-care physicians and their specialists (e.g., what types of capitation arrangements and fee schedules are used and for which physicians); (3) how do they monitor the care delivered by their physicians (e.g., what use is made of techniques such as profiling); and (4) what methods do they use to influence the practice patterns of their physicians (e.g., how do they use practice guidelines).

(9) *Categorization of ICD–9–CM diagnostic data.* The Commission is interested in developing a general-purpose research tool using ICD–9–CM diagnosis data. It plans to use this tool to investigate access to care in the elderly population using both outpatient and inpatient diagnostic data available on Medicare claims records.

At a minimum, it is looking for a summary and critique of the currently available commercial software packages that categorize patients by diagnosis and procedure. In addition, it is interested in developing a database (or possibly software) to analyze diagnosis data along several dimensions, including: (1) Broad and detailed categories of disease; (2) conditions avoidable through early detection or preventive care; (3) stage of disease (as in cancer staging); (4) conditions requiring follow-up care; (5) conditions requiring routine and periodic monitoring; (6) conditions attributable to socioeconomic but possibly non-medical factors (malnutrition, contagious disease); (7) chronic diseases common in the elderly; (8) conditions that limit ability to travel for care; (9) conditions indicative of significant cognitive impairment; (10) conditions for which there are clear-cut alternative surgical and medical treatment paths, and (11) such other categories as the researcher believes would be helpful in assessing access to care and patterns of health care delivery.

(10) *Episode of care analysis.* The Commission is interested in research to develop flexible definitions of episodes of care for the elderly, along with methods to categorize patterns of care. It intends to apply this research to its Medicare claims files to analyze differentials in access to care across the Medicare population. An example might clarify the type of research that is needed. A typical episode might center around hospitalization for diabetic ketoacidosis, and would examine the patterns of service use both before and after hospitalization. A lack of care prior to hospitalization or a lack of follow-up after discharge might both be considered indicators of poor access. This research project would determine a list of such sentinel events, appropriate pre- and post-event periods to include in the episode, and markers for adequate and inadequate care both prior to and following the event.

Application Process

The Commission encourages applications that seek to make significant contributions to knowledge in any of the areas mentioned above. All interested organizations that wish to be considered for an award must submit a letter of intent.

Criteria for Letter of Intent

Six copies of the letter of intent must be submitted by June 7, 1993. The letter should be double-spaced and contain the following:

1. Proposed area of research.
2. Brief summary of the application's objectives (2–3 paragraphs).
3. Brief summary of the proposed project including issues to be examined, research design, analysis plan, and data sources as appropriate (not to exceed 3–5 pages).
4. Resources available to conduct project (not to exceed 1 page).
5. Estimated budget and duration of project (not to exceed 1 page).
6. Knowledge and experience of principal investigator (not to exceed 1 page).

Applicants are discouraged from including extensive discussions of the nature of the problem, extensive reviews of the literature, general statements of capabilities, and summaries of the Commission's statements on the issues to be addressed.

Evaluation of Letters of Intent

Applicants' letters of intent will be reviewed by a technical review panel composed of at least three (3) persons. The panel will evaluate all letters and determine which applicants will be requested to submit a complete proposal. The recommendations for review will be based on the following criteria.

1. The relevance of the project to the Commission's work.
2. Description of the project objectives.
3. The adequacy of the study design, including specific hypotheses to be examined and data sources, as appropriate.
4. What the project will accomplish and how it relates to or differs from previous work in the area.
5. Investigator's knowledge and experience in the area.
6. The level of effort needed to conduct the project.

In addition to the recommendation of the review panel, the Commission may consider other factors in selecting which applicants will be asked to submit a formal proposal. These include compatibility of applications with

Commission priorities, as judged by senior staff, and the availability of resources.

The Commission will notify those applicants who have been selected to submit full proposals by sending them a formal Request for Proposal. Applicants will be given a minimum of 30 days to submit their formal proposal.

Formal Proposals

The following provides a basic outline of what selected applicants will be expected to submit in a formal proposal:

1. Project title and objectives.
2. Background and policy relevance of issue to be studied.
3. Study design, including statement of hypotheses, specification of variables, data source, sampling strategy, development of measures and/or survey instruments, and database management, as appropriate.
4. Analysis plan, including how data will be used and analyzed, analytic methods, potential problems and strategies for resolving problems.
5. Work plan including description of tasks, time schedule, and level of effort for key individuals and the number of days devoted to each task.
6. Qualifications of key project staff.
7. Organizational chart.
8. Detailed budget providing justifications and explanations for amounts requested.

Review of Proposals

Proposals will be reviewed by a panel composed of at least three (3) individuals. Reviewers will score applications, basing their scoring decisions and approval recommendations on the criteria published in the Commission's Request for Proposals, Part IV, Section M, "Technical Evaluation and Criteria for Award." This information is provided to all applicants invited to submit proposals.

General Information

Number and Size of Projects

The number of agreements depends on the availability of funds. Most awards range from $50,000 to $350,000 per project. It is anticipated that up to six (6) projects could be awarded through this solicitation.

Authority: The Commission's authority for making these awards is based on section 1845(c)(2)(B) of the Social Security Act (42 U.S.C. section 1395–1).

Regulations

General policies and procedures that govern the administration of cooperative agreements and grants are located in title 45 of the Code of Federal Regulations parts 74 and 92. Applicants are urged to review the requirements contained in those regulations.

Submission Address: Physician Payment Review Commission, 2120 L Street, NW., Suite 510, Washington, DC 20037.

Obligation

This solicitation in no way obligates the Commission to fund any applicant.

Contact: Paul B. Ginsburg, Ph.D., Director or Lauren LeRoy, Ph.D., Deputy Director, Physician Payment Review Commission, 2120 L Street NW., Suite 510, Washington, DC 20037. (202) 653–7220.

Dated: April 28, 1993.

Paul B. Ginsburg,

Executive Director.

[FR Doc. 93–10423 Filed 5–3–93; 8:45 am]

BILLING CODE 6820–BE–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–32221; File No. SR–NSCC–93–3]

Self-Regulatory Organizations; National Securities Clearing Corporation; Order Approving on a Temporary Basis a Proposed Rule Change Regarding the Establishment of a Pilot Program Relating to the Handling of Physical Securities and Paper Transactions for Participants Located in New York City

April 26, 1993.

On January 27, 1993, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR–NSCC–93–3) under section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] to establish a pilot program relating to the receipt, delivery, and handling of physical securities and paper transactions for participants located in New York City. Notice of the proposal was published in the Federal Register on February 16, 1993.[2] No comment letters were received. This order approves the proposal on a pilot basis until April 30, 1994.

I. Description

A. Background

Currently, NSCC offers certain services (collectively "Direct Clearing services")[3] to and acts as agent for participants not located in New York City. Direct Clearing services include: (i) Over-The-Window ("OTW") service;[4] (ii) interfacing with NSCC's Envelope Settlement Service ("ESS"),[5] Funds Only Settlement Service ("FOSS"),[6] and

---

[1] 15 U.S.C. 78(b)(1) (1988).

[2] Securities Exchange Act Release No. 31861 (February 16, 1993), 58 FR 9582.

[3] NSCC's Direct Clearing services are covered in NSCC's Procedures Section IX (Special Services), Subsections C (Depository Processing), D (Direct Clearing Department), and E (Cashiering Services).

[4] The Over-The-Window ("OTW") service accepts securities on behalf of, and delivers securities to, parties designated by participants. Securities received are checked for good form and apparent negotiability, and then are matched with receive instructions. Securities which are not in good form (i.e., not negotiable) or do not match receive instructions within specified tolerances are returned to the delivering participant. OTW receives can be reclaimed upon instruction from the delivering participant.

[5] ESS facilitates physical securities deliveries among participants. Participants may deliver envelopes containing securities to NSCC's designated location in New York (i.e., The Depository Trust Company ("DTC")) or at NSCC branch offices. Each delivery must be accompanied by a credit list, in duplicate, which lists each of the envelopes being delivered, the participant number of the participant to whom each envelope is addressed, and the total money value of the items contained in each envelope. Along with each envelope, the participants must include the corresponding balance order ticket issued by NSCC.

All envelopes delivered to NSCC will be verified against the credit list to ensure that each listed envelope, has, in fact, been received. If the envelopes are properly listed on the credit list, NSCC will stamp the duplicate copy of the credit list and make it available to the participant's representative making the delivery.

NSCC neither examines the contents of the envelopes nor verifies the amounts of money shown on the credit list, and is not responsible for such. NSCC is responsible only to deliver the envelopes accepted by it to the authorized representatives of the participants to whom they are addressed and to receive payment.

After the envelopes are verified against the credit list, they are then made available to participants designated as receivers on the envelopes. In the case of any irregularity in the item being delivered (e.g., incorrect securities, number of shares, or contra-party number, etc.), the receiving participant may return such item to the delivering participant under NSCC's reclamation procedures. Such reclaims must be submitted to NSCC on the day the items were received for same day credit or on the following day for next day credit.

At the time NSCC stamps the envelope's credit list, the envelope shall be deemed, according to NSCC Rules, to have been delivered to the receiving participant. Once the credit list is stamped, NSCC guarantees payment or a return of the envelope to the delivering participant. This means that in the event a receiving participant becomes insolvent, NSCC either will make payment to the deliverer for the value of the envelope in the event that NSCC has already delivered the envelope or, if possible, will intercept the envelope and return it to the delivering participant.

[6] FOSS facilitates delivery of money-only charges among participants. FOSS operates under the same procedures as ESS. A settling participant who desires to charge the account of another settling participant for a FOSS charge may do so by delivering a FOSS envelope to NSCC's designated location. The envelope must be accompanied by a credit list containing, among other items, the clearing number of the settling participant to whom each FOSS envelope is addressed and the amount of charges for each envelope.

Upon receiving the envelopes, NSCC neither examines the contents thereof nor verifies the

Dividend Settlement Service ("DSS");[7] (iii) processing transfers of physical securities;[8] (iv) processing securities deposits to and withdrawals from The Depository Trust Company ("DTC");[9] and (v) processing securities deliveries to designated agents in connection with reorganizations and other corporate actions.[10] In the course of providing these and other Direct Clearing services, NSCC may have custody of participants' physical securities, including overnight custody for one or more days, and may assist participants in orchestrating physical underwritings.[11]

Direct Clearing services are provided under the following conditions. First, in all instances, NSCC acts as agent for the applicable Direct Clearing participant and not as principal. Second, all actions taken by NSCC are based on instructions from the applicable Direct Clearing participant.[12] Finally, each Direct Clearing participant agrees that it will not be entitled to reimbursement from NSCC for any losses suffered or liabilities incurred as a result of Direct Clearing operations.[13]

B. NSCC's Rationale for the Proposed Rule Change

In recent years, NSCC participants who are located in New York City have been experiencing a continual decline in their activities associated with the processing of physical securities ("window activity").[14] This has been primarily a result of the increasing book-entry eligibility of securities that previously had been settled physically. Because window operations of NSCC participants have high fixed costs, the declining volume of window activity has caused certain participants, who for financial reasons no longer find it desirable to maintain their own window operations, to ask NSCC to offer Direct Clearing type services to participants located in New York City ("New York Window" or "NYW" service).

C. New York Window Services

The services to be offered under the NYW pilot program will be in the same general categories as those Direct Clearing services enumerated above which are offered to participants not located in New York City. That is, the NYW pilot program will include: (i) OTW service;[15] (ii) interface with NSCC's ESS, FOSS, and DSS functions; (iii) process transfers of physical securities;[16] (iv) process deposits to and withdrawals from DTC; and (v) process deliveries to designated agents in connection with reorganizations and other corporate actions. In the course of providing these services, NSCC may have custody of a participant's physical securities and may assist a participant in orchestrating a physical underwriting.

The NYW services will also be offered under the same conditions noted above which govern Direct Clearing services.[17] These conditions include: (i) In all instances, NSCC would act as agent for the applicable NYW pilot participant and not as principal; (ii) all actions taken by the NYW will be based on

---

amounts listed on the FOSS credit list against the amounts of the FOSS charges contained in the FOSS envelopes. NSCC also does not verify that the clearing number of the receiver listed on the FOSS credit list is identical to the clearing number listed on the FOSS envelope.

If the number of FOSS envelopes listed on the FOSS credit list is received by NSCC, NSCC will stamp the duplicate copy of the credit list and will return it to the settling participant's representative making the delivery. After NSCC stamps the credit list, such FOSS envelopes referenced on the stamped list are deemed for all purposes to have been delivered to the settling participants to whom they are addressed, and the envelopes will be made available at NSCC's designated locations to the settling participants. NSCC then will credit the delivering settling participant's account with the total amount of FOSS charges shown on the stamped FOSS credit list and will debit the receiving settling participants' accounts. FOSS charges are not guaranteed by NSCC and are subject to reversal.

In the case of any irregularity or error in a FOSS charge, the settling participant receiving the FOSS charge may adjust the FOSS charge directly with the charging settling participant or may reclaim the FOSS charge by submitting on the same day a Reclamation Notice setting forth the reason for the reclamation and delivering it to NSCC.

[7] DSS allows participants to submit claims against other participants for dividends or interest payments owed to the claiming participant. Prior to any charge against a participant for dividends or bond interest, the participant making the claim ("receiving participant") must submit a Notice of Intent to notify the delivering participant that a charge for such item will be made. Five business days after the day the Notice of Intent is sent to the delivering participant, the receiving participant will forward two copies of a Claim Form to the delivering participant. All Notices and Forms are sent to NSCC via the envelope system.

Similar to ESS and FOSS, DSS envelopes must be accompanied by a credit list. NSCC will stamp the duplicate list and will return it to the delivering participant's representative. Once the list is stamped, the envelopes referenced on the list are deemed for all purposes to have been delivered to the participants to whom the envelopes are addressed. NSCC then will credit the receiving participants' accounts with the dollar amount stated on the credit list and debit the delivering participants' accounts for the same amount.

DSS claims are not guaranteed by NSCC and are subject to reversal. The participant against whom the charge is made can reconcile a disputed charge directly with the charging participant or through NSCC by delivering a Reclamation Notice to NSCC on the same day the disputed claim is received or on a subsequent day.

[8] Using Direct Clearing services, a participant can have securities delivered to a designated transfer agent and/or picked up after the securities have been reregistered.

[9] Through Direct Clearing, participants can have securities held in custody or received through the OTW or ESS Interface services packaged and delivered to DTC for deposit. Using Direct Clearing, participants also can deliver prepackaged securities for deposit at DTC. At the request of participant, NSCC also will retrieve withdrawals and rejected securities deposits from DTC.

[10] Direct Clearing handles reorganizations and other corporate actions to the extent that it is instructed to do so by participants. Direct Clearing is not responsible for following or informing participants of any upcoming or impending corporate reorganizations or other actions. It is each participant's responsibility to instruct NSCC to make Direct Clearing deliveries of securities (either out of custody positions or from OTW or ESS Interface receives) to the designated agent. Furthermore, as distinct from the Transfer service, in Direct Clearing NSCC only acts in the capacity of a messenger for the securities being delivered to the designated agent. Thus, if any documentation is required to accompany the securities delivery (e.g., letters of transmittal), the participant must complete the necessary documents and must arrange for these documents to be picked up by or delivered to NSCC so that NSCC can include the documents with the securities delivery through Direct Clearing. NSCC does not examine these documents.

[11] A participant that is the lead manager in a physical underwriting can use Direct Clearing to assist in orchestrating the closing. Specifically, a lead manager participant can use Direct Clearing to pick up the securities at closing from a registrar based in New York City, to count them, to verify that they are registered in accordance with the lead manager's instructions, to receive checks from selling group members, and to release securities to selling group members after closing. For purposes of monitoring flipping activity, the lead manager can use Direct Clearing to track the certificate numbers that are delivered to each member of the selling group and that are received through Direct Clearing on behalf of the lead manager during the stabilization period.

[12] These instructions may be special instructions or standing instructions.

[13] In compliance with New York law, there is an exception for losses resulting from NSCC's gross negligence or willful misconduct. As with any NSCC operations, any lack of entitlement to reimbursement for losses does not prevent NSCC from determining in its sole and absolute discretion to provide such reimbursement in particular instances.

[14] The activities associated with the processing of physical securities are similar to those provided by NSCC in its Direct Clearing service described above.

[15] The pilot program's scope of services is narrower than the Direct Clearing services currently offered (*supra*, note 4). To the extent that OTW deliveries are to be paid for by check, NSCC's NYW will accept checks on behalf of NYW participants and either deliver them to participants or deposit them on behalf of participants. If the payment obligation is to settle in same day funds, NSCC will transmit related wire payment instructions to NYW participants for their execution. NSCC's NYW service will neither actually make wire payments nor will it sign checks on behalf of participants.

[16] The NYW will offer both accommodation transfers and direct transfers. For accommodation transfers, the NYW will act simply as a messenger service which makes deliveries to and pickups from transfer agents. NSCC will not examine the items being delivered or picked up. In a direct transfer, the NYW participant must specify which securities should be sent to the transfer agent and the registration details. NSCC then will prepare appropriate transfer documentation and make the delivery to the transfer agent. Upon pickup, NSCC will check to ensure that the transfer agent has complied with the transfer instructions.

[17] *Supra* notes 12 and 13 and accompanying text.

instructions from the applicable NYW pilot participant; and (iii) each NYW pilot participant will agree that it will not be entitled to reimbursement from NSCC for any losses suffered or liabilities incurred as a result of the operations of the NYW pilot program. Additionally, the NYW pilot participants will each be responsible for their own payment obligations resulting from NYW processing. Thus, to the extent that receives or deliveries processed by the NYW result in same-day funds payment obligations, the wire transfers will be made directly between the NYW participants and the other parties to the transactions and not through NSCC. To the extent that they result in next-day funds payment obligations, checks will be exchanged directly between the NYW participants and the other parties to the transactions with the NYW serving only as a conduit through which checks can be received and picked up.[18]

The needs of NYW participants differ from the needs of direct clearing participants located outside of New York; therefore, NSCC will keep the NYW program operationally separate and distinct from the direct clearing services currently offered to non-New York City participants. The participants' needs differ primarily because the physical securities processed for participants located in New York City will consist mostly of money market instruments (e.g., commercial paper, bankers acceptances, certificates of deposit, etc.) and asset-backed securities, whereas the physical securities processed under current direct clearing operations for non-New York City participants are primarily equity securities and corporate and municipal debt.

A result of helping New York City participants manage deliveries and receipts of money market instruments will be a greater need for NSCC to process same day turnarounds. Another result will be an increase in the dollar value of securities being held in temporary custody by NSCC. A difference in custodial needs not related to the processing of money market instruments is that NSCC expects to be asked to hold certain securities (i.e., primarily non-money market securities) for longer periods of time than is usual in current direct clearing operations.[19]

NSCC will lease vault space from DTC in order to safeguard the securities they expect to hold overnight under the NYW program. DTC personnel will not have access to the vault space leased to NSCC.[20] NSCC will have full responsibility for the securities under its custody, and only its staff will have access to and will handle these securities. In addition, NSCC will be responsible for keeping the books and records with respect to securities so held.

The securities belonging to different participants will not be commingled with the securities being held for any other participant, and unless these securities are bearer instruments, they will be held in street name or in customer name but not in NSCC's nominee name. NSCC will be responsible for following participants' instructions regarding the segregation of customer positions which are held in custody by NSCC, and no deliveries will be made from customer positions absent specific instructions from the relevant participant. All deliveries from NSCC, as custodian, to the relevant participant will be free deliveries (i.e., they will not require payment), and NSCC will specifically disclaim any lien on customer positions held in custody.

In its initial phase, the NYW pilot program will utilize the systems of the participants in the program. Thus, each participant in the pilot program will install at the NYW location the terminals and printers currently used in its own New York window operations. NSCC NYW employees, to the extent they are not hired from the participating firms, will be trained to use these systems, and the receives and deliveries for each participant will be processed by the NYW in the same manner as they are currently processed by the participants in their own New York window operations.

II. Discussion

Section 17A(a)(1)(B) of the Act sets forth Congress' findings that inefficient procedures for clearance and settlement of securities transactions impose unnecessary costs on investors and persons facilitating transactions by and acting on behalf of investors.[21] Section 17A(a)(1)(D) states Congress' findings that the linking of all clearance and settlement facilities and the development of uniform standards and procedures for clearance and settlement will reduce unnecessary costs and increase the protection of investors and persons facilitating transactions by and acting on behalf of investors.[22]

The Commission believes that NSCC's proposed pilot program will help minimize the inefficient procedures currently utilized by the individual New York City participants by concentrating these operations in one centralized location. As a result, the individual participants will be able to eliminate their New York City window operations and the high fixed costs associated with them and will be able to rely upon NSCC's experience in providing Direct Clearing services.

As stated above, during the pilot stage NSCC will operate the individual participants' window programs. After operating the pilot for a period of time, NSCC will evaluate the program to determine whether any changes should be made and whether to expand and standardize the operations to allow a larger number of participants to participate.[23] The Commission believes that by enabling NSCC to coordinate the processing of physical securities NSCC should be able to develop more efficient and standardized procedures for the clearance and settlement of physical securities and, thereby, should be able to reduce unnecessary costs on investors and persons facilitating transactions by and acting on behalf of investors.

Section 17A(b)(3)(A) of the Act requires that a clearing agency be organized and have the capacity to safeguard securities and funds in its custody or control or for which it is responsible.[24] NSCC will undertake several safeguards to comply with this statutory mandate. The safety procedures established and currently employed in Direct Clearing services for participants not located in New York City will be incorporated into the NYW program. As previously stated, NSCC will act only as agent for NYW participants and will act only upon instructions from the participants. NSCC also will limit its liability for direct clearing losses to losses resulting from NSCC's gross negligence or willful misconduct.

[18] Service charges resulting from NSCC's ESS, FOSS, or DSS functions will continue to be settled through NSCC's net settlement system.

[19] This can partially be attributed to NYW participants wanting NSCC to hold these securities in anticipation of a redelivery, generally to another New York City participant, within a few days of receipt. It is inefficient to have NSCC deliver these securities to the receiving participant where the receiving participant soon will redeliver them to NSCC for delivery to another participant. Non-New York City participants generally do not redeliver these securities as quickly, if at all and, therefore, prefer to take physical possession. Meeting between Peter J. Axilrod, Vice President and Associate General Counsel, NSCC, and Peter R. Geraghty, Attorney, Division of Market Regulation ("Division"), Commission (March 3, 1993).

[20] Letter from Karen G. Lind, Associate Counsel, DTC, to Peter R. Geraghty, Attorney, Division, Commission (April 5, 1993).

[21] 15 U.S.C. 78q–1(a)(1)(B).

[22] 15 U.S.C. 78q–1(a)(1)(D).

[23] Any changes to the New York Window program will necessitate the filing of a proposed rule change under section 19(b)(2) of the Act.

[24] 15 U.S.C. 78q–1(b)(3)(A).

In addition, NSCC will initiate procedures and safeguards specific to the NYW program. Under the NYW program, NSCC will serve only as a conduit through which participants can deliver checks to and receive checks from other participants and will not wire funds to participants. NSCC will take additional precautionary measures to help ensure the safety of the securities for which it has custody under the NYW program. NSCC will lease separate vault space to hold only these securities, and access will be restricted to NSCC personnel. NSCC also will be responsible for keeping the books and records for securities held under the NYW program. Securities belonging to different participants will not be commingled, and NSCC will follow participants' instructions regarding the segregating of customer accounts. Securities in NSCC's custody will not be held in NSCC's nominee name. The Commission believes the measures taken by NSCC enable NSCC to meet its statutory responsibility regarding safeguarding the securities in its custody or control or for which it is responsible under the NYW program.

The Commission is approving NSCC's pilot program on a temporary basis until April 30, 1994, in order that the Commission and NSCC may further study the effects and efficiencies of the program.

III. Conclusion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular with the requirements of section 17A of the Act.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act,[25] that the proposed rule change (File No. SR-NSCC-93-3) be, and hereby is approved on a temporary basis until April 30, 1994.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[26]

Jonathan G. Katz,

Secretary.

[FR Doc. 93-10490 Filed 5-3-93; 8:45 am]

BILLING CODE 8010-01-M

[25] 15 U.S.C. 78s(b)(2).

[26] 17 CFR 200.30-3(a)(12).

Self-Regulatory Organizations; Participants Trust Co.; Filing and Order Granting Accelerated Approval of a Proposed Rule Change Relating to an Increase in the Number of Directors

[Release No. 34-32213; File No. SR-PTC-93-01]

April 26, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on March 26, 1993, Participants Trust Company ("PTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice and order to solicit comments on the proposed rule change and to grant approval of the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would amend Article 3, Section 3.2 of PTC's By-laws to increase the number of directors on PTC's Board of Directors from twelve to fifteen.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Section 3.2 (Number; Classification; Election; Term of Office) of Article 3 (Directors) of PTC's Bylaws provides that PTC's Board of Directors shall consist of twelve directors, divided into three classes of four directors each. PTC proposes to amend Section 3.2 of PTC's By-laws to increase the number of directors to fifteen by the addition of one director to each of the three classes. The change would be implemented commencing with the election of directors to be held at the 1993 annual stockholders meeting.[2] PTC believes that the increase in directors will enhance the fair representation of its stockholders. The additional positions will provide the stockholders an increased opportunity to elect directors who represent their views.

PTC believes that the proposed rule change is consistent with the requirements of section 17A of the Act.[3] Specifically, PTC believes the proposed rule change is consistent with section 17A(b)(3)(C) of the Act in that it helps assure the fair representation of stockholders and participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

PTC does not believe that the proposed rule change will impose any burden upon competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments were not and are not intended to be solicited with respect to the proposed rule change, and none were received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

PTC requests the Commission find good cause for approving the proposed rule change on an accelerated basis prior to the thirtieth day after the date of publication of notice of the filing. The Commission finds good cause exists under section 19(b)(2) of the Act for granting accelerated approval in that accelerated approval would permit the stockholders of PTC to elect directors for the newly created positions at the Annual Meeting of Stockholders to be held on April 28, 1993.[4]

Section 17A(b)(3)(C) of the Act requires that the rules of a clearing

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] At the annual meeting, scheduled for April 28, 1993, the shareholders first will vote on the proposed Board increase, as required by Section 3.2 of PTC's By-laws, prior to the election of the new directors.

[3] 15 U.S.C. 78q-1.

[4] Pursuant to section 19(b)(4)(A) of the Act, 15 U.S.C. 78s(b)(4)(A) (1988), the Commission contacted the Board of Governors of the Federal Reserve System ("Federal Reserve"), PTC's appropriate regulatory agency, regarding the proposed rule change. Staff of the Federal Reserve believes that the proposed rule change is consistent with PTC's obligation to safeguard securities and funds in its custody or control or for which it is responsible, and did not object to the proposed accelerated approval. Telephone conversation between Don R. Vinnedge, Manager, Trust Activities Program, Federal Reserve, and Christine Sibille, Staff Attorney, Division of Market Regulation, Commission (April 16, 1993).

agency assure the fair representation of its stockholders and participants in the election of its directors and administration of its affairs. The Commission previously has found that PTC's rules for selecting its directors were designed to assure fair representation.[5] Under PTC's Rules, only a participant of PTC may become a PTC stockholder. Once a year, all participants are given an opportunity to purchase shares of PTC stock, either from PTC or from stockholders who want to sell some of their holdings. At no time may a single stockholder own more than 5% of the total issued and outstanding PTC stock. The stockholders agreement, executed upon the initial purchase of shares by each participant, provides for cumulative voting in the election of directors.[6]

By permitting each participant to decide how much PTC stock to own, and thereby to decide the size of the role it wishes to play in the election process, PTC provides an opportunity to each participant to be represented on the Board. This, along with the 5% limitation on stock ownership by any individual participant, will restrict the ability of any large participant to control the Board to the detriment of the smaller participants. The increase in the number of directors, from twelve to fifteen, will permit the Board to represent a larger portion of the participant base in a fair way, by permitting greater representation of different interests on the Board. The change, together with the cumulative voting feature of PTC's rules, should provide for fair representation from all segments of PTC's market participant base. The Commission therefore finds that the proposed rule change is consistent with section 17A(b)(3)(C) of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549.

Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to File Number SR-PTC-93-01 and should be submitted by May 25, 1993.

V. Conclusion

On the basis of the foregoing, the Commission finds that PTC's proposed rule change is consistent with the Act and, in particular, with section 17A of the Act.

It is therefore ordered, Under section 19(b)(2) of the Act, that the proposal (File No. SR-PTC-93-01) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93-10493 Filed 5-3-93; 8:45 am]

BILLING CODE 8010-01-M

[5] See Securities Exchange Act Release No. 26671 (March 28, 1989), 54 FR 13266.

[6] Section 3.2 of PTC's By-laws provides for stockholder election of directors. Under cumulative voting, a stockholder is given a total number of votes it may cast, equalling the number of shares owned times the number of directors' positions to be filled. The stockholder may give all its votes to one candidate, or may divide its votes among the candidates in any manner.

[Rel. No. IC-19442; 811-3413]

American General Equity Accumulation Fund, Inc.; Application for Deregistration

April 28, 1993.

AGENCY: Securities and Exchange Commission ("SEC" or the "Commission").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "1940 Act").

APPLICANT: American General Equity Accumulation Fund, Inc.

RELEVANT 1940 ACT SECTION: The application was filed pursuant to section 8(f) of the 1940 Act and Rule 8f-1 thereunder.

SUMMARY OF APPLICATION: The applicant seeks an order declaring that it has ceased to be an investment company as defined by the 1940 Act.

FILING DATE: The application was filed initially on February 9, 1993. An amended and restated application was filed on April 23, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving the applicant with a copy of the request, personally or by mail. Hearing requests must be received by the SEC by 5:30 p.m. on May 24, 1993, and should be accompanied by proof of service on the applicant in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, Huey P. Falgout, Jr., Esq., American Capital Asset Management, Inc., 2800 Post Oak Blvd., Houston, TX 77056.

FOR FURTHER INFORMATION CONTACT: Patrice M. Pitts, Attorney, or Michael V. Wible, Special Counsel, at (202) 272-2060, Office of Insurance Products (Division of Investment Management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application. The complete application may be obtained for a fee from the Commission's Public Reference Branch.

Applicant's Representations

1. The applicant was organized as a Maryland corporation on December 4, 1981.

2. On March 10, 1982, the applicant filed a notification of registration on Form N-8A under the 1940 Act. On that same date, the applicant filed a registration statement under the 1940 Act and the Securities Act of 1933 on Form N-1 (File No. 2-76419) for five hundred million (500,000,000) shares of common stock of a single class. The Form N-1 registration statement became effective on June 29, 1982, and the initial public offering commenced on July 23, 1982.

3. The Variable Annuity Life Insurance Company ("VALIC"), American General Life Insurance Company of New York ("AGNY"), and American General Life Insurance Company of Delaware ("AG Life") each maintain and operate separate accounts (the "Separate Accounts") which invest in the applicant, the American General Fixed-Income Accumulation Fund, Inc., and the American General Money Market Accumulation Fund, Inc. (collectively, the "ACAM Funds").

4. After experiencing several years of substantial net redemptions of ACAM Funds shares, the management of the ACAM Funds met with representatives

of VALIC, AGNY, and AG Life to discuss means of reversing that trend. These discussions led VALIC, AGNY, AG Life, and the Separate Accounts, to pursue the substitution of shares of the American General Series Portfolio Company ("AGSPC") and the American Capital Life Investment Trust (the "LIT Fund") for shares of the ACAM Funds.

5. In March 1991, VALIC, AGNY, AG Life, the Separate Accounts, AGSPC, the LIT Fund, and the ACAM Funds filed an application with the Commission requesting an order under section 26(b) of the Investment Company Act of 1940 (the "1940 Act") approving the substitution of AGSPC and LIT Fund shares for ACAM Funds shares (the "Substitution"), and, under section 17(b), or alternatively, under section 6(c) of the 1940 Act, granting exemptions from sections 17(a)(1) and 17(a)(2) of the 1940 Act to the extent necessary to permit the transfer of portfolio securities of the ACAM Funds to AGSPC and the LIT Fund.

6. On September 20, 1991, the Commission issued an order pursuant to section 26(b) of the 1940 Act, approving the substitution of shares of AGSPC and the LIT Fund, and pursuant to section 17(b) or, alternatively, section (6)(c) of the 1940 Act, exempting VALIC, AGNY, AG Life, and the Separate Accounts from section 17(a) of the 1940 Act to the extent necessary to permit certain purchase and sale transactions between affiliates in connection with the Substitution.

7. Effective September 30, 1991, the applicant, acting on behalf of its shareholders and in satisfaction of redemption requests by such shareholders in connection with the Substitution, transferred: To the LIT Fund, securities valued at $7,022,837.50, and $5,630,383.52 in cash; and to AGSPC, securities valued at $28,141,962.50, and $22,029,763.93 in cash.

8. All expenses incurred in connection with carrying out the Substitution were borne by American Capital Asset Management, Inc., the applicant's investment adviser.

9. In connection with Substitution, the applicant made distributions to all of its security holders.

10. The applicant has no assets, debts, other liabilities, or security holders. The applicant has not transferred any of its assets to a separate trust, the beneficiaries of which were security holders of the applicant.

11. The applicant is not a party to any litigation or administrative proceeding (other than this deregistration proceeding).

12. The applicant presently is not engaged, nor does it propose to engage, in any business activities other than those necessary to wind up its affairs.

13. The applicant represents that, as of the time of the filing of this application, it was current in all filings required to be made pursuant to the 1940 Act, including any required Forms N-SAR.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93-10489 Filed 5-3-93; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-19438; 812-7972]

The Benchmark Funds, et al.; Application for Exemption

April 27, 1993.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: The Benchmark Funds ("Trust"), The Northern Trust Company ("Northern"), and Goldman, Sachs & Co. ("Goldman Sachs").

RELEVANT ACT SECTIONS: Exemption requested pursuant to section 6(c) from sections 2(a)(32), 2(a)(35), 18(f)(1), 18(g), 18(i), 22(c), 22(d) and rule 22c-1 thereunder.

SUMMARY OF APPLICATION: Applicants seek a conditional order pursuant to section 6(c) of the Act to permit the Trust and other investment companies for which Northern acts in the future as investment adviser, sub-adviser or, if and when permitted under applicable law, distributor to issue and sell an unlimited number of classes or series of new units of securities representing interests in the same portfolio, and to permit the imposition and waiver of a contingent deferred sales charge ("CDSC") on certain redemptions of units.

FILING DATE: The application was filed on July 2, 1992, and amended on November 18, 1992. By supplemental letters dated April 9, 1993 and April 22, 1993, counsel, on behalf of applicants, agreed to file a further amendment during the notice period to make certain technical changes. This notice reflects the changes to be made to the application by such further amendment.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Any interested person may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 24, 1993 and should be accompanied by proof of service on applicants in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants: The Benchmark Funds, 4900 Sears Tower, Chicago, Illinois 60606; The Northern Trust Company, 50 S. LaSalle Street, Chicago, Illinois 60675; and Goldman, Sachs & Co., 85 Broad Street, New York, New York 10004.

FOR FURTHER INFORMATION CONTACT: Felicia H. Kung, Senior Attorney, at (202) 504-2803, or Elizabeth G. Osterman, Branch Chief, at (202) 272-3016 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Trust is a Massachusetts business trust registered under the Act as an open-end management investment company. Northern is the Trust's investment adviser, transfer agent and custodian. Goldman Sachs is the Trust's distributor and administrator. The Trust currently offers twelve series of units representing interests in twelve separate investment portfolios: The Diversified Assets Portfolio, the Government Portfolio, the Government Select Portfolio, the Tax-Exempt Portfolio, the California Municipal Portfolio, the Equity Index Portfolio, the Small Company Index Portfolio, the Diversified Growth Portfolio, the U.S. Treasury Index Portfolio, the U.S. Government Securities Portfolio, the Short-Intermediate Bond Portfolio, and the Bond Portfolio. The Diversified Assets, Government, Government Select, Tax-Exempt and California Municipal Portfolios use the amortized cost method of valuation under rule 2a-7 of the Act (together with any similar future investment portfolios, the "Money Market Portfolios"). The Trust's registration statement has been

amended to include two additional portfolios, but shares of such portfolios currently are not offered.

2. Units of the Trust's active portfolios currently are offered by Goldman Sachs exclusively to Northern, its affiliates, and correspondent banks and their customers at net asset value.

3. Applicants seek an exemptive order from the SEC permitting the Trust and other investment companies for which Northern acts in the future as investment adviser, sub-adviser or, if and when permitted under applicable law, distributor (collectively with the Trust, the "Companies") to offer an unlimited number of classes or series of new units of securities in their existing and future investment portfolios ("New Classes"). These classes may be offered (a) in connection with a plan adopted pursuant to rule 12b–1 ("Distribution Plan"); and/or (b) in connection with a non-rule 12b–1 administrative plan ("Administrative Plan"); and/or (c) subject to the imposition of varying front-end sales charges; and/or (d) subject to the imposition of varying CDSCs.

4. With respect to each New Class, a Company could adopt a Distribution Plan and/or an Administrative Plan (collectively, "Plan" or "Plans")[1] concerning the financing of marketing programs intended to result in the sale of units and the provision of various distribution and administrative services. Such services might be provided directly by a Company's distributor, or by groups, organizations, or institutions ("Organizations") which have entered into agreements (collectively, "Plan Agreements") with the Company or its distributor or administrator concerning the provision of services to the clients, members, or customers of such Organizations who from time to time beneficially own units of a particular class ("Class Unitholders").

5. Under a Distribution Plan, a Company's distributor or Organizations could provide distribution-related services undertaken in connection with the sale of units covered by the plan. For example, such services could include engaging in advertising provided on behalf of the Company for clients, and preparing, printing, and distributing prospectuses and unitholder reports. For New Classes with a CDSC, under a Distribution Plan a Company might pay an annual fee to the Company's distributor as compensation related to the offering of such New Classes. These expenses could include, but would not be limited to, the payment of sales commissions and incentive compensation, as well as advertising and promotional costs. Organizations also may provide administrative services under a Distribution Plan.

6. Under an Administrative Plan, Organizations would provide services relating to the indirect relationship between a Company and the beneficial unit owners, such as, for example, aggregating and processing purchase exchange and redemption requests for units from clients, and placing net purchase exchange and redemption orders with the distributor. The services provided under an Administrative Plan would not duplicate the services provided by a Company's investment adviser, transfer agent, and administrator. In addition, Organizations may charge other fees directly to their Class Unitholders in connection with their Class Unitholder accounts. These fees would be in addition to any amounts received by the Organization under a Plan Agreement.

7. Payments to a Company's distributor or Organizations for expenses, services, and assistance would be made in accordance with the terms of the particular Plan ("Plan Payments") and would be borne entirely by the beneficial owners of the New Class of the portfolio to which the payments relate. Plan Payments paid pursuant to a Distribution Plan currently are not expected to exceed .75% per annum of the average daily net asset value of the units of the New Class subject to the particular Distribution Plan. Payments paid pursuant to an Administrative Plan also are not expected to exceed .75% per annum of the average daily net asset value of the units of the New Class subject to the particular Administrative Plan. In addition, for any New Class having both a Distribution Plan and an Administrative Plan, total Plan Payments under both Plans currently are not expected to exceed 1.25% per annum of the average daily net asset value of the units of the New Class. Certain provisions of Article III, Section 26 of the Rules of Fair Practice of the National Association of Securities Dealers, Inc. ("NASD") relating to the maximum amount of asset based sales charges that may be imposed by an investment company, which become effective on July 7, 1993, would effectively limit total Plan Payments under a Distribution Plan and an Administrative Plan to 1.00% per annum of the average daily net asset value of the units of a New Class with both Plans. The maximum level of payments made pursuant to a Plan might vary based upon an independent determination by the board of trustees of the Company involved, and in the case of a Distribution Plan, subject to unitholder approval of the affected New Class. In all cases, however, the Companies shall comply with Article III, Section 26 of the Rules of Fair Practice of the NASD as it relates to the maximum amount of asset-based sales charges that may be imposed by an investment company, when and in the form (as amended from time to time) the provisions of such Rules relating to such charges become effective, and for as long as they remain in effect.

8. Expenses of a Company that could not be attributed directly to any one portfolio ("Company Expenses") would be allocated to each portfolio based on the relative net assets of such portfolio or as otherwise determined under the supervision of its trustees. Such expenses could include, for example, trustees' fees and expenses, and insurance premiums. Certain expenses may be attributable to a portfolio but not to a particular class ("Portfolio Expenses"). All such Portfolio Expenses incurred by a portfolio would be allocated to each class based on the relative net asset value of the respective classes in the portfolio. Portfolio Expenses could include, for example, advisory fees, portfolio accounting fees, custodian fees, and fees related to preparation of separate documents of the portfolio. In addition, certain expenses may be directly attributable to a particular class and will be allocated to that class exclusively ("Class Expenses"), in accordance with the conditions described hereinafter.

9. The net asset value per unit in each portfolio would be calculated and determined in the same manner and on the same days and at the same times, regardless of class. The net investment income and capital gains, if any, of each portfolio would be declared and paid at the same times to all unitholders of the portfolio. Expenses, other than Plan Payments and Class Expenses, would be borne on a *pro rata* basis by each class on the basis of the relative net asset value of the respective class. Although the method of determining net asset value of classes within a portfolio would be identical, the net asset value of classes within the portfolios (excluding the Money Market Portfolios, which maintain a stable net asset value per unit) may differ because of different

[1] Units offered in connection with an Administrative Plan will not necessarily be accorded the voting rights specified in rule 12b–1, although the trustees of the Company involved might approve an Administrative Plan with such rights in order to give holders of such units rights identical to holders of units subject to a Distribution Plan.

Plan Payments and Class Expenses assessable to a particular class.

10. Units of certain of the New Classes may be subject to the imposition of a CDSC if such units are redeemed within a particular period of time after their purchase. The CDSC would be imposed at a rate equal to a specified percentage or percentages of the lesser of the net asset value of the units at the time of purchase or the net asset value of the units at the time of redemption. The CDSC would be deducted from the redemption proceeds otherwise payable to the unitholder and would be retained by the distributor.

11. No CDSC would be imposed with respect to: (a) The portion of redemption proceeds attributable to increases in the value of the units due to capital appreciation; (b) units acquired through the reinvestment of income dividends or capital gain distributions; or (c) units held for more than a certain period of time after their purchase.

12. In determining whether a CDSC would be payable, it would be assumed that units, or amounts representing units, that are not subject to a CDSC would be redeemed first and other units or amounts would be redeemed in the order purchased. The same CDSC would be imposed on all unitholders of a New Class except that scheduled variations in or elimination of CDSCs may be offered to particular classes of unitholders or in connection with classes of particular transactions.

13. The amount of the CDSC and the timing of its imposition for a New Class of a portfolio may vary among the portfolios, as may the circumstances under which the CDSC may be waived. Any change in the specified terms of a CDSC arrangement with respect to its implementation by a portfolio will be reflected in the portfolio's prospectus, and will not affect units already issued unless such change will result in more favorable terms to the holders of such units. No CDSC would be imposed on any units purchased prior to the effective date of the requested order or prior to the amendment of the affected portfolio's prospectus disclosing the CDSC arrangement.

14. The CDSC would be waived for the following redemptions: (a) Redemptions in connection with distributions to participants or beneficiaries of an employee pension, profit-sharing or other trust or qualified retirement plan; (b) redemptions in connection with distributions to participants in qualified retirement plans due to death, disability or the attainment of age 59½; (c) redemptions effected pursuant to a portfolio's right to liquidate a unitholder's account if the aggregate net asset value of units held in the account is less than the minimum account size; or (d) redemptions in connection with the combination of the portfolios with any other investment company registered under the Act by merger, acquisition of assets, or by any other transactions.

15. A Company will offer an exchange privilege whereby units of a New Class in a portfolio could be exchanged for units of the corresponding New Class in another portfolio in accordance with rule 11a–3.

Applicants' Legal Analysis

1. Applicants request an exemptive order under section 6(c) to permit the proposed issuance and sale of units representing interests in a Company's existing and future portfolios to the extent that such issuance and sale might be deemed to: (a) Result in the issuance of a "senior security" within the meaning of section 18(g), (b) be prohibited by section 18(f)(1), and (c) violate the equal voting provisions of section 18(i). Applicants also seek an exemption from sections 2(a)(32), 2(a)(35), 22(c) and 22(d) of the Act and rule 22c–1 thereunder to the extent necessary to permit the imposition and waiver of a CDSC on redemption of units of the non-Money Market Portfolios.

2. Applicants contend that the proposed multi-class system will better enable Companies to facilitate the distribution of their securities while expanding the scope of their services without excessive operational costs or unnecessary investment risks. Applicants also contend that the proposed multi-class structure would permit Companies to match more precisely their distribution costs, administrative support, and transfer agency and other expenses with those investors on whose behalf such costs and expenses are incurred. In addition, applicants assert that the proposed arrangement will enable a Company and its unitholders to save the organizational and other continuing costs that would be incurred if a Company were required to establish a new separate investment portfolio for each class of units.

3. Applicants assert that the requested relief does not present the concerns which section 18 was designed to address because the proposed arrangement does not involve borrowings or affect the Companies' existing assets or reserves. Applicants further assert that the proposed arrangement does not increase the speculative character of the units in a portfolio because all units in a portfolio will participate *pro rata* in all of the portfolio's income and expenses, with the exception of the proposed Plan Payments and Class Expenses. In addition, applicants contend that the Companies' capital structures under the proposed arrangement will not induce any group of unitholders to invest in risky securities to the detriment of any other group of unitholders since the investment risks of each portfolio will be borne equally by all of its unitholders. Applicants assert that mutuality of risk will be preserved with respect to all units in a portfolio.

4. Applicants assert that investors will not be given misleading impressions as to the safety from risk of the units and the nature of the units will not be rendered speculative because all units in a portfolio will be redeemable at all times, no class of units will have any distribution or liquidation preference or priority over another class of units in the portfolio and no class will be protected by any reserve or other account, and the similarities of the units will be fully disclosed in the portfolio's prospectuses.

5. Applicants represent that the Companies' capital structures under the proposed arrangement will not enable insiders to manipulate the expenses and profits among the classes of units because (a) the Companies are not organized in a pyramid fashion, (b) all expenses and profits of a class, except the Plan Payments and Class Expenses, will be allocated in proportion to the net asset values of the units of each portfolio, irrespective of class, and (c) all unitholders will have equal voting rights, except with respect to matters pertaining to the Plans and Plan Agreements applicable to particular classes of units of a portfolio.

Conditions to Relief

If the requested relief is granted, applicants agree to the following conditions:

1. Each class of units representing interests in the same portfolio of investments of a Company will be identical in all respects, except as set forth below. The only differences between the classes of units of the same portfolio will relate solely to: (a) The impact of (i) expenses assessed to a class pursuant to a Plan; (ii) other Class Expenses which would be limited to (A) transfer agent fees identified by the transfer agent as being attributable to a specific class of units; (B) printing and postage expenses related to preparing and distributing materials such as unitholder reports, prospectuses and proxies to current unitholders of a class; (C) blue sky registration fees incurred by

a class of units; (D) SEC registration fees incurred by a class of units; (E) the expense of administrative personnel and services as required to support the unitholders of a specific class; (F) litigation or other legal expenses or audit or other accounting expenses relating solely to one class of units; and (G) trustees' fees incurred as a result of issues relating to one class of units; and (iii) any other incremental expenses subsequently identified that should be properly allocated to one class and which are approved by the Commission pursuant to an amended order; (b) the fact that the classes will vote separately with respect to a portfolio's Plans; (c) the different exchange privileges of the classes of units; (d) the designation of each class of units of a portfolio; (e) the front-end sales load that certain classes may carry due to differing distribution methods; (f) the CDSCs that certain classes may carry; and/or (g) the net asset values of the various classes of units in a non-Money Market Portfolio that may differ as a result of the expenses described above and the allocation of portfolio expenses and income in proportion to the different net asset values of each class.

2. The board of trustees of a Company, including a majority of the independent trustees, will approve the offering of different classes of units under the multi-class distribution system. The minutes of the meetings of the trustees regarding the deliberations of the trustees with respect to the approvals necessary to implement a multi-class system will reflect in detail the reasons for the trustees' determination that the proposed multi-class system is in the best interests of both the Company involved and its unitholders.

3. The initial determination of the Class Expenses that will be allocated to a particular class and any subsequent changes thereto will be reviewed and approved by a vote of the board of trustees of a Company, including a majority of the trustees who are not interested persons of the Company. Any person authorized to direct the allocation and disposition of monies paid or payable by a Company to meet Class Expenses shall provide to the board of trustees, and the trustees shall review, at least quarterly, a written report of the amounts so expended and the purposes for which such expenditures were made.

4. On an ongoing basis, the trustees of a Company, pursuant to their fiduciary responsibilities under the Act and otherwise, will monitor each portfolio having a multi-class system for the existence of any material conflicts among the interests of the various classes of each portfolio. The trustees, including a majority of the independent trustees, shall take such action as is reasonably necessary to eliminate any such conflicts that may develop. A portfolio's investment adviser and distributor will be responsible for reporting any potential or existing conflicts to the trustees. If a conflict arises, a portfolio's investment adviser and distributor at their own cost will remedy such conflict up to and including establishing a new registered management investment company.

5. Any Administrative Plan will be adopted and operated in accordance with the procedures set forth in rule 12b–1 (b) through (f) as if the expenditures made thereunder were subject to rule 12b–1, except that unitholders will not enjoy the voting rights specified in rule 12b–1.

6. The trustees of a Company will receive quarterly and annual statements concerning the expenditures under each Plan complying with paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time. In the statements, only expenditures properly attributable to the sale or servicing of a particular class of units will be used to justify any distribution or servicing expenditure charged to that class. Expenditures not related to the sale or servicing of a particular class will not be presented to the trustees to justify any fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review and approval of the independent trustees in the exercise of their fiduciary duties.

7. Dividends paid by a portfolio with respect to each class of its units, to the extent any dividends are paid, will be calculated in the same manner, at the same time, on the same day, and will be in the same amount, except that Plan Payments relating to each respective class of units and the Class Expenses relating to each class of units will be borne exclusively by that class.

8. The methodology and procedures for calculating the net asset value and dividends and distributions of the various classes in any portfolio having a multi-class distribution system and the proper allocation of expenses among the various classes in each such portfolio have been reviewed by an expert ("Expert") who has rendered a report to the Company involved, which report has been provided to the staff of the Commission, that such methodology and procedures are adequate to ensure that such calculations and allocation will be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, will render at least annually a report to the Company involved that the calculations and allocations are being made properly. The reports of the Expert will be filed as part of the periodic reports filed with the Commission pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following request by the Company involved (which the Company agrees to provide), will be available for inspection by the Commission staff upon written request to the Company for such work papers by a senior member of the Division of Investment Management or a regional office of the SEC. Authorized staff members would be limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, an Assistant Director, and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert is a "Special Purpose" report on the "Design of a System" as defined and described in SAS No. 44 of the AICPA, and the ongoing reports will be "reports on policies and procedures placed in operation and tests of operating effectiveness" as defined and described in SAS No. 70 of the AICPA, as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

9. The applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends and distributions of the various classes of units and the proper allocation of expenses among the classes of units and this representation will be concurred with by the Expert in the initial report referred to in condition 8 above and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in condition 8 above. The Applicants will take immediate corrective measures if this representation is not concurred in by the Expert or appropriate substitute Expert.

10. The prospectuses of each portfolio having a multi-class system will contain a statement to the effect that a salesperson and any other person entitled to receive compensation for selling or servicing units in a portfolio may receive different compensation with respect to one particular class of units over another in the same portfolio.

11. The distributor for a Company having a multi-class system will adopt

compliance standards for any portfolio which has a multi-class system, which standards will relate to when each class of units may appropriately be sold to particular investors. The applicants will require all persons selling units of a portfolio having a multi-class system to agree to conform to such applicable standards.

12. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the trustees with respect to the multi-class system will be set forth in guidelines which will be furnished to the trustees of a Company having a multi-class system.

13. Each portfolio having a multi-class system will disclose the respective expenses, performance data, distribution arrangements, services, fees, front-end sales loads, CDSCs, and exchange privileges applicable to each class of units in a portfolio in every prospectus relating to such portfolio, regardless of whether all classes of units are offered through each prospectus. Each such portfolio will disclose the respective expenses and performance data applicable to all classes of units in a portfolio in every unitholder report relating to such portfolio. The unitholder reports will contain, in the statement of assets and liabilities and statement of operations, information related to the portfolio as a whole generally and not on per class basis. Each portfolio's per unit data, however will be prepared on a per class basis with respect to all classes of units of such portfolio. To the extent any advertisement or sales literature describes the expenses or performance data applicable to any class of units, it will also disclose the respective expenses and/or performance data applicable to all classes of units. The information provided by the applicants for publication in any newspaper or similar listing of any portfolio's net asset value and public offering price will present each class of units separately.

14. The applicants acknowledge that the grant of the exemptive order requested by the application will not imply Commission approval, authorization or acquiescence in any particular level of payments that the portfolios may make pursuant to a Plan in reliance on the exemptive order.

15. If a CDSC arrangement is implemented with respect to units of a portfolio, the applicants agree to comply with the provisions of proposed rule 6c-10 under the Act, Investment Company Act Release No. 16619 (November 2, 1988), as currently proposed and as it may be reproposed, adopted or amended.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary,

[FR Doc. 93-10491 Filed 5-3-93; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-19436; 812-7925]

Liberty All-Star Equity Fund, et al.; Application for Exemption

April 27, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Liberty All-Star Equity Fund ("All-Star"); and Liberty Asset Management Company ("LAMCO").

RELEVANT ACT SECTIONS: Conditional order requested under section 6(c) for an exemption from section 15(a) of the Act.

SUMMARY OF APPLICATION: Applicants, for themselves and on behalf of present and future sub-advisers of All-Star and their successors, request an order which would permit All-Star and LAMCO to enter into a new sub-advisory agreement incident to a change in sub-advisers recommended by LAMCO or an addition of a sub-adviser recommended by LAMCO, and delay shareholder approval of such contract until All-Star's next annual meeting.

FILING DATE: The application was filed on May 20, 1992 and amended on July 9, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 24, 1993, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, Federal Reserve Plaza, Boston, Massachusetts 02210.

FOR FURTHER INFORMATION CONTACT: James E. Anderson, Staff Attorney, at (202) 272-7027, or Elizabeth G. Osterman, Branch Chief, at (202) 272-3016 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. All-Star is a closed-end diversified investment company. All-Star's shares are listed and traded on the New York Stock Exchange. In accordance with that exchange's rules, All-Star holds annual meetings of its shareholders.

2. LAMCO is a registered investment adviser and an indirect wholly-owned subsidiary of Liberty Financial Companies, Inc. ("LFC"). LFC is an indirect wholly-owned subsidiary of Liberty Mutual Insurance Company.

3. All-Star allocates its investment portfolio on an approximately equal basis among several independent investment management firms ("Sub-Advisers") selected and recommended by LAMCO based on specific criteria. The goal of this multi-manager methodology of portfolio management is to produce better investment performance over time with less volatility than that of the average single-manager fund with the same investment objective and policies. To achieve this goal (a) each of All-Star's Sub-Advisers must consistently employ a distinct, identifiable investment style; (b) each Sub-Adviser's style must be different from those of the other Sub-Advisers; (c) the blending of the different styles employed by the Sub-Advisers must be appropriate to All-Star's investment objective, and the range of styles represented must be sufficiently broad so that at least one of such styles can reasonably be expected to be in market favor in all reasonably foreseeable market conditions; and (d) each Sub-Adviser's longer-term investment performance must be satisfactory when compared to other investment management firms employing a similar style.

4. LAMCO continuously reviews the performance of the Sub-Advisers to identify the presence of factors or conditions which would tend to neutralize the effect of All-Star's multi-management methodology, such as a departure by a Sub-Adviser from its investment style, a deterioration in its investment performance relative to that of other investment management firms employing similar styles, or an adverse change in its personnel or organization,

and recommends changes in Sub-Advisers accordingly.

5. Each new sub-advisory agreement initially affects no more than 25% of All-Star's assets. In addition, each new sub-advisory agreement contains substantially the same terms and conditions as existing agreements. A new Sub-Adviser's fee can be no higher than that provided in All-Star's existing sub-advisory agreements. In the event that fees under the new sub-advisory agreement are less than in the existing agreements, the difference will be passed on to All-Star through a corresponding reduction in the fund management fee payable to LAMCO.

6. None of the Sub-Advisers have any affiliation with All-Star or LAMCO other than as Sub-Adviser, and the responsibility of the Sub-Advisers is limited to the discretionary investment management of the respective portions of All-Star's portfolio assets assigned to them by LAMCO from time to time, and related recordkeeping and reporting.

Applicant's Legal Analysis

1. Section 15(a) makes it unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract, whether with such registered company or with an investment adviser of such registered company, which has been approved by the vote of a majority of the outstanding voting securities of such registered company and which precisely describes all compensation to be paid thereunder.

2. Rule 15a–4 permits an investment adviser to an investment company to act under an agreement not approved by shareholders for up to 120 days after the termination of an investment advisory agreement by the board of directors or the shareholders of the investment company. Rule 15a–4 does not provide adequate relief to All-Star because a change in Sub-Adviser often occurs more than 120 days before the next regularly scheduled annual meeting, resulting in the necessity of a special meeting of shareholders.

3. Applicants submit that requiring shareholder approval consistent with section 15(a) before changing a Sub-Adviser in accordance with All-Star's multi-manager methodology results in substantial expense to All-Star, without any corresponding benefit in terms of shareholder protection.

4. Applicants assert that because of the lack of affiliation between LAMCO and the Sub-Advisers (unlike conventionally structured single-manager investment companies), LAMCO has no interest other than the efficient and effective functioning of All-Star's multi-manager methodology and the enhancement of All-Star's investment performance when recommending the replacement or addition of a Sub-Adviser.

5. Applicants assert that the terms and conditions of All-Star's "employment" of its Sub-Advisers will in effect have already been approved by shareholders because any new sub-advisory agreements will be identical in all material respects to the existing agreements which have been approved by shareholders, with no increase in expense to All-Star.

6. Applicants further assert that in view of the limited function of the Sub-Advisers and the fact that no more than 25% of All-Star's assets will be affected by any one Sub-Adviser change or addition, All-Star's shareholders are significantly less dependent on any one Sub-Adviser than are the shareholders of a conventionally structured single manager fund, and the need for the protection provided by the shareholder approval requirement of section 15(a) is correspondingly less.

7. Applicants submit that the requested relief 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.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. Each new sub-advisory agreement is submitted for ratification and approval to the vote of All-Star's shareholders no later than at the regularly scheduled annual meeting of shareholders of All-Star (usually held in the third week of April) next following the effective date of the new agreement, and its continuance after such meeting is conditioned on approval by the required majority vote of such shareholders.

2. All-Star continues to hold annual meetings of its shareholders, whether or not required to do so by the rules of the New York Stock Exchange, Inc. or otherwise.

3. The trustees of All-Star, in addition to approving the new sub-advisory agreement in accordance with the requirements of section 15(c) of the Act, specifically determine that entering into a sub-advisory agreement with the new or additional Sub-Adviser in advance of the next regular annual meeting of shareholders of All-Star and without prior shareholder approval is in furtherance of All-Star's multi-manager methodology and is in the best interest of All-Star and its shareholders.

4. The new sub-advisory agreement involved will, when entered into, affect no more than 25% of All-Star's assets.

5. The new Sub-Adviser will have no affiliation with All-Star or LAMCO other than as Sub-Adviser, and will have no duties or responsibilities with respect to All-Star beyond the investment management of the portion of All-Star's portfolio assets allocated to it by LAMCO from time to time and related record keeping and reporting.

6. The new sub-advisory agreement provides for a sub-advisory fee no higher than that provided in All-Star's existing sub-advisory agreements, and, except for the provisions relating to shareholder approval referred to in condition 1, is on substantially the same other terms and conditions as such existing agreements, and, if the new sub-advisory agreement provides for sub-advisory fees at rates less than those provided in the existing sub-advisory agreements, the difference will be passed on to All-Star and its shareholders through a corresponding voluntary reduction in the fund management fee payable by All-Star to LAMCO.

7. The appointment of the new Sub-Adviser is announced by press release promptly following the trustees' action referred to in condition 3 above, and a notice of the new sub-advisory agreement, together with a description of the new Sub-Adviser, is included in All-Star's next report to shareholders.

8. LAMCO will provide general management and administrative services to All-Star, including overall supervisory responsibility for the general management and investment of all of All-Star's securities portfolio subject to All-Star's investment objectives and policies and any directions of All-Star's Trustees. In particular, LAMCO will (i) provide overall investment programs and strategies for All-Star, (ii) recommend to All-Star's Trustees investment management firms for appointment or replacement as All-Star Sub-Advisers, (iii) allocate and reallocate All-Star's portfolio assets among the Sub-Advisers, and (iv) monitor and evaluate the investment performance of the Sub-Advisers, including their compliance with All-Star's investment objectives, policies and restrictions.

By the Commission.

Jonathan G. Katz.

Secretary.

[FR Doc. 93–10494 Filed 5–3–93; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC-19439; 812-8164]

The Preferred Group of Mutual Funds; Application for Exemption

April 27, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANT: The Preferred Group of Mutual Funds (the "Trust").

RELEVANT ACT SECTIONS: Order requested pursuant to sections 6(c) and 17(b) of the Act granting an exemption from section 17(a) of the Act.

SUMMARY OF APPLICATION: Applicant seeks an order pursuant to sections 6(c) and 17(b) of the Act granting an exemption from section 17(a) of the Act to the extent necessary to permit each present or future series of the Trust to engage in principal transactions with securities dealers that may be deemed to be affiliated persons of affiliated persons of the series solely because of subadvisory relationships with one or more of applicant's other series.

FILING DATE: The application was filed on November 13, 1992, and an amendment thereto was filed on March 26, 1993. By supplemental letter dated April 19, 1993, counsel, on behalf of applicants, agreed to file a further amendment during the notice period to make certain technical changes. This notice reflects the changes to be made to the application by such further amendment.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 24, 1993, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 100 NE. Adams Street, Peoria, Illinois 61629-5330.

FOR FURTHER INFORMATION CONTACT: John V. O'Hanlon, Staff Attorney, at (202) 272-3922, or Elizabeth G. Osterman, Branch Chief, at (202) 272-3016 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. The Trust is a Massachusetts business trust registered under the Act as an open-end, diversified investment company, and is a "series company" as described in Rule 18f-2 under the Act. The Trust has seven investment series (together with each future series of the Trust, the "Funds") with different investment objectives and strategies.

2. Applicant's investment adviser is Caterpillar Investment Management Ltd. ("CIML"). CIML also provides executive and other personnel for management of the Trust. Shares of each Fund are offered without a sales charge at net asset value by Caterpillar Securities Inc., the Trust's principal underwriter and a wholly-owned subsidiary of CIML.

3. In order to assist it in carrying out its responsibilities, CIML has retained several subadvisers (the "Subadvisers") to render advisory services to the Funds (other than the Preferred Short-term Government Securities Fund, for which CIML provides advisory services) under the supervision of CIML and the Trust's board of trustees. CIML pays the fees of each of the Subadvisers.

4. Oppenheimer Capital serves as Subadviser to the Preferred Value Fund. Jennison Associates Capital Corp. serves as Subadviser to the Preferred Growth Fund. Mellon Capital Management Corporation and PanAgora Asset Management, Inc. each serve as a Subadviser to the Preferred Asset Allocation Fund. Mercator Asset Management, Inc. serves as Subadviser to the Preferred International Fund. J.P. Morgan Investment Management Inc. ("Morgan") serves as Subadviser to the Preferred Money Market Fund and the Preferred Fixed Income Fund. Pursuant to subadvisory agreements with CIML, each Subadviser provides investment advisory services to a single Fund (except for Morgan which provides such services to two Funds).

Applicant's Legal Analysis

1. Applicant requests an order pursuant to sections 17(b) and 6(c) of the Act to permit each present or future series of the Trust to engage in principal transactions with securities dealers that may be deemed to be affiliated persons of affiliated persons of the series solely because of subadvisory relationships with one or more of applicant's other series.

2. Section 17(a), among other things, prohibits an affiliated person of a registered investment company, or any affiliated person of such a person, acting as principal, (a) from selling to or purchasing from such registered company, or any company controlled by such registered company, any security or other property, or (b) from borrowing money or other property from such registered company. Section 17(b) provides, however, that the Commission may exempt a transaction from the provisions of section 17(a) if evidence establishes that the terms of the proposed transaction, including the consideration to be paid, are reasonable and fair and do not involve overreaching on the part of any person concerned, and that the proposed transaction is consistent with the policy of the registered investment company concerned and with the general purposes of the Act.

3. Section 6(c) provides that the Commission 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 or of any rule or regulation thereunder, if and to the extent that 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.

4. Because the Funds have the same investment adviser and the same trustees and officers, each Fund might be deemed to be under common control with all other Funds and, therefore, an affiliated person (within the meaning of section 2(a)(3) of the Act) of each other Fund. While applicant does not concede that all Funds are under common control, it assumes, solely for purposes of the application, the existence of such control relationship so that each Fund may be deemed to be an affiliated person of each other Fund. Accordingly, because a Subadviser is an affiliated person of any Fund that it advises, it may be deemed to be an affiliated person of an affiliated person of any Fund that it does not advise.

5. Each Subadviser, as an affiliated person of each Fund it advises and as an affiliated person of an affiliated person of each other Fund, is prohibited by section 17(a) of the Act from engaging in principal transactions with any of the Funds. In addition, affiliated persons of each Subadviser are prohibited from engaging in principal transactions with a Fund advised by that Subadviser. Finally, because the staff has, in a number of instances,

treated a parent company and it wholly-owned subsidiary as a single entity for purposes of the affiliated person definition, section 17(a) may also prohibit wholly-owned subsidiaries of a Subadviser, parents of a Subadviser, and wholly-owned subsidiaries of such parents from engaging in principal transactions with Funds not managed by such Subadviser.[1]

6. Applicant asserts that under the terms of the requested order, a Subadviser would not be able to cause a Fund to trade with an affiliated person of anyone with the theoretical or actual power to affect its business relationship as Subadviser to the Fund. In each transaction permitted by the requested relief, the Subadviser would be dealing, on behalf of the Fund it managed, with an entity that, in economic reality, is a competitor of that Subadviser. Each such transaction would be the product of arms-length bargaining between competitors. Applicant submits that this is not a situation where a controlling person of an investment company might try to circumvent the prohibition against self-dealing by acting through an affiliate. Applicant states that it would be contrary to the interests of applicant's shareholders to create artificial barriers to dealing with any registered securities dealer where there is not the possibility of self-dealing.

7. Applicant believes that the proposed transactions will meet the standards of sections 6(c) and 17(b). Because there will be no conflict of interest inherent in a Subadviser's decision to execute a portfolio transaction with a dealer that is an affiliated person of an affiliated person of the Trust solely because of a subadvisory relationship with one or more of applicant's other Funds, there is no danger of overreaching on the part of any person concerned with the transaction. Because the pecuniary interests of the Subadvisers are solely and directly aligned with those of the Funds they advise, it is reasonable to conclude that the consideration to be paid or received by the Funds will be reasonable and fair. Moreover, transactions permitted by the requested order will be consistent with the policies of the Fund involved, inasmuch as each Subadviser is required by its agreement with CIML to formulate and implement a continuous investment program for each Fund consistent with the investment objectives and related investment policies for each such Fund. Finally, applicant argues that permitting the proposed transactions is consistent with the general purposes of the Act, because the ability to engage in such transactions increases the likelihood of the Funds achieving the best price and execution on their principal transactions.

8. Based upon the foregoing, applicant believes that it is 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 to issue an order pursuant to sections 6(c) and 17(b) of the Act exempting principal transactions of the type for which relief is requested from the provisions of section 17(a) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93-10492 Filed 5-3-93; 8:45 am]

BILLING CODE 8010-01-M

[1] Applicant states that in the alternative, if it is assumed that the Trust (and not the Funds) is the only relevant registered investment company, CIML and each of the Subadvisers could be affiliated persons of the Trust. Each Subadviser could be prohibited by section 17(a) from engaging in principal transactions with any of the Funds. In addition, affiliated persons of each Subadviser would be prohibited from engaging in such transactions with any of the Funds. Applicant assumes, solely for purposes of the application, that each Subadviser is an affiliate of the Trust and that any affiliated person of any Subadviser would be prohibited from engaging in any such transaction with any of the Funds.

DEPARTMENT OF TRANSPORTATION

Coast Guard

[GGD-93-025]

National Boating Safety Advisory Council; Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. app. 1), notice is hereby given of a meeting of the National Boating Safety Advisory Council to be held on Monday and Tuesday, May 17 and 18, 1993, at the Stouffer Rochester Plaza Hotel, 70 State Street, Rochester, New York, beginning at 8:45 a.m. and ending at 4 p.m. The agenda for the meeting will be as follows:

1. Review of action taken at the 50th meeting of the Council.
2. Executive Director's Report.
3. Update on Global Positioning System.
4. Report of the Consumer Affairs and Standards Review Subcommittee.
5. Multiple-Use Waterways Subcommittee Report.
6. Personal Watercraft Definition and Requirements Subcommittee Report.
7. Presentation on the Clean Vessel Act of 1992.
8. Report on Boat Factory Visit Program.
9. Boating Education Update.
10. Report on Recreational Boat Collision Accident Research.
11. Anchoring Regulation Discussion.
12. Presentation on New Boating Safety Videos.
13. Boat Operation Simulator Discussion.
14. Report on Boating Accident Investigation Seminars.
15. Chairman's Session.

Attendance is open to the interested public. With advance notice, members of the public may present oral statements at the meeting. Persons wishing to present oral statements should so notify the Executive Director no later than the day before the meeting. Any member of the public may present a written statement to the Council at any time. Additional information may be obtained from Mr. Albert J. Marmo, Executive Director, National Boating Safety Advisory Council, U.S. Coast Guard, (G-NAB), Washington, DC 20593-0001, or by calling (202) 267-1077.

Dated: April 15, 1993.

W.J. Eckers,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 93-10357 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-14-M

[CGD8 93-11]

Lower Mississippi River Waterway Safety Advisory Committee: VTS Subcommittee Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L 92-463; 5 U.S.C. app. II) notice is hereby given of the VTS Subcommittee of the Lower Mississippi River Waterway Safety Advisory Committee meeting. The meeting will be held on Thursday, May 27, 1993. The meeting will be held at the Crescent River Port Pilots office. 409 Belle Chasse Hwy. South, Belle Chasse, LA 70037. The meeting is scheduled to begin at 9 a.m. The agenda for the meeting consists of the following items:

1. Call to order.
2. Update the proposed New Orleans Vessel Traffic Service.
3. Adjournment.

The meeting is open to the public. Members of the public may present written or oral statements at the meeting.

Additional information may be obtained from Mr. M.M. Ledet, USCG, Recording Secretary, Lower Mississippi River Waterway Safety Advisory

Committee, c/o Commander, Eighth Coast Guard District (oan), room 1209, Hale Boggs Federal Building, 501 Magazine Street, New Orleans, LA. 70130-3396, telephone number (504) 589-4686.

Dated: April 27, 1993.

C. B. Newlin,

Chief of Staff, Eighth Coast Guard District.

[FR Doc. 93-10473 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-14-M

[GGD-93-027]

National Boating Safety Advisory Council; Subcommittee Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. 1), notice is hereby given of meetings of the National Boating Safety Advisory Council's Subcommittees on Consumer Affairs and Standards Review, Personal Watercraft Definition and Requirements and Multiple-Use Waterways to be held on Saturday, May 15, 1993, at the Stouffer Rochester Plaza Hotel, 70 State Street, Rochester, New York, between 1:30 p.m. and 5:30 p.m. The agenda for each meeting will be to review the status of various projects undertaken by the subcommittee and initiate any necessary new tasks.

Attendance is open to the interested public. With advance notice, members of the public may present oral statements at the meeting. Persons wishing to present oral statements should so notify the Executive Director no later than the day before the meeting. Any member of the public may present a written statement to the Council at any time. Additional information may be obtained from Mr. Albert J. Marmo, Executive Director, National Boating Safety Advisory Council, U.S. Coast Guard, (G-NAB), Washington, DC 20593-0001, or by calling (202) 267-1077.

Dated: April 15, 1993.

W. J. Ecker,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 93-10355 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-14-M

National Highway Traffic Safety Administration

[Docket No. 93-08; Notice 2]

Determination That Nonconforming 1975 Laverda 1000 Motorcycles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of determination by NHTSA that nonconforming 1975 Laverda 1000 motorcycles are eligible for importation.

SUMMARY: This notice announces the determination by NHTSA that 1975 Laverda 1000 motorcycles not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to a vehicle originally manufactured for importation into and sale in the United States and certified by its manufacturer as complying with the safety standards (the U.S.-certified version of the 1975 Laverda 1000 motorcycle), and they are capable of being readily modified to conform to the standards.

DATES: The determination is effective May 4, 1993.

FOR FURTHER INFORMATION CONTACT: Ted Bayler, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

SUPPLEMENTARY INFORMATION:

Bakground

Under section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act), 15 U.S.C. 1397(c)(3)(A)(i), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States on and after January 31, 1990, unless NHTSA has determined that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under section 114 of the Act, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility determinations may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the Federal Register of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA determines, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this determination in the Federal Register.

J.K. Motors, Inc. of Kingsville, Maryland (Registered Importer R-90-006) petitioned NHTSA to determine whether 1975 Laverda 1000 motorcycles are eligible for importation into the United States. NHTSA published notice of the petition on March 8, 1993 (58 FR 12979) to afford an opportunity for public comment. The reader is referred to that notice for a thorough description of the petition. No comments were received in response to the notice. Based on its review of the information submitted by the petitioner, NHTSA has determined to grant the petition.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final determination must indicate on the form HS-7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. VSP 37 is the vehicle eligibility number assigned to vehicles admissible under this determination.

Final Determination

Accordingly, on the basis of the foregoing, NHTSA hereby determines that a 1975 Laverda 1000 motorcycle not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1975 Laverda 1000 motorcycle originally manufactured for importation into and sale in the Untied States and certified under section 114 of the National Traffic and Motor Vehicle Safety Act, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Authority: 15 U.S.C. 1397(c)(3)(A)(i)(I) and (C)(ii); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 27, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93-10428 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-59-M

[Docket No. 93-30; Notice 1]

Receipt of Petition for Determination that Nonconforming 1981 Volvo 262C Passenger Cars are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for determination that nonconforming 1981 Volvo 262C passenger cars are eligible for importation.

SUMMARY: This notice requests comments on a petition submitted to the National Highway Traffic Safety Administration (NHTSA) for a

determination that a 1981 Volvo 262C passenger car that was not originally manufactured to comply with all applicable Federal motor vehicle safety standards is eligible for importation into the United States because (1) it is substantially similar to a vehicle that was originally manufactured for importation into and sale in the United States and that was certified by its manufacturer as complying with the safety standards, and (2) it is capable of being readily modified to conform to the standards.

DATES: The closing date for comments on the petition is June 3, 1993.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Section, room 5109, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. (Docket hours are from 9:30 a.m. to 4 p.m.).

FOR FURTHER INFORMATION CONTACT: Ted Bayler, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act), 15 U.S.C. 1397(c)(3)(A)(i), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States on and after January 31, 1990, unless NHTSA has determined that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under section 114 of the Act, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility determinations may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA determines, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this determination in the **Federal Register**.

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas ("WETL") (Registered Importer R–90–005) has petitioned NHTSA to determine whether 1981 Volvo 262C passenger cars that were not originally manufactured in conformity with all applicable Federal motor vehicle safety standards are eligible for importation into the United States. The vehicle that WETL believes is substantially similar is the 1981 Volvo 262C that was manufactured for importation into and sale in the United States and that was certified by Volkswagen as complying with all applicable Federal motor vehicle safety standards.

The petitioner stated that it performed a careful evaluation of the non-U.S.-certified 1981 Volvo 262C, and determined that it is substantially similar to its U.S.-certified counterpart. Based on this evaluation, the petitioner contends that the non-U.S.-certified 1981 Volvo 262C, as originally manufactured, conforms to many Federal motor vehicle safety standards in the same manner as the U.S.-certified 1981 Volvo 262C, or is capable of being readily modified to conform to those standards.

Specifically, the petitioner claims that the two models are identical with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence* * * *, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 107 *Reflecting Surfaces*, 109 *New Pneumatic Tires*, 111 *Rearview Mirrors*, 113 *Hood Latch Systems*, 114 *Theft Protection*, 116 *Brake Fluid*, 118 *Power Window Systems*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 203 *Impact Protection for the Driver From the Steering Control System*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 208 *Occupant Crash Protection*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 211 *Wheel Nuts, Wheel Discs and Hubcaps*, 212 *Windshield Retention*, 214 *Side Door Strength*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, and 302 *Flammability of Interior Materials*.

Petitioner also contends that the non-U.S.-certified 1981 Volvo 262C is capable of being readily modified to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* Recalibration of the speedometer/odometer from kilometers to miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:*

(a) Installation of U.S.-model headlights;

(b) Installation of sidemarkers and reflectors.

Standard No. 110 *Tire Selection and Rims:* Installation of a tire information placard.

Standard No. 115 *Vehicle Identification Number:* Installation of a VIN plate that can be read from outside the left windshield pillar, and a VIN reference label on the edge of the door or latch post nearest the driver.

Standard No. 301 *Fuel System Integrity:* Installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

Additionally, the petitioner states that a certification label must be affixed to the vehicle to comply with vehicle certification requirements found in 49 CFR part 567.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, room 5109, 400 Seventh Street SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 15 U.S.C. 1397(c)(3)(A)(i)(I) and (C)(ii); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 27, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93–10429 Filed 5–3–93; 8:45 am]

BILLING CODE 4910–59–M

[Docket No. 93–27; Notice 1]

Receipt of Petition for Determination That Nonconforming 1986 Volkswagen Scirocco Passenger Cars Are Eligible for Importation:

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for determination that nonconforming 1986 Volkswagen Scirocco passenger cars are eligible for importation.

SUMMARY: This notice requests comments on a petition submitted to the National Highway Traffic Safety Administration (NHTSA) for a determination that a 1986 Volkswagen Scirocco passenger car that was not originally manufactured to comply with all applicable Federal motor vehicle safety standards is eligible for importation into the United States because (1) it is substantially similar to a vehicle that was originally manufactured for importation into and sale in the United States and that was certified by its manufacturer as complying with the safety standards, and (2) it is capable of being readily modified to conform to the standards.

DATES: The closing date for comments on the petition is June 3, 1993.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Section, room 5109, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590. (Docket hours are from 9:30 a.m. to 4 p.m.)

FOR FURTHER INFORMATION CONTACT: Ted Bayler, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act), 15 U.S.C. 1397(c)(3)(A)(i), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States on and after January 31, 1990, unless NHTSA has determined that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under section 114 of the Act, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility determinations may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA determines, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this determination in the **Federal Register.**

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas ("WETL") (Registered Importer R–90–005) has petitioned NHTSA to determine whether 1986 Volkswagen Scirocco passenger cars that were not originally manufactured in conformity with all applicable Federal motor vehicle safety standards are eligible for importation into the United States. The vehicle that WETL believes is substantially similar is the 1986 Volkswagen Scirocco that was manufactured for importation into and sale in the United States and that was certified by Volkswagen as complying with all applicable Federal motor vehicle safety standards.

The petitioner stated that it performed a careful evaluation of the non-U.S.-certified 1986 Volkswagen Scirocco, and determined that it is substantially similar to its U.S.-certified counterpart. Based on this evaluation, the petitioner contends that the non-U.S.-certified 1986 Volkswagen Scirocco, as originally manufactured, conforms to many Federal motor vehicle safety standards in the same manner as the U.S.-certified 1986 Volkswagen Scirocco, or is capable of being readily modified to conform to those standards.

Specifically, the petitioner claims that the two models are identical with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence* * * *, 103 *Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 107 *Reflecting Surfaces*, 109 *New Pneumatic Tires*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 118 *Power Window Systems*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 203 *Impact Protection for the Driver From the Steering Control System*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 211 *Wheel Nuts, Wheel Discs and Hubcaps*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, and 302 *Flammability of Interior Materials.*

Petitioner also contends that the 1986 Volkswagen Scirocco is capable of being readily modified to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:*

(a) Substitution of a lens marked "Brake" for a lens with an ECE symbol on the brake failure indicator lamp;

(b) Recalibration of the speedometer/odometer from kilometers to miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:*

(a) Installation of U.S.- model headlights;

(b) Installation of sidemarkers and reflectors;

(c) Installation of a high mounted stop lamp.

Standard No. 110 *Tire Selection and Rims:* Installation of a tire information placard.

Standard No. 111 *Rearview Mirrors:* Replacement of the passenger's outside rearview mirror with one bearing the required warning statement or permanently marking that statement on the existing mirror.

Standard No. 114. *Theft Protection*: Installation of a buzzer microswitch in the steering lock assembly, and a warning buzzer.

Standard No. 115 *Vehicle Identification Number:* Installation of a VIN plate that can be read from outside the left windshield pillar, and a VIN reference label on the edge of the door or latch post nearest the driver.

Standard No. 208 *Occupant Crash Protection:*

(a) Installation of a seat belt warning system;

(b) Replacement of the seat belt latch with one containing a microswitch to activate the seat belt warning system.

Standard No. 214 *Side Door Strength:* Installation of reinforcing beams.

Standard No. 301 *Fuel System Integrity:* Installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

Additionally, the petitioner states that a certification label must be affixed to the vehicle to comply with vehicle certification requirements found in 49 CFR part 567.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, room 5109, 400 Seventh Street SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the

closing date will also be considered. Notice of final action on the petition will be published in the Federal Register pursuant to the authority indicated below.

Authority: 15 U.S.C. 1397(c)(3)(A)(i)(I) and (C)(ii); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 27, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93-10430 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-59-M

[Docket No. 93-13; Notice 2]

Determination That Nonconforming 1970 Mercedes-Benz 300SEL Passenger Cars Are Eligible for Importation.

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of determination by NHTSA that nonconforming 1970 Mercedes-Benz 300SEL passenger cars are eligible for importation.

SUMMARY: This notice announces the determination by NHTSA that 1970 Mercedes-Benz 300SEL passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to a vehicle originally manufactured for importation into and sale in the United States and certified by its manufacturer as complying with the safety standards (the U.S.certified version of the 1970 Mercedes-Benz 300SEL), and they are capable of being readily modified to conform to the standards.

DATE: The determination is effective May 4, 1993.

FOR FURTHER INFORMATION CONTACT: Ted Bayler, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

SUPPLEMENTARY INFORMATION:

Background

Under section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act), 15 U.S.C. 1397(c)(3)(A)(i), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards must be refused admission into the United States on and after January 31, 1990, unless NHTSA has determined that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under section 114 of the Act, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility determinations may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the Federal Register of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA determines, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this determination in the Federal Register.

Champagne Imports Inc. of Lansdale, Pennsylvania (Registered Importer R-90-009) petitioned NHTSA to determine whether 1970 Mercedes-Benz 300SEL passenger cars are eligible for importation into the United States. NHTSA published notice of the petition on March 8, 1993 (58 FR 12980) to afford an opportunity for public comment. The reader is referred to that notice for a thorough description of the petition. No comments were received in response to the notice. Based on its review of the information submitted by the petitioner, NHTSA has determined to grant the petition.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final determination must indicate on the form HS-7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. VSP 36 is the vehicle eligibility number assigned to vehicles admissible under this determination.

Final Determination

Accordingly, on the basis of the foregoing, NHTSA hereby determines that a 1970 Mercedes-Benz 300SEL (Model ID 109.056) not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1970 Mercedes-Benz 300SEL originally manufactured for importation into and sale in the United States and certified under section 114 of the National Traffic and Motor Vehicle Safety Act, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Authority: 15 U.S.C. 1397(c)(3)(A)(i)(I) and (C)(ii); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 27, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93-10427 Filed 5-3-93; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171, Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Bureau of Alcohol, Tobacco and Firearms

OMB Number: 1512-0026.

Form Numbers: ATF F 3 (5320.3).

Type of Review: Extension.

Title: Application for Tax Exempt Transfer of Firearms and Registration of Special (Occupational) Taxpayer (26 U.S.C. 53, Firearms).

Description: This application allows a special taxpayer firearms licensee to transfer National Firearms Act firearms without payment of tax to another eligible special taxpayer upon approval of ATF. The approved form is proof that the firearm is legally held and legally transferred to the current holder of the firearm. Conversely, lack of the form could indicate illegal possession.

Respondents: Individuals or households, State or local governments, Businesses or other for-profit, Small businesses or organizations.

Estimated Number of Respondents: 3,000.

Estimated Burden Hours Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 15,000 hours.

Clearance Officer: Robert N. Hogarth, (202) 927-8930, Bureau of Alcohol, Tobacco, and Firearms, Room 3200, 650 Massachusetts Avenue, NW., Washington, DC 20226.

OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Dated: April 28, 1993.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 93-10475 Filed 5-3-93; 8:45 am]

BILLING CODE 4810-31-M

Public Information Collection Requirements Submitted to OMB for Review

April 28, 1993.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Review Service

OMB Number: 1545-1045.

Form Number: None.

Type of Review: Reinstatement.

Title: Conducting 1993 Focus Group Interviews on Federal Tax Forms.

Description: Focus group interviews are necessary to obtain public input on revised and new tax forms. The results will be used to further simplify and improve the forms so that taxpayers will understand them more easily.

Respondents: Individuals or households.

Estimated Number of Respondents: 3,000.

Estimated Burden Hours Per Respondent: 3 hours.

Frequency of Response: Other (One-time focus group interviews).

Estimated Total Reporting Burden: 1,152 hours.

Clearance Officer: Garrick Shear (202) 622-3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93-10476 Filed 5-3-93; 8:45 am]

BILLING CODE 4830-01-M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 84
Tuesday, May 4, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL ENERGY REGULATORY COMMISSION

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: April 26, 1993, 58 FR 22019.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:00 a.m., April 28, 1993.

CHANGE IN THE MEETING: The following Docket Numbers have been added to Item CAG–57 on the Agenda scheduled for April 28, 1993:

Item No., Docket No. and Company

CAG–57
RP92–104–000 and RP92–131–000, K N Energy, Inc.

Lois D. Cashell,
Secretary.

[FR Doc. 93–10538 Filed 4–30–93; 8:45 am]

BILLING CODE 6717–02–M

FEDERAL RESERVE SYSTEM

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday May 10, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 30, 1993.

Jennifer J. Johnson,
Associate Secretary of the Board.

[FR Doc. 93–10606 Filed 4–30–93; 2:51 pm]

BILLING CODE 6210–01–M

NATIONAL SCIENCE BOARD

DATE AND TIME: May 13, 1993, 2:00 p.m., Open Session; May 14, 1993, 9:00 a.m., Closed Session; May 14, 1993, 9:40 a.m., Open Session.

PLACE: National Science Foundation, 1800 G Street, NW., Rm. 540, Washington, DC 20550.

STATUS: Part of this meeting will be open to the public. Part of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Thursday, May 13, 1993

Open Session (2:30 p.m.–4:30 p.m.)

Role of National Science Board

Friday, May 14, 1993

Closed Session (9:00 a.m.–9:40 a.m.)

1. Minutes—March 1993 Meeting
2. Election of Executive Committee Members
3. Future NSF Budgets
4. Grants and Contracts

Friday, May 14, 1993

Open Session (9:40 a.m.–11:00 a.m.)

5. Program Approval(s)
6. Chairman's Report
7. Minutes—March 1993 Meeting
8. NSB Calendar of Meetings for 1994
9. Acting Director's Report
10. Executive Committee Annual Report
11. Director's Annual Report on Merit Review
12. Other Business/Adjourn

Marta Cehelsky,
Executive Officer.

[FR Doc. 93–10528 Filed 4–30–93; 9:10 am]

BILLING CODE 7555–01–M

federal register

Tuesday
May 4, 1993

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1926

Lead Exposure in Construction; Interim Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket No. H-004L]

Lead Exposure in Construction

AGENCY: Occupational Safety And Health Administration (OSHA), Labor.

ACTION: Interim final rule.

SUMMARY: This interim final rule amends the Occupational Safety and Health Administration (OSHA) standards for occupational health and environmental controls in subpart D of 29 CFR part 1926 by adding a new § 1926.62 containing employee protection requirements for construction workers exposed to lead.

This standard reduces the permitted level of exposure to lead for construction workers from 200 micrograms per cubic meter of air (200 μg/m³) as an 8-hour time weighted average (TWA) to an 8-hour TWA of 50 μg/m³. The standard also includes requirements addressing exposure assessment, methods of compliance, respiratory protection, protective clothing and equipment, hygiene facilities and practices, medical surveillance, medical removal protection, employee information and training, signs, recordkeeping, and observation of monitoring. An action level of 30 μg/m³ as an 8-hour TWA is established as the level at which employers must initiate certain compliance activities. In instances where employers can demonstrate that employee exposures are below 30 μg/m³ as an 8-hour TWA, the employer is not obligated to comply with most of the requirements in this interim final rule.

This interim final rule is mandated by, and issued under the exclusive authority of, title X, subtitle C, sections 1031 and 1032, Worker Protection, of the Housing and Community Development Act of 1992.

DATES: This interim final standard shall become effective June 3, 1993. Start-up dates for various provisions are set forth in paragraph (r) of the standard (§ 1926.62(r)).

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, U.S. Department of Labor, Occupational Safety and Health Administration, Office of Public Affairs, room N-3647, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 219-8151.

SUPPLEMENTARY INFORMATION:

I. Background

In 1971, in accordance with section 6(a) of the OSH Act, OSHA adopted standards incorporating a permissible exposure limit (PEL) of 200 μg/m³ to regulate occupational exposure to lead in general industry (29 CFR 1910.1000) and in the construction industry (29 CFR 1926.55). In both standards, the PEL had to be achieved by engineering and work practice controls. Some years later in 1978, after a section 6(b) rulemaking, OSHA promulgated a final lead standard for general industry (29 CFR 1910.1025), which lowered the PEL to 50 μg/m³. The 1978 lead standard also required that the PEL be achieved, to the extent feasible, by engineering and work practice controls and in addition included a number of ancillary provisions requiring employers to provide medical surveillance, medical removal protection (MRP), hygiene facilities, appropriate respirators, and air monitoring, among other things.

The 1978 lead standard in paragraph (a) excluded the construction industry from its coverage. OSHA in the preamble explained that it had exempted the industry because of insufficient information in the record to resolve issues raised about the applicability of the standard to conditions in the construction industry. OSHA said it would request the Construction Advisory Committee (ACCSH) to review the record and make recommendations for a lead standard for the construction industry (43 FR 52986, November 14, 1978).

Subsequently, OSHA's exemption of the construction industry was challenged in litigation involving the lead standard for general industry. In response to that challenge, the court upheld OSHA's decision. Although the court declared that "OSHA would be shirking its statutory responsibilities if it made no effort to protect workers in the construction industry from lead exposure * * *" the court accepted OSHA's assurances at the time "that it will take reasonably prompt steps to fashion this protection", and indicated that "So long as it does so, OSHA has met its duty." "Nothing in the Act," the court said, "prevents the agency from exercising discretion in delaying specific standards according to the unique problems of specific industries. * * *" (*United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1310 (DC Cir. 1980).)

Since 1979, employers have been required to comply with a PEL for lead in the construction industry that is four times the PEL for general industry. Employers have also been required to take other actions to protect construction workers from excess lead exposure to the extent that employers' obligations to provide respirators, protective clothing, hygiene facilities, training, and the like were imposed by generic standards that covered construction (e.g., 1910.20; 1910.94; 1910.134; 1926.20; 1926.21; 1926.28; 1926.51; 1926.55; 1926.57; 1926.59; 1926.103; 1926.200; 1926.353; 1926.354). However, there has still been no comprehensive standard regulating occupational lead exposure in construction.

In 1990, NIOSH set as a national goal the elimination of exposures that result in workers having blood lead concentrations greater than 25 μg/dL of whole blood. Under these circumstances, OSHA in the fall of 1990 announced it would begin to develop a proposal for a comprehensive standard regulating occupational lead exposure in construction. In addition, on June 12, 1992 OSHA proposed to amend its existing air contaminants standards by, among other things, reducing the PEL for occupational lead exposure in construction from 200 μg/m³ to 50 μg/m³ (57 FR 26001). However, progress on that air contaminants proposal was suspended because of the decision by the U.S. Court of Appeals for the Eleventh Circuit vacating an earlier rule on air contaminants for general industry (*AFL-CIO* v. *OSHA* 965 F.2d, 962 (1992)).

The Housing and Community Development Act of 1992

Because Congress did not anticipate publication of OSHA's proposed comprehensive lead standard for the construction industry before late spring of 1993 or publication of a final standard before 1996 (House Report on H.R. 5730, pp. 14–15), Congress in October 1992 passed Sections 1031 and 1032 of Title X of the Housing and Community Development Act of 1992 ("the Act," Pub. L. 102–550, signed by the President on October 28, 1992, 106 Stat. 3924).

In those sections, Congress included worker protection provisions expressly requiring that:

(1) No later than 180 days after enactment (April 26, 1993), the Secretary of Labor must issue an interim final lead standard covering the construction industry.

(2) The standard must be as protective as the worker protection guidelines for identification and abatement of lead-based paint in public and Indian housing issued by the Department of Housing and Urban Development

(Revised Chapter 8, "HUD Guidelines"; 55 FR 38973, Aug. 1991).

(3) The interim final standard is to take effect upon "issuance," except that the standard may include a reasonable delay in the effective date.

(4) The standard will have the effect of an OSH Act standard and will apply until a final standard becomes effective under Section 6 of the OSH Act.

(5) The Secretary of Labor in developing this standard must consult and coordinate with the Environmental Protection Agency (EPA) to achieve maximum enforcement of the Toxic Substances Control Act (TSCA) and the OSH Act while minimizing duplication.

Congressional Intent

From its language and legislative history, the broad Congressional intent behind the Act of 1992 is clear. OSHA is required within 180 days after enactment to issue an interim final regulation that provides protection to construction workers from occupational exposure to lead that is as effective as the HUD guidelines and OSHA's lead standard for general industry.

Congressional intent is clear as well with regard to many particular provisions. OSHA is mandated, for example, to include medical surveillance provisions similar to the HUD Guidelines and OSHA's lead standard. Engineering controls are to continue to be preferred, to the extent feasible, over respirators as the method of choice for compliance. More generally, most of the provisions of the interim final standard, such as those concerning housekeeping, air monitoring, record keeping, and hazard communication, are to be like those in the Guidelines and general industry lead standard, except insofar as it was necessary to adapt requirements of the interim final to conditions in the construction industry.

To determine Congressional intent, OSHA looked to the relevant language in the worker protection provisions of Section 1031 of title X of the Housing and Community Development Act of 1992 and to the legislative history of that section of the Act. As can be seen below, the language of the Act provides help in resolving many of the issues raised. Nonetheless, OSHA has had to rely at times on the legislative history to clarify Congress' mandate.

The legislative history is embodied in and essentially limited to three sources. First, the primary source is the House Committee on Labor and Education Report on H.R. 5730, which is the origin of the worker protection requirements that were then incorporated in House housing bill, H.R. 5334 and were adopted without objection by the conference committee. Second, there is a statement concerning the conference bill H.R. 5334 on the House floor by Rep. William D. Ford, the author of the worker protection provisions, which repeats verbatim relevant portions of the House Report on H.R. 5730 (138 Cong. Rec., H11475–76; daily ed. Oct. 5, 1992). And third, there is a statement by ranking minority member Representative Paul B. Henry (138 Cong. Rec. H11470; daily ed. Oct. 5, 1992).

II. Key Issues

(A) Procedural Requirements

Aside from the general requirement that the Secretary of Labor consult and coordinate with EPA, Congress in the 1992 Act did not impose any procedural requirements that must be followed in developing and promulgating the interim final standard. Furthermore, the legislative history of the Act makes it clear that Congress intended the Secretary to be free to follow whatever procedures he chooses. Specifically, the Secretary need not follow the procedural requirements of the OSH Act or the Administrative Procedures Act ("APA"; 5 U.S.C.A. 551, 553).

The Secretary's freedom from procedural constraints imposed by this legislation is clear from the Report on H.R. 5730, p. 16, where the House Committee states:

(1) "[T]he procedural requirements of section 6 of the OSH Act do not apply to the promulgation of the interim final regulation."

(2) "Nor * * * do the notice and comment provisions of the Administrative Procedures Act apply."

(3) Indeed, "the Secretary is not required to follow any specific notice and comment procedures before issuing the interim final regulation * * *."

Nonetheless, the Committee does say that "it is the Committee's hope that the Secretary [will] solicit input from and consider the views of affected industry and labor representatives as well as public health and industrial hygiene experts in fashioning an interim lead regulation for the construction industry." But here again, the Committee declares that "The Secretary is free to select whatever method she feels is best suited to obtain public input into the development of the interim final regulation, so long as the procedures she selects do not have the effect of delaying publication of the regulation."

Prior to issuing this interim final rule OSHA consulted members of the Lead Work Group of the Construction Advisory Committee, which included representatives of labor, management and the public health community. In the process, OSHA provided the work group with a draft of the interim final, listened to members' comments on the draft, and made modifications to the draft in response to their comments. The chairman of the work group was sufficiently satisfied with the results that in his report to the full ACCSH on February 16, 1993, he made a motion recommending that the full Committee support OSHA's efforts, which was unanimously passed by the Advisory Committee.

In addition, in accordance with Congress' mandate, OSHA has established a dialogue with EPA in order to coordinate the actions of the two agencies to maximize effectiveness and minimize duplication. This began with a preliminary meeting on February 22, 1993. Subsequently, OSHA and EPA are sharing working documents and will continue this cooperative effort throughout the ongoing EPA work on its rulemaking, also mandated by the Housing and Community Development Act of 1992.

(B) Scope

The language of the 1992 Act, in conjunction with the legislative history, leave little doubt that Congress intended the interim final rule to extend to all lead exposed construction workers, not simply to those removing lead-based paint. Thus, the worker protection section of the Act uses all-inclusive language: It requires OSHA to issue "an interim final regulation regulating occupational exposure to lead in the construction industry". Moreover, by its terms, the interim final is to "apply until a final standard becomes effective under section 6 of the Occupational Safety and Health Act of 1970." As Congress knew, OSHA has been developing a lead standard for all workers in the construction industry, not simply those engaged in lead paint abatement. Nowhere in the 1992 Act or the legislative history does Congress say that it intended the interim final regulation to have a narrower scope than OSHA's final standard.

In addition, from the legislative history it is clear that the gap Congress sought to fill by passing this Act was nothing less than the gap left when OSHA exempted the construction industry as a whole from the 1978 general industry standard for lead. The Committee report repeatedly refers to the general failure to protect construction workers and does not limit its focus to workers engaged in lead paint abatement. Indeed, the HUD Guidelines, which apply only to lead-

based paint abatement work, are first raised in the Report only as the "most significant" effort to provide "alternative forms of protection to construction workers * * * [i]n the absence of a comprehensive OSHA lead standard protecting workers in the construction industry * * *" Thus, the protections Congress mandated OSHA to incorporate in its interim final rule are to be extended to all construction workers exposed to lead.

There are a few indications in the 1992 Act and legislative history that Congress might have intended to protect only construction workers engaged in lead paint abatement, but they are not persuasive. For example, the short title of title X of the Act is the "Residential Lead-Based Paint Hazard Reduction Act of 1992" and the short title of Subtitle C—Worker Protection is the "Lead-Based Paint Exposure Reduction Act." Moreover, the criterion in the Act for assessing the sufficiency of the interim final regulation is the HUD guidelines, which apply only to lead paint abatement in housing. Furthermore, related sections of the Act focus on lead paint abatement (e.g., Sec. 1032). Finally, remarks by Representative Paul Henry suggest that he thought the scope of the interim standard would be limited to residential lead-based paint abatement work (138 Cong. Rec. H11470; daily ed. Oct. 5, 1992).

Nevertheless, conventional rules of legislative interpretation give considerably more weight to the express language in legislation than to its title. Moreover, the fact that the source of the criterion for determining the level of protection to be afforded workers is guidelines for abating lead paint in residential housing does not necessarily mean or imply that the intention was to protect only those engaged in such abatement. Finally, Representative Henry's views on scope seem to misunderstand and diverge from the views on scope of the majority. Indeed, Representative Henry was not present when the provisions that became section 1031 were discussed, did not seek clarification of the scope issue, voted against the conference agreement, and did not sign the Conference Report to H.R. 5334. His views, then, can hardly be taken to represent the intention of the majority. This understanding is confirmed by a letter from Representative William D. Ford, the Chairman of the originating House Committee on Education and Labor written on November 26, 1992, after the fact, to then Secretary of Labor, Lynn Martin.

(C) The Justification and Explanation Required for the Interim Final Rule

The in the Act of 1992 does not impose an independent duty to justify the interim final rule. Without such a duty in the authorizing legislation, if OSHA has a duty to provide a justification or explanation, it must come from two sources: First, the common law or generic legislation like the APA; and second, any other applicable specific law or regulation, such as the OSH Act or Executive Order ("EO") 12291. As to the first of these, the Agency believes that it is inherently obligated under the APA to give a reasonable explanation for its actions in order to provide a basis for judicial review (5 U.S.C.A. 551, 553(C)).

As to the second, because the interim final is being issued under the authority of the Housing and Community Development Act of 1992 and not under the OSH Act, OSHA is not required to comply with any of the requirements of the OSH Act for 6(b) rulemakings. Consequently, for example, OSHA need not undertake and provide a formal analysis of economic and technological feasibility. Nor need the Agency make a determination of significant risk. As a result, no quantitative risk assessment is required.

The Act does state that the interim final regulation "shall have the legal effect of an Occupational Safety and Health Standard * * *." However, by that, Congress seems only to mean that the interim final is to be enforced by OSHA as a 6(b) standard. There is no reason to infer from such language that OSHA must justify the interim final in accordance with the legal tests developed under the OSH Act. On the contrary, precisely because the interim final is not a 6(b) standard it was necessary for Congress to give it that "effect." If Congress had expected OSHA to justify the interim final in the same manner that OSHA justifies 6(b) standards, the legislature could hardly have expected OSHA to issue the interim final in 180 days.

However, the 1992 Act does not appear to exempt OSHA from any other preexisting duties to explain the interim rule. Thus, OSHA still might be required to perform some form of regulatory impact analysis ("RIA") under Executive Order 12291. The extent of that obligation is limited in this case by three considerations: (1) Congress ordered OSHA to produce this rule. OSHA did not, based upon its own priorities, decide to issue it at this time. The Agency therefore should not be responsible for justifying the rule as if it were a typical OSHA determination. (2) Congress also broadly decided the level of protection that must be provided. OSHA, therefore, should not be responsible for justifying that decision as if it were a typical OSHA determination. For all practical purposes, whatever the costs and benefits, OSHA must issue the interim final with the level of protection determined by Congress. (3) The duty to perform an RIA may be further limited by the time constraints imposed by the Congressional deadline. The EO by its own terms is inapplicable to any regulation for which performing the analysis required by the Order "would conflict with the deadlines imposed by statute or by judicial order * * *." (EO 12291, sec. 8(a)(2)). As a result, in the event of conflict, the duty to perform an RIA is limited by the statutory deadline."

In summary, in issuing this interim final rule, OSHA must: (1) comply with the Congressional mandate in Section 1031 of Title X of the Housing and Community Development Act of 1992; and (2) provide a sufficiently reasoned explanation for the rule to permit judicial review (5 U.S.C.A. 551, 553(C); and see note 198).

That is the focus of what follows in this preamble. First comes a general discussion of the criteria for compliance with the Congressional mandate. That is followed by a conventional "summary and explanation" to help employers, employees and others understand the particular provisions in the interim final standard and to help them and the courts understand why OSHA chose to require certain things and not others.

(D) Complying With the Congressional Mandate That the Interim Final be as Protective as the HUD Guidelines

Applying Congress mandate to issue an interim final standard that provides workplaces that are "as safe and healthful as those that would prevail under" the HUD Guidelines raises a number of questions. Some are relatively easy, but others are difficult, to answer.

In the first place, the HUD Guidelines (Revised Chapter 8) are neither sufficiently comprehensive nor sufficiently clear to be translated directly into an enforceable OSHA standard regulating occupational exposure to lead in the construction industry. Second, the HUD Guidelines were written exclusively with regard to lead paint abatement in housing and therefore have to be adapted to the diverse conditions in the construction industry as a whole. Third, the HUD Guidelines expressly incorporate many provisions of the OSHA lead standard

for general industry, but the extent to which the lead standard is incorporated differs in different provisions.

Fourth, there is the question of what criterion should be used to trigger application of the standard in the first place. Although the HUD Guidelines refer to the OSHA general industry standard, there is no explicit reference to a general action level or PEL. In fact, there is no reference to any trigger level or in Chapter 8 of the Guidelines. The only such reference is in the Introduction to the Guidelines and that reference is not in the context of worker protection. (This issue is discussed later in more detail).

Thus, OSHA has to fill in the gaps, clarify, modify, make choices, and adapt the Guidelines to conditions in the construction industry at large. Based upon the Committee report, Congress clearly understood this and signalled that it did not intend for OSHA to simply adopt the HUD Guidelines whole cloth. Rather, the Guidelines are to serve "as the basis" for developing the interim final rule, but "the Secretary may alter the provisions of the HUD Guidelines, so as long as the interim regulation provides workers with health and safety protections which are equally as effective." (House Committee report on H.R. 5730, pp. 15–16). Thus, Congress provided OSHA with flexibility to determine what modifications should be made to those Guidelines, in part based upon the need to adapt the HUD Guidelines to the broader construction industry. So Congress expected that OSHA would have to exercise judgement in determining the contents of the interim final rule.

OSHA considered somewhat different interpretations of how Congress intended the Guidelines to relate to the OSHA general industry standard with regard to such issues as trigger levels. After careful consideration, OSHA has concluded that the Guidelines were intended to be understood in conjunction with OSHA's lead standard for general industry.

The Guidelines are based on, and to a substantial degree repeat, much of the language of the standard. In most respects the Guidelines and the lead standard can be read to be consistent. The close relationship between the two is attested to by the many, often sweeping references in the Guidelines to OSHA's lead standard. For example, the introduction to the worker protection chapter in the Guidelines declares that the Guidelines "are intended to provide, at a minimum, the level of protection afforded by * * * OSHA['s] general industry lead standard" (55 FR 39874). Similarly, in paragraph 8.6 concerning MRP, the Guidelines say that public housing agencies should "refer to OSHA's general industry standard for lead for complete guidance on this subject." Again, in paragraph 8.8 regarding worker training, the employer is required to inform workers of the content of the OSHA lead standard and its appendices. Likewise, just preceding a list of the major elements that employers are advised to include in their employee protection plan, the Guidelines note that "Employers can refer directly to the OSHA lead standard * * * for complete requirements." Finally, near the end of the Guidelines, HUD says, "In addition to the lead standard, there are many standards that abatement employers must comply with." But abatement employers need not comply with OSHA's lead standard, which exempts construction, unless "required" to do so by the HUD Guidelines. These and other similar references to OSHA's lead standard give the strong impression that HUD Guidelines either incorporate that standard or are so dependent on it that they cannot be understood separately from it.

The legislative history of the 1992 Act makes clear that Congress regarded the Guidelines as very similar in essentials to OSHA's lead standard for general industry. Thus, the Committee Report states that "The HUD guidelines are based on, and in most respects mirror, OSHA's general industry lead standard." It further adds that, "Where the guidelines differ from OSHA's standard, the differences are intended to reflect the unique circumstances of the construction industry." Moreover, by requiring OSHA to issue an interim final regulation as protective as the HUD Guidelines, Congress' overriding intention appears to have been to extend to construction workers the protection afforded by OSHA's lead standard for general industry: "By relying on the HUD guidelines as the basis for the Secretary's interim final regulation, the Committee expects that construction workers will gain the same benefits available to general industry workers under the lead standard, i.e., a PEL of 50 μg/m³, medical surveillance, medical removal protection, etc." The reference to a PEL of 50 μg/m³ is repeated elsewhere in the legislative history: "the HUD guidelines recognize that compliance with a 50 μg/m³ PEL in the construction industry likely will require greater reliance on respirator use than is accepted in general industry."

The references to the PEL are important. If the HUD Guidelines were not understood by Congress to have incorporated requirements from the general industry standard, Congress could not have expected a PEL of 50 μg/m³ to apply to construction since there is no explicit reference to a PEL in the language of the Guidelines. Thus, from the legislative history it is clear that Congress intended the interim final regulation to incorporate the PEL and other provisions from the general industry standard. This interim final standard is patterned very closely on the HUD Guidelines and the general industry standard for lead.

OSHA is confirmed in this position by its understanding, based upon the language of the Act and its legislative history, that Congress conceived of the interim final standard within a broader perspective. First, Congress intended the interim final as a long overdue protective measure which generally would not break significant new ground. Second, Congress expected that the interim final would involve an adaption of OSHA's lead standard for general industry to the construction industry along the lines of the HUD Guidelines, which incorporate much of OSHA's lead standard. Finally, Congress assumed that a stricter construction standard or one that breaks new ground, if OSHA determines that one is needed, should be the product of a future 6(b) rulemaking, which provides for extensive notice and comment.

(E) Reasons for Differences With HUD Guidelines on Certain Provisions

In the previous discussion, issues involved in satisfying Congress' mandate that the interim final standard should be as protective as the HUD Guidelines were outlined. In what follows, the resolution of some of these issues is discussed with particular reference to where and why this interim final standard may differ somewhat in specific instances from the HUD Guidelines and/or from the OSHA lead standard. Further detailed discussion of the contents of each of the individual provisions of the standard is provided in the Summary and Explanation below.

Trigger Levels

One of the most important of these issues concerns the criteria by which applicability of the standard and of particular provisions of the standard are triggered. The most basic trigger determines whether an employer is covered by the standard at all. In addition, specific provisions of the standard can be triggered by other criteria or exposure levels.

The trigger criteria for the OSHA general industry standard and the HUD Guidelines appear to be different. For

example, the general industry standard triggers are the PEL of 50 μg/m³ and the action level of 30 μg/m³. Exposures above the PEL require implementation of feasible engineering and work practice controls, and provision of personal protective equipment and hygiene facilities supplemented by the use of respirators, if necessary, to reduce exposures to below 50 μg/m³. For employees exposed at or above the action level of 30 μg/m³, employers must provide biological monitoring. Additional medical examinations are required for those with elevated blood-lead levels, and upon development of signs of lead intoxication. Exposures at or above the action level also require implementation of exposure monitoring and training.

Chapter 8 of the Guidelines seems to require the employer to comply with all provisions where there is any potential of exposure to lead at any level. These provisions include use of respirators (Section 8.2), medical surveillance (Section 8.5), protective clothing (Section 8.3), hygiene facilities (Section 8.4), medical examinations (Section 8.53) and training (Section 8.8) for all employees who work where there is any potential of exposure to lead at any level. Chapter 8 further states that engineering controls, where feasible, must be used to minimize employee exposures (Section 8.1) without regard to the specific air level. That could mean that if it is feasible, engineering controls must be used to reduce exposures to zero.

Thus if OSHA were to adopt the seeming requirements of Chapter 8 without modification, it would apply all of the above provisions to people who are exposed at any level as well as to people who are exposed to higher levels. This would not only be unduly costly but would be impossible to comply with. For example, nearly every person on nearly every lead-related construction site would have to wear protective clothing and a respirator, and would have to be provided an annual medical examination even if they were only exposed to an air lead level of 5 μg/m³ for less than one hour per day and for one week per year. OSHA does not believe this is what Congress intended; nor is it what HUD intended in its Guidelines.

Although the HUD Guidelines do not address a specific trigger in the context of worker protection, the Introduction to the Guidelines states that wherever the lead concentration in a painted surface exceeds 1 mg/cm², abatement is required. This level is based on the hazard which the painted surface presents to occupants of the building, and the abatement is for their protection. It is only where abatement is already required in the Guidelines that most provisions in Chapter 8 are triggered by "any potential exposure". Since abatement is required only when the surface concentration of the painted surface exceeds 1 mg/cm², this level effectively establishes a trigger for the worker protection provisions.

On the basis of the foregoing, several options were theoretically open to OSHA in deciding the basic trigger for application of the standard and its provisions. The first was to trigger the standard, as Chapter 8 of the Guidelines appears to, at any potential exposure. In this case, requirements would be triggered in cases where little risk can be shown to exist. Every workplace where any lead can be shown to exist would be covered, even if the exposures could be shown, for example, to be 1 or 2 μg/m² of lead in the air. Such a requirement could not be justified in terms of substantial adverse health effects and would involve unprecedented annual costs.

An alternative option that would follow the Guidelines would be to trigger the standard based on a minimum lead concentration in paints or coatings of 1 mg/cm³ in any surface coated with lead-containing material. However, there is no reliable connection between such a concentration and any risk of adverse health effects. That connection would have to be established by relating the surface concentration to an air concentration. Where this has been tried, the results were so variable as to be impossible to apply.

For example, in preparing a proposal for a standard for lead in construction, the state of California developed a mathematical model with which they calculated the air lead levels that would arise in certain specific work situations as a result of having 1 mg/cm³ of lead in a painted surface. (Draft proposed standard: Occupational Exposure to Lead in Construction Operations, May 11, 1992, Department of Health Services/Department of Industrial Relations, State of California). The results are highly variable, depending in part on the method of removing the paint from the surface. For example, in the case of wet scraping of paint containing 1 mg/cm² it was calculated that an air lead level of about 37 μg/m³ would result. However, dry scraping of the same surface was estimated to result in an exposure level of about 371 μg/m³. Therefore, in the latter case, if OSHA were to follow the HUD guidelines approach, it could permit exposures to 371 μg/m³ of lead in the air before the standard would be applicable. Thus in the absence of a firm correlation between lead-in-paint concentration and air lead levels, OSHA would have no idea what health effects might be produced by such a surface concentration. Moreover, the trigger applies only to lead painted surfaces. It does not deal at all with the broad range of jobs in the construction industry that involve lead that is not in paint. As a result, the incorporation of this trigger from the HUD Guidelines into an OSHA standard would not be appropriate. Nor did Congress intend such a result. To quote the conference report once more, "By relying on the HUD guidelines as the basis for the Secretary's interim final regulation, the Committee expects that construction workers will gain the same benefits available to general industry workers under the lead standard, i.e., a PEL of 50 μg/m³ * * *." Thus, Congress intended OSHA to incorporate a PEL of 50 μg/m³ into the interim final standard regardless of whether such a PEL was part of the HUD Guidelines.

This approach follows the general industry standard for lead and establishes that a potential hazard must exist prior to requiring an employer to implement the standard. As described above, some provisions will be triggered by the 50 μg/m³ PEL, while others will be triggered by a 30 μg/m³ action level. These trigger levels are taken from the OSHA lead standard for general industry and are based upon health effects data generated for that standard and thus have a health-related foundation.

Task-related Triggers

In response to Congress' mandate that OSHA should modify the HUD Guidelines in this interim final standard as needed to adapt to the particular conditions in the construction industry, OSHA has added a provision included in neither the HUD Guidelines nor the general industry standard. This approach is consistent with the approach taken in the HUD Guidelines. The air lead levels that trigger the standard are determined by an employee exposure assessment, most often containing air sampling. However, there is often a time lapse between taking the sample and receiving the results. Certain construction tasks are known to commonly produce exposures above the PEL—sometimes many orders of magnitude above the PEL. In such tasks, workers could be exposed to high concentrations of lead in air during the period between sampling and receipt of the results without sufficient protection. In addition, because many construction jobs are of short duration, workers could

complete one job before monitoring results are in and go on to another, again in a high exposure situation, still without adequate protection in the absence of monitoring results.

To address this problem, OSHA has included within the regulatory text three lists of tasks, the performance of which in the presence of lead trigger basic protective provisions prior to air lead monitoring. The first consists of tasks which commonly produce a substantial proportion of exposures above the PEL of 50 μg/m³, but less than 10 times the PEL. The second consists of tasks which commonly produce a substantial proportion of exposures greater than 10 times the PEL (500 μg/m³), but less than 50 times the PEL (2500 μg/m³). The third set of tasks consists of those which commonly produce a substantial proportion of exposures greater than 50 times the PEL (2500 μg/m³). For all three sets of tasks, employers are required to provide respiratory protection appropriate to the tasks' anticipated exposure level, protective work clothing and equipment, change areas, hand washing facilities, training, and initial medical surveillance consisting of blood sampling and analysis. OSHA believes that these basic provisions are essential where employees are exposed to air levels above the PEL. In the absence of monitoring results to the contrary, tasks which commonly produce air levels above the PEL must be assumed to continue to do so and, thus, it is necessary to require these provisions. The only difference in the provisions among task categories is in the kind of respirators which are required. For example, abrasive blasting workers need a much higher performance respirator than do workers doing spray painting.

Criteria for selection of the tasks in each category were based on three sources—advice from the Department of Labor Advisory Committee on Construction Safety and Health (ACCSH) Lead Workgroup; recommendations of the Society for Occupational and Environmental Health (SOEH) in conference proceedings entitled Protective Work Practices for Lead-Based Paint Abatement; and limited exposure data provided to OSHA by a firm contracted to perform an assessment of lead exposure levels encountered in the construction industry.

The first set of tasks, consisting of those which commonly produce exposures between 50 μg/m³ PEL and 500 μg/m³, includes manual demolition; manual scraping; manual sanding; heat gun applications; general cleanup; power tool cleaning with dust collection systems; and spray painting. This selection of tasks was suggested by the chairman of the ACCSH Lead Workgroup. It is further supported by the SOEH recommendation that, when these tasks are performed, halfmask air purifying respirators—with a protection factor of 10—should be used. In addition, the selection of these tasks is based partly on limited exposure data available to OSHA.

Since the data which OSHA has obtained indicate a wide range of exposure levels in particular tasks, and are sometimes based on a limited number of samples, OSHA had to consider the data in relation to recommendations from knowledgeable people or organizations. For example, in the case of spray painting, available data showed exposures ranging from 1 μg/m³ to 460 μg/m³. However, the average exposure was 74 μg/m³, and a level of 101 μg/m³ would be expected to be exceeded only five percent of the time. Moreover, SOEH recommends using halfmask negative pressure air purifying respirators for this task, i.e., respirators with a protection factor of 10. Therefore, spray painting seems to belong in the task category with anticipated exposures between 50 μg/m³ and 500 μg/m³. In general, the other tasks in this category also entail a likelihood of exposures in this range, which is supported both by the contractor data and the SOEH recommendations.

The second category, from 500 μg/m³ to 2500 μg/m³, includes the use of lead-containing mortar; lead burning; rivet busting; power tool cleaning without dust collection systems; cleanup of dry expendable abrasives; and abrasive blasting enclosure movement and removal. Following is a discussion of why these tasks were selected for this exposure range and why powered air purifying respirators (PAPRs) are required to be used when performing them.

The only information OSHA has on the use of lead-containing mortar and lead burning comes from its contractor report which suggests control exposure levels for both that are greater than 600 μg/m³, greater than would be safe with an air purifying respirator with a protection factor of 10. ("Control exposure levels" here refers to levels that would not be expected to be exceeded in 95% of the time the activity was monitored.) With an assigned protection factor of from 25 to 50, depending on which specific type is used, a PAPR will provide adequate protection in an exposure range from 1250 to 2500 μg/m³, and thus appears to be effective for these applications.

Rivet busting falls under the SOEH category of "Chipping and Breaking with Pneumatic Tools". SOEH recommends that powered air purifying respirators be used for this group of tasks. Since such respirators have protection factors greater than 10, OSHA infers that SOEH regards likely exposures for rivet busting to be greater than ten times the PEL—greater than 500 μg/m³. Data reflecting actual exposures in this task, however, were not provided to OSHA by its contractor.

Without the use of dust collection systems, the use of power tools for grinding, sanding and wire brushing can raise large concentrations of lead in the air. The OSHA contractor report suggests control exposure levels of more than 1000 μg/m³. SOEH recommends the use of powered air purifying respirators. Thus, placing this task in the 500 μg/m³—2500 μg/m³ category is consistent with both sources.

Clean-up after abrasive blasting when the blasting involves dry expendable abrasives, while not characterized by exposure data available to OSHA, was identified by SOEH as a task with potentially high exposures. SOEH consequently recommends powered air purifying respirators as the minimum respiratory protection. OSHA has classified it accordingly.

In addition to the high concentrations of air lead produced by abrasive blasting operations, the enclosures within which the work is done are left with a substantial accumulation of lead when the blasting is completed. Therefore, movement and removal of these enclosures can themselves create high air lead concentrations, although not to the same extent as the blasting. Available contractor data show a control exposure level for this operation to be between 1100 and 1200 μg/m³. On this basis OSHA has included abrasive blasting enclosure movement and removal in the category where exposures between 500 and 2500 μg/m³ can commonly be expected.

The final category requiring interim protection prior to receiving exposure assessment covers tasks commonly associated with air lead exposures greater than 2500 μg/m³ (50 times the PEL). This category includes abrasive blasting as well as welding, cutting and torch burning on steel structures. In the case of abrasive blasting, the possibility of extremely high exposures is well known and documented by data which show control exposure levels between 20,000 and 40,000 μg/m³. Consistent with these numbers, SOEH recommends the use of supplied air respirators.

Data obtained by OSHA's contractor regarding welding, cutting and burning

show control exposure levels to be from about 970 to about 1560 μg/m³, depending on the specific operation involved. Such levels would not seem to qualify these tasks for the over-2500 μg/m³ exposure category. The numbers, however, represent estimates from a very wide spread of data points, thus providing a high degree of uncertainty. The data show that actual exposures can reach 28,000 μg/m³. Further, SOEH recommends use of supplied air respirators during performance of welding, cutting and burning on steel structures. Therefore, based on exposure data showing that exposures often exceed 2,500 μg/m3 and based on the SOEH recommendation, OSHA has chosen to be conservative and has assigned these tasks to its highest hazard category with respect to required interim protection.

OSHA believes that it has taken a well-reasoned approach to identifying tasks in the foregoing categories, given the limited amount of firm data available at the time of promulgation of this standard. Because the interim protection of workers in these tasks is very important, the approach has been conservative. If the Agency has erred in selecting these tasks, it has erred as authorized by the U.S. Supreme Court on the side of overprotection (*IUD* v. *API*, 448 U.S. 601 (1980)). In any event, once the monitoring results are received, if they show air lead levels to be lower than presumed, the presumed level of protection need no longer be provided. OSHA intends to study this issue comprehensively in a forthcoming rulemaking on a permanent final rule for lead exposures in the construction industry.

Medical Surveillance

One of the most important sets of provisions of any substance specific standard is that of medical surveillance. Medical surveillance is particularly relevant to lead exposures because, in the measurement of blood lead levels, there is a true indicator of health risk and, in the case of high blood lead levels, a course of action to address the risk. The medical surveillance provisions of the HUD Guidelines are essentially the same as in the OSHA general industry standard. The essential difference is in the conditions under which the provisions must be implemented. The medical surveillance provisions of this interim final standard are in most respects similar to those in the HUD Guidelines and the OSHA lead standard for general industry.

The Guidelines, in Chapter 8, appear to require full medical surveillance whenever any employee working in lead paint abatement is potentially exposed to any concentration of lead. This effectively places all workers covered by the Guidelines under medical surveillance. If this requirement were used in the interim final standard, it would apply to all of the more than 900,000 workers who might have some contact with lead, no matter how small the exposure. However, limited available data indicate that most exposures in many highly-populated segments of the industry are well below the 30 μg/m³ action level of the general industry standard, and the blood lead levels of such employees are almost always below any level that, based upon the health effects analysis accompanying the OSHA general industry lead standard, would require medical action. For example, exposure data collected by NIOSH during the Demonstration Project for HUD Lead-based Paint Abatement (The HUD Lead-Based Paint Abatement Demonstration (FHA), U.S. Department of Housing and Urban Development, August 1991), revealed that, in those cases where surface concentration exceeded 1 mg/cm², "Over 80% of the combined numbers of all air samples, both personal and area, showed airborne lead levels below 10 μg/m³." Therefore, in a very large number of cases, the full medical surveillance would serve no purpose and would entail very significant costs. Under these conditions, the same degree of real worker protection can be obtained without the identical requirements of the Guidelines.

The medical surveillance provisions of the OSHA general industry standard are triggered initially by air lead exposure levels. Since it is the air lead level that is relevant, not the industry in which one is exposed, specific air lead triggers in the construction industry should be the same as those in general industry. Thus, medical surveillance in the interim final standard is triggered by the same exposure levels as in the general industry standard.

There are, however, two modifications to this program. As discussed above, in the three categories of high exposure tasks, blood sampling and analysis are triggered by performance of the specified tasks when lead is involved. In addition, the employer must provide every worker who will be exposed to an air lead level greater than the 30 μg/m³ action level, if only for a single day in any consecutive 12 month period, with blood testing. The construction-related reason for the blood testing related to the high exposure task categories has been discussed earlier. The reason for blood monitoring for workers exposed above the action level, even on one day, also arises from the peculiarities of the construction industry where jobs are frequently of short term, turnover is rapid and exposure levels vary. OSHA believes it important that exposures of duration up to 30 days not be neglected since such exposures in some applications will be very high. A worker exposed at high levels for only a few days can still incur a large lead burden in his or her blood and, if that happens, it is important to keep track of the levels.

In view of the fact that workers who need medical surveillance, based on air lead levels established in the rulemaking for the general industry standard, on high exposure tasks, and on short duration exposures above the action level receive it, the medical surveillance provisions of the interim final standard are more protective than the OSHA general industry standard and are as protective as the Guidelines.

Exposure Assessment

The HUD Guidelines do not require initial monitoring. They do, however, require that an initial determination be made "to determine whether employees are potentially exposed to lead. The goal is to establish the level of exposure expected." The Guidelines go on to say, "Indications of possible overexposure to lead, such as employee health complaints, prior abatement experience, and prolonged or intense lead-based paint removal, should lead to an initial monitoring of the workplace." The monitoring results are to be used to determine the frequency of further monitoring, and to select appropriate respiratory devices and determine the need for engineering controls. However, in using monitoring results for the foregoing purposes, the Guidelines refer to the PEL of the OSHA general industry standard and the respirator selection table that is used for selecting a respirator that will maintain exposures below the PEL. They allow consideration of objective factors before initial monitoring needs to be performed. Thus, every workplace with very low exposures need not do monitoring where it serves no purpose in identifying excessive exposures. If monitoring is done, however, the Guidelines recommend that the procedures in the general industry standard be followed.

The interim final standard is effectively very similar to the Guidelines. It requires, as a first step, an initial determination which can be an objective assessment of exposure, based on specific data or on previous

monitoring or on past experience in identical workplaces. Once again, however, the requirements for the high exposure tasks are slightly more stringent. In order for any data other than from initial monitoring to be acceptable, it must be based on specific and documented monitoring performed during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations. Also the sampling and analytical methods used to obtain the data must meet the accuracy and confidence levels specified in the standard.

The remainder of the monitoring requirements are the same as in the general industry standard and the same as the Guidelines for situations where monitoring is performed.

On balance, the exposure assessment requirements for the interim final standard are more specific and somewhat more stringent than those in the Guidelines.

Protective Clothing and Respiratory Protection

Protective clothing and respirators are required in the Guidelines whenever the potential for exposure is present. As discussed earlier in this paragraph, this provision, on its face, would place every worker in a respirator and protective clothing regardless of extent of exposure. When applied across the entire spectrum of construction operations, the overall burden of this provision would be extremely high and difficult to justify. In particular, requiring respirators and personal protective equipment in the 80% of all cases in which NIOSH found that air lead exposures were less than 10 $\mu g/m^3$ would be difficult to justify on health grounds. Such a requirement would thus entail a significant burden to employers and employees without demonstrated benefit. For these reasons, and because there is no reason to believe that the relationship between health risks in the construction industry and air lead levels is different from that in general industry, the provisions for protective clothing and respiratory protection in this interim final standard are triggered by the PEL, as in the general industry standard.

The actual provisions covering the use and selection of respirators in the Guidelines are the same as in the general industry standard. The interim final standard, however, has one important difference. The respirator selection table of the general industry standard was based on information as of 1978 and contained no specific reference to construction—particularly abrasive blasting. The selection table in the interim final standard has expanded the types of respirators permitted under the various exposure categories, including those uniquely permitted for abrasive blasting, and added another exposure level category (1250 $\mu g/m^3$) to provide greater flexibility in selection and higher probability of adequate fit. The table has been taken from the latest version of the NIOSH Respirator Decision Logic, which has been a standard reference since its publication. Therefore, in terms of respirator selection the interim final rule is more appropriate and more protective than the HUD Guidelines.

Information and Training

Regarding employee information and training, the Guidelines require comprehensive training for everyone who may be potentially exposed to lead. As discussed previously, this provision, applied to the entire construction work force, would cover a large number of workers who encounter only minimal exposure. The OSHA general industry standard requires comprehensive training only for those workers who are exposed above the action level. The interim final standard has the same provision for comprehensive training; however, other training provisions are also included. First, all employees, regardless of exposure, are required by the Hazard Communication Standard (29 CFR 1926.59) to receive training regarding any hazardous materials, including lead, they may be exposed to at their work site. The interim final standard specifically incorporates this requirement by reference. Second, all construction employees are required to undergo training relevant to all the health and safety hazards of the workplace by the Safety Training and Education Standard (29 CFR 1926.21) which the interim final standard also incorporates by reference. In addition, for those tasks listed as likely to encounter high exposure levels, training in use of respirators is required automatically, until it is shown by monitoring results that exposures will not reach the level at which respiratory protection is necessary.

In view of the foregoing, OSHA believes that the interim final standard requires training as protective as that provided for in the HUD Guidelines.

III. Summary and Explanation of the Standard

As discussed earlier, OSHA believes that the intent of Congress' mandate, to a significant degree, was the issuance of a interim final standard that provided a level of protection to workers exposed to lead in construction equivalent to that afforded other lead workers under OSHA's general industry standard. To that end, the interim final construction standard incorporates many provisions as they are set-forth in the general industry standard. Although some provisions carried from the general industry standard into the interim rule are not adopted verbatim, the regulatory intent of the provisions in the rules is consistent. Thus, the discussion and justifications set forth in the preamble and supplements to the general industry standard (43 FR 52985) are applicable to the "Summary and Explanation" in this interim final rule. Provisions derived from the general industry standard and incorporated into the interim final standard include the following paragraphs of this rule: (b) Definitions; (c)(1),(2),(3), Permissible exposure limit; (d)(1),(3),(4),(5),(6),(7),(8), Exposure assessment; (e)(2)(i)-(v),(4) Methods of compliance; (f)(1)(i)-(iv),(2),(3),(4), Respiratory protection; (g)(1),(2), Protective work clothing and equipment; (h)(1),(2),(3),(4), Housekeeping; (i)(1),(2), Hygiene facilities and practices; (j)(1)(ii)-(iv),(2)(i)(B)-(C),(ii)-(iv),(3),(4), Medical surveillance; (k)(1)(ii)-(v),(2), Medical removal protection; (l)(1)(ii)-(iii),(2),(3), Information and training; (m)(1),(2), Signs; (n)(1),(2),(3),(5),(6), Recordkeeping; and (o)(1),(2), Observation of monitoring.

A. Scope and Application Paragraph (a)

This interim final lead standard for the construction industry applies to all occupational exposure to lead in all construction work in which lead, in any amount, is present in an occupationally related context. Exposure of employees to the ambient environment which may contain small concentrations of lead unrelated to the job is not subject to this standard; however, where the source of lead is employment related, all exposure to lead is covered by the standard. The forms of lead to which this construction standard applies is defined to include metallic lead, all inorganic lead compounds, and organic lead soaps.

Construction work is defined as work involving construction, alteration and/or repair, including painting and decorating. Such work includes but is not limited to: demolition or salvage of structures where lead or materials containing lead are present; removal or encapsulation of materials containing lead; construction, alteration, repair, or renovation of structures, substrates, or portions thereof, that contain lead, or

materials containing lead; installation of products containing lead; lead contamination/emergency cleanup; transportation, disposal, storage, or containment of lead or materials containing lead on the site or location at which construction activities are performed; and maintenance operations associated with the construction activities described above. All construction work excluded from coverage in the general industry standard, section 1910.1025(a)(2), is covered by this interim final rule. OSHA intends that there should be no gaps and no overlaps between the two standards.

It should be recognized that although this standard may apply to a particular employer or workplace, almost all of the obligations in the standard are triggered by certain minimum levels of lead exposure. For example, the employer is required to provide requirements for periodic exposure monitoring and medical surveillance only if employees are exposed to airborne lead in excess of the action level. Employers whose employees are exposed below this level are not required to comply with most provisions of the standard. This distinction is made in order to differentiate between hazardous and relatively unhazardous work operations and to impose obligations commensurate to the degree of hazard present.

B. Definitions: Paragraph (b)

The terms "*Action Level*", "*Assistant Secretary*", "*Director*" and "*Lead*" in this interim standard are defined as set forth in 29 CFR 1910.1025.

"Action level" is defined as an airborne concentration of lead of 30 μg/m³ of air calculated as an 8-hour time-weighted average. Several provisions of the standard, such as periodic exposure monitoring, biologic monitoring and initial and annual employee training are triggered whenever exposure measurements reach or exceed the action level. For employees exposed to lead at or above the action level for more than 30 days per year, employers are also required to provide an ongoing medical surveillance program. Past experience with the action level concept in other OSHA standards has demonstrated its usefulness to employers as an objective means of determining whether compliance activities are required, thus relieving them of most compliance obligations where exposures are maintained below the action level.

Action levels are important because their use permits employers to concentrate their resources on those employees and workplace conditions with the potential for high lead exposures. Thus the action level in the interim standard provides for the most cost-effective means of employee protection. The action level provides a mechanism to tailor certain requirements of the standard to a minimum level of employee exposure to lead by triggering preventive action by the employer for employees who face exposure at or above that level. The use of the action level to trigger various provisions of the lead standard is consistent with other final OSHA health standards (e.g., the Lead standard for general industry, as well as Asbestos, 51 FR 22612, June 20, 1986; Benzene, 52 FR 34460, September 11, 1987; Formaldehyde, 52 FR 4668, December 4, 1987; Ethylene Oxide decision (796 F.2d 1479 (DC Cir., 1986) and, *Public Citizen Health Research Group* v. *Tyson*, 796 F.2d 1479 (DC Cir., 1986), and Acrylonitrile, 43 FR 45809, October 3, 1978).

This substantive consistency provides administrative consistency and continuity to employers in developing and implementing compliance strategies for this and other applicable OSHA health standards at individual worksites. In addition, use of an action level has been found to encourage employers, where feasible, to lower lead exposure levels to below the action level to avoid the added costs of required compliance with provisions triggered by the action level.

A definition of "*Competent person*" is included in this paragraph. Paragraph (e)(2)(iii) of the standard broadly establishes the duties of the "competent person." The duties and definition of the "competent person" under this standard are essentially identical to those already prescribed for construction work in 29 CFR 1926.20 and 29 CFR 1926.32, respectively, and are included in this section to primarily ensure that employers are aware of these existing requirements. Thus, no new burdens are imposed by the "competent person" provisions in this section. The term "competent person" means a person who is capable of identifying hazards and has authorization to take corrective measures to eliminate them. Compliance programs required to be developed by employers under paragraph (e) of this section must provide for inspections of job sites, materials, and equipment to be made by the "competent person" to achieve the duties of the competent person set forth in the definition.

C. Permissible Exposure Limit: Paragraph (c)

The employer is required to assure that no employee is exposed to lead at concentrations in excess of the PEL of fifty micrograms of lead per cubic meter of air (50 μg/m³). The PEL adopted in this interim rule is the same as the PEL provided for in OSHA's general industry lead standard (29 CFR 1910.1025). This is in accordance with Congress' intention, as expressed in the legislative history of the 1992 Act.

The PEL is an eight-hour average of exposure for any work day. If respiratory protection is permissibly being used to comply with this limit and all of the requirements relating to selection, fitting, and maintenance of respirators are met, the employee needs to wear the respirator only for a period of time that, when averaged with periods of time the respirator is not worn, will result in a TWA exposure to or below the PEL. For this purpose, the employee's exposure level when a respirator is worn may be considered to be the airborne concentration, without regard to the respirator, divided by the protection factor of the respirator. For example, if an employee is exposed to 100 ug/m³ for 8 hours without a respirator, he would have to wear a respirator with a protection factor of 10 for about 4.4 hours or with a protection factor of 50 for about 4.1 hours, in order to comply with the PEL.

Of course, a class of respirator more protective than required by paragraph (f) may be selected, and if selected, would reduce the amount of time a respirator would need to be worn.

OSHA recognizes that workshifts can extend beyond the regular 8-hour period as the result of overtime or other alterations of the work schedule. This extension of worktime also extends the time during which the employee is exposed. The effects of this additional exposure time must be considered in arriving at a permissible level of exposure. For the purpose of calculating such a level, the relationship of concentration and length of time of exposure has been assumed to be linear. As the exposure time increases, the factor of concentration multiplied by time ($C \times T$) should remain constant. As a result, it is believed that by not exceeding the total allowable exposure of the 8-hour time-weighted average (8 hrs × 50 μg/m³=400), reasonable assurance of maintaining a safe exposure level is retained.

The interim final standard contains a formula by which adjustments to the permissible exposure limit can be made due to overtime. For example, if an

employee is exposed to lead for 10 hours, the permissible limit as a 10 hour average would be 400/10 or 40 μg/m³. This is the same formula used in the lead General Industry Standard to calculate the allowable exposure level for employees working beyond 8 hours in lead exposed jobs.

D. Exposure Assessment: Paragraph (d)

Each employer who has a workplace or work operation covered by this standard is required to determine if any employee may be exposed to lead at or above the action level of 30 μg/m³ as an 8-hour TWA. This initial determination need not be based exclusively on employee exposure monitoring. Where the employer has objective data demonstrating that under any expected conditions of use a particular product or material containing lead or a specific process, operation or activity involving lead cannot result in employee exposure to lead at or above the action level during processing, use, or handling, the employer may rely upon such data instead of implementing initial monitoring. The employer must establish and maintain a record documenting the nature and relevancy of the objective data (see paragraph (n)(4)). As is discussed elsewhere in this preamble, certain specified tasks are treated differently.

Where objective data as described above is not available to employers, employers must monitor employee exposures, except as noted below, and base initial determinations on the employee exposure monitoring results and any of the following relevant considerations: Any information, observations, or calculations which would indicate employee exposure to lead; any previous measurements of airborne lead; and any employee complaints of symptoms which may be attributable to exposure to lead.

Historical measurements of airborne lead may be used to satisfy the initial exposure assessment requirement if all the requirements of (d)(3)(iii) are met. OSHA has included this provision to allow employers who have been conducting relevant exposure monitoring on construction sites to use such data for current construction jobs that are substantially similar to previous jobs for which monitoring was conducted.

However, such monitoring data must have been obtained from projects conducted by the employer within the past 12 months under conditions which in all relevant and significant respects are essentially the same as the current project. These conditions include the following:

(1) The data upon which employee exposure assessments are based are scientifically sound and collected using methods that are sufficiently accurate and precise.

(2) The processes and work practices in use when the historical data were obtained are essentially the same as those to be used during the job for which initial monitoring will not be performed.

(3) The characteristics of the lead containing material being handled when the historical data were obtained are essentially the same as those on the job for which initial monitoring will not be performed.

(4) Environmental conditions prevailing when the historical data were obtained are essentially the same as for the job which initial monitoring will not be performed.

OSHA believes that if an employer has previous monitoring data that meet all these conditions, these data can be reasonably assumed to be representative of employee exposures that will be encountered on a new construction site. The employer must develop and maintain a record of the relevancy of previous exposure data if used for the initial exposure assessment. These provisions are set-forth in paragraph (d)(3)(iii) of this section.

The initial monitoring requirement only requires monitoring of a representative sample of the employees believed to have the highest exposure levels. If these measurements indicate exposures are all below the action level no further monitoring is required except where subsequent process or control changes would trigger a redetermination pursuant to paragraph (d)(8) due to additional employee exposure. If any employee is determined to be at or above the action level, then full-scale representative monitoring for all exposed employee is required as set-forth in paragraph (d)(4) of this section. However, under paragraph (d)(4)(ii) historical exposure monitoring data, which is permitted to be used to assess whether exposures are either above or below the action level, as discussed above, can also be used to satisfy the determination of the level of exposure that employees will be subject to above the action level.

In conducting the monitoring of employee exposures under paragraph (d)(4), the standard does not require that each individual employee's exposure level be measured. In establishments having more than one work operation involving the use of lead, in order for monitoring to be representative, it must be performed for each type of employee exposure within each operation. An employer, of course, is allowed to take individual exposure measurements of each of his employees. Representative monitoring merely establishes the minimum that the employer must meet.

All exposure monitoring performed pursuant to this section must consist of personal breathing zone samples which are representative of the monitored employee's regular, daily exposure to lead over a full shift and which must consist of at least one sample for each job classification in each work area either for each shift or for the shift with the highest exposure level. The exposure data may be collected during a single shift only if the activities in the other shifts are essentially the same as that shift.

The purposes served by air sampling for employee exposures include: Determination of the extent of exposure at the worksite; prevention of employee overexposure; identification of the sources of exposure to lead; collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of selected controls. Monitoring further enables employers to notify employees of their exposure levels, as required by section 8(c)(3) of the Act.

Required periodic monitoring provides the employer with assurance that employees are not experiencing higher exposures that may require the use of additional controls. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to lead.

The collection of exposure monitoring data also enables an examining physician to be informed of the existence and extent of potential sources of occupational diseases.

The results of initial and periodic monitoring determine whether subsequent monitoring is necessary. Exposure monitoring is important not only to determine the level of lead to which employees are exposed and the frequency at which employees should be monitored, but also determine whether other protective provisions of the standard need to be implemented.

Where exposure monitoring is required under this standard samples must be taken within the employee's breathing zone (i.e., personal samples) and must reflect the employee's exposure, without regard to the use of respirators, to airborne concentrations of lead over an eight-hour period. A full description of "Breathing zone" is provided in the OSHA Instruction CPL 2-2.20B, CH-1, Nov. 13, 1990, Directory of Technical Support, Basically, it

encompasses a sampling area as close as practical to the nose and mouth of the employee.

If the initial determination or subsequent determination reveals employee exposure to be at or above the action level but at or below the PEL the employer is required to perform monitoring at least every 6 months. The employer must continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee.

If the initial determination reveals that employee exposure is above the PEL the employer must perform monitoring at least quarterly. The employer must continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are at or below the PEL but at or above the action level at which time the employer shall repeat monitoring at least every 6 months.

Within 5 working days after completion of the exposure assessment, the employer is required to notify each employee in writing of the results which represent that employee's exposure. Whenever the results indicate that the representative employee exposure, without regard to respirators, is at or above the PEL, the employer shall include in the written notice a statement that the employees exposure was at or above that level and a description of the corrective action taken or to be taken to reduce exposure to below that level. Section 8(c)(3) of the Act requires employee notification of monitoring results which reveal excess exposures to toxic substances, and requires employers to also notify affected employees of corrective actions that will be taken to reduce exposures.

Where monitoring is required under this standard the employer must use a method of monitoring and analysis which has an accuracy (to a confidence level of 95%) of not less than plus or minus 25 percent for airborne concentrations of lead equal to or greater than 30 $\mu g/m^3$. This accuracy requirement is consistent with the most recent criterion established under the NIOSH/OSHA Standards Completion Program with regards to monitoring and analyses of airborne lead concentrations.

As discussed earlier, OSHA is aware that in many instances in the construction industry the exposure assessment required under this standard will not be completed until after lead operations have begun or even ended (i.e. exposure monitoring usually must be conducted during actual performance of the lead activity in order to be representative). Thus, employees performing certain tasks which will generate airborne lead due to the presence of lead either in paint or in other materials being worked on, might be exposed without protection to some unknown, and potentially high concentrations of lead, pending the outcome of the exposure assessment. The Lead Workgroup of the Department of Labor's Advisory Committee on Construction Safety and Health (ACCSH), which was consulted by OSHA in development of this standard expressed concern to the Agency regarding this issue. The ACCSH Workgroup comprised of representatives from labor, industry, state government, and the public, recommended that some degree of interim protection, pending completion of the exposure assessments, should be provided to employees performing activities which are recognized as having the potential to produce exposures to lead in excess of the PEL. The Agency agrees with the ACCSH Workgroup that the need for interim employee protection should be presumed necessary for certain tasks until demonstrated otherwise. The Workgroup indicated that minimal interim protective measures, pending completion of the exposure assessment, should include provision of respirators, protective clothing and equipment, hygiene facilities, training, and biological monitoring.

The list of lead-related tasks/operations that have been developed by OSHA are based on available exposure data and recommendations of SOEH and the Workgroup, and are grouped by the presumed degree of overexposure to lead and, therefore, are differentiated by the type of respirator to be provided. One group of tasks/operations presumes employee exposures above the PEL, but not so high as to require the employer to provide the employee with more than the least protective, allowable respirator (e.g. a respirator with a protection factor of 10). The second task group presumes employee exposure above 500 $\mu g/m^3$ and requires the employer to provide the employee with a respirator with a protection factor of at least 25. The third task group presumes very high exposures to lead (in excess of 2500 $\mu g/m^3$) and, therefore, requires the employer to provide the employee with a respirator permitted by the standard for use during that exposure condition (e.g a respirator with a protection factor above 50).

The tasks identified as requiring interim worker protection are briefly described below.

Abrasive blasting: Removes scale, paint, and dirt from surfaces prior to repainting; abrasive media includes sand, steel grit, steel shot, aluminum oxide, "Black Beauty" (processed boiler slag, and others).

Welding, cutting and burning on steel structures: Involves the process of heating coated steel to its melt temperature typically by using an oxy-acetylene torch or an arc welder.

Lead burning: Involves torch melting or fusing of lead or alloyed lead to another lead object.

Manual scraping and sanding: Associated with lead paint removal and involves the application of hand-held scraping or sanding tool to the painted surface containing lead.

Manual demolition of structures: Involves removal of walls (plaster, gypsum) or building components coated with lead based paint by sledge hammer or similar tool.

Heat gun application: Involves use of a heat gun that produces a stream of hot air which is directed to surfaces to melt lead paint which is subsequently scraped off.

Using lead containing mortar: Typically used in high pressure acid tanks lined with specialized tile or lead brick held in place with specialized lead-containing mortar or grout; these tank linings periodically require repainting, repairing or relining involving lead containing mortar.

Abrasive blasting enclosure movement and removal: Involves movement and removal of blasting enclosure or containment units as work proceeds on structures; such units are often comprised of flexible nylon, plastic or burlap tarpaulins upon which lead dust will accumulate and be reentrained when movement of the structure occurs.

Power tool cleaning: Involves the use of power tools (grinders, brushes, needle guns, sanders, etc.) to remove dirt, scale, or paint from structures where lead based paint is present.

Rivet busting: Involves removal of rivets from steel structures where lead containing paints are present; rivet busting can involve use of torches and mechanical means for rivet extraction.

Cleanup activities where dry expendable abrasives are used: Pertains to the use of non-recycled dry abrasives during abrasive blasting operations on structures where lead containing paint is found.

The requirements regarding interim employee protection during performance of these specific tasks, when lead is involved typically as in a paint or coating, are discussed below.

Paragraph (d)(2)(i) includes a listing of the following tasks which are presumed to frequently entail lead exposure levels above the PEL: Where lead containing coatings or paint are present; manual demolition of structures (e.g. dry wall), manual scraping, manual sanding, heat gun applications, and power tool cleaning with dust collection systems; and spray painting with lead based paint. With respect to these tasks, paragraph (d)(2)(i) requires that, until the employer performs an employee exposure assessment as required in paragraph (d) of this section and documents that the employee performing any of the listed tasks is not exposed above the PEL, the employer must treat the employee as if the employee were exposed above the PEL by providing the protective measures as prescribed in paragraph (d)(2)(v) of the standard (discussed below).

In addition, with regard to tasks not listed in paragraph (d)(2)(i), paragraph (d)(2)(ii) requires that where the employer has any reason to believe that an employee performing a task may be exposed in excess of the PEL, until the employer performs an employee exposure assessment as required by paragraph (d) and documents that the employee's lead exposure is not above the PEL, the employer must treat the employee as if the employee were exposed above the PEL by providing the protective measures as prescribed in paragraph (d)(2)(v) of this standard.

Paragraph (d)(2)(iii) includes a listing of the following tasks: Using lead containing mortar; lead burning; rivet busting; power tool cleaning without dust collection systems; cleanup activities where dry expendable abrasives are used; and abrasive blasting enclosure movement and removal. With respect to these tasks, paragraph (d)(2)(iii) requires that until the employer performs an employee exposure assessment as required in paragraph (d) of this section and documents that the employee performing any of the listed tasks is not exposed in excess of 500 $\mu g/m^3$, the employer must treat the employee as if the employer were exposed to lead in excess of 500 $\mu g/m^3$ by providing the protective measures prescribed in paragraph (d)(2)(v) of this section. Where the employer has established that employee exposure is at or below 500 $\mu g/m^3$ during these tasks, a less protective respirator, in accordance with Table 1 of this section, shall be provided as protection.

Paragraph (d)(2)(iv) includes a listing of the following tasks which are presumed to frequently entail exposures to lead above 2,500 $\mu g/m^3$: Abrasive blasting, and welding, cutting, and torch burning on steel structures where lead containing coatings or paint are present.

With respect to these tasks, paragraph (d)(2)(iv) requires that until the employer performs an employee exposure assessment as required in paragraph (d) and documents that the employee performing any of the listed tasks is not exposed to lead in excess of 2,500 $\mu g/m^3$ (50 × PEL), the employer must treat the employee as if the employee were exposed to lead in excess of 2,500 $\mu g/m^3$ by providing the protective measures prescribed under paragraph (d)(2)(v) of the standard. Where the employer has established that the employee is exposed to levels of lead below 2,500 $\mu g/m^3$ during these tasks, the employer shall provide the exposed employee with a less protective respirator in accordance with Table I of this section.

Paragraph (d)(2)(v) of the standard sets forth the interim protective measures that employers must implement during performance of the tasks discussed above at least until an exposure assessment as prescribed in paragraph (d) of the standard is completed.

These protections are required when an employee performs a specified task where lead is present. Interim protection to be provided to affected employees includes: (1) Appropriate respiratory protection in accordance with paragraph (f) of the standard; (2) appropriate personal protective clothing and equipment in accordance with paragraph (g) of the standard; (3) change areas in accordance with paragraph (i)(2) of the standard; (4) hand washing facilities in accordance with paragraph (i)(5) of the standard; (5) biological monitoring in accordance with paragraph (j)(1)(i) of the standard; and (5) training as required under paragraph (l)(1)(i) of the standard, which incorporates the relevant requirements of 29 CFR 1926.59 (Hazard Communication), as required under 29 CFR 1926.21 (Safety training and education), and as required under paragraph (l)(2)(ii)(c) of the standard regarding the purpose, selection, fitting, use and limitation of respirators.

It should be noted that the interim respiratory protection required to be provided to employees performing the tasks listed above is based on a presumed 8-hour exposure period. Where the tasks listed above are performed for lesser periods than 8-hours, the employer may be able to provide a less protective respirator if compliance with the PEL as an 8-hour TWA can be achieved.

E. Methods of Compliance: Paragraph (e)

The interim final standard requires employers to institute engineering and work practice controls to the extent feasible to reduce exposures to or below the PEL. Where all feasible engineering and work practice controls that can be instituted are not sufficient to reduce employee exposure to or below the PEL, appropriate respiratory protection is required to be provided as a supplement to such controls to reduce employee's exposures to lead to or below the PEL.

OSHA thus continues to maintain its preference for engineering and work practice controls in this standard. However, in the construction industry generally based on available data, OSHA is unable to show for purposes of this interim final rule that the PEL can be achieved by engineering and work practice controls in most operations most of the time. Consequently, as Congress anticipated, OSHA expects employers to place broader reliance on respirators than in General Industry.

The standard has a requirement for the development and implementation of a written compliance plan prior to the commencement of the job where employee exposure to lead, without respect to respiratory protection, will be in excess of the PEL. The plan should be a written strategy and schedule for protecting workers from occupational hazards, and must incorporate all relevant information that relates to those goals, so that one could determine whether the employer reasonably analyzed the problems and their solutions, including alternatives and has implemented the plan in accordance with its schedules.

These written plans must be furnished upon request for examination and copying to affected employees and their designated representatives and to representatives of the Assistant Secretary and the Director. They must be reviewed and updated periodically at least every 6 months to reflect the current status of exposure control. OSHA views the requirement for written plans as an essential part of the compliance program since it will form the basis for determining the employer's ability to achieve the controls and provide the necessary documentation to employees and their designated representatives of the compliance methods chosen, the extent to which controls have been instituted, and of the plans to institute further controls.

Where mechanical ventilation is used to control employee exposure to lead, the employer is required to evaluate the performance of the system in controlling

exposure as necessary to maintain its effectiveness.

Finally, the standard requires that when administrative controls are used to lower employee exposure, a rotation schedule is to be kept and followed and made a part of the written compliance plan. This will enable affected employees and OSHA to determine the effectiveness of the administrative control program.

F. Respiratory Protection: Paragraph (f)

This section contains specific requirements for the usage, selection, maintenance, and fitting of respirators.

The interim final standard, requires that respirators be used whenever the concentration of lead is at or above the PEL, in work situations in which engineering and work practice controls are not sufficient to reduce exposures to or below the PEL, or whenever an employee requests a respirator. This last requirement is to provide protection for those employees who wish to reduce their lead burden below what is required by the interim standard. For example, male and female workers whose blood lead levels are in the 30–50 μg/100g range may desire increased protection, especially if they intend to parent in the near future.

Because of the discomfort and hazards associated with negative pressure respirators, coupled with the possibility of routine and long-term use in some industries, OSHA has required employers to provide powered, air purifying (positive pressure) respirators (PAPR) to employees who request one, so long as it will provide adequate protection against the hazard for which a respirator is worn. Powered air positive-pressure respirators simultaneously provide greater protection to individuals, especially those who cannot obtain a good face fit on a negative pressure respirator, and greater comfort when a respirator needs to be worn for long periods of time. OSHA believes employees will have a greater incentive to wear respirators if discomfort is minimized.

The standard requires the employer to provide respirators at no cost to the employee and to select respirators from those approved by MSHA or NIOSH under the provisions of 30 CFR part 11 and in accordance with the respirator selection table (Table I) set-forth in the standard. The respirator selection table will enable the employer to provide the type of respirator which affords the proper degree of protection based on the airborne concentration of lead. While the employer must select the appropriate respirator from the table on the basis of the airborne concentration of lead, the employer may always select a respirator providing greater protection, that is, one prescribed for higher concentration of lead than present in the workplace. The respirator table is based on NIOSH recommendations.

The standard requires that the employer institute a respirator program in accordance with 29 CFR 1910.134 which contains basic requirements for proper selection, use, cleaning and maintenance of respirators. Under the respirator program the employer must change the filter elements of filter respirators whenever an employee detects an increase in breathing resistance, and must permit employees to leave work areas to wash their face and respirator facepiece when necessary to prevent skin irritation associated with respirator use.

The employer is also required to assure that the respirator facepieces fit properly and exhibit minimum facepiece leakage. Proper fit of the respirator is critical. As a negative pressure is created within the facepiece when the wearer inhales, unfiltered air may enter the facepiece between the facepiece and the employees' face. Obtaining a proper fit on each employee may require the employer to provide two or three different mask styles.

Employers are required to perform either quantitative or qualitative face fit tests at the time of initial fitting and at least every six months thereafter for each employee wearing negative pressure respirators. The qualitative fit tests may be used only for testing the fit of half-mask respirators where they are permitted to be worn, and must be conducted in accordance with appendix D. The tests are to be used to select facepieces that provide the required protection as prescribed in the respirator selection table included in the standard (Table I).

G. Protective Clothing and Equipment: Paragraph (g)

This paragraph contains requirements that the employer provide, at no cost to employees, protective clothing and equipment that are appropriate for the hazard. Such clothing and equipment is necessary in order to protect employees from lead compounds which may cause skin or eye irritation (e.g., lead arsenate, lead azide) where encountered and, for employees who are exposed to lead above the PEL, to assure that clothing, shoes, and equipment on which lead dust can accumulate during the work shift are not worn home. Wearing contaminated clothing outside the work place will lengthen the duration of the employee's exposure through both inhalation and ingestion routes and potentially expose others in the family.

Clean work clothing is required to be provided at least weekly to employees whose exposure levels are above the PEL and daily to those above 200 $\mu g/m^3$ as an 8-hour TWA. The employer must also repair or replace required protective clothing and equipment as needed to maintain its effectiveness. Removal of lead from protective clothing or equipment by blowing, shaking, or other means which disperses lead into the air is prohibited in order to minimize secondary exposure to lead in work areas.

The employer is required to provide for the cleaning, laundering, or disposal of protective clothing and equipment and must repair or replace required protective clothing and equipment as needed to maintain its effectiveness. The employer must assure that all protective clothing is removed at the completion of a work shift only in change areas provided for that purpose and must assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closed labelled container in the change area.

The employer must also inform in writing any person who cleans or launders protective clothing or equipment of the potentially harmful effects of exposure to lead. These requirements regarding personal protective equipment and clothing are commonplace in OSHA standards.

H. Housekeeping: Paragraph (h)

The interim standard requires that all surfaces be maintained as free as practicable of accumulation of lead dust. This is to be accomplished primarily by vacuuming floors, rafters, and other surfaces or by methods equally effective in preventing the dispersal of lead into the workplace. This clean-up is an exceptionally important provision because it minimizes the reentrainment of lead dust into the air which can provide an additional source of exposure that engineering controls are generally not designed to control.

OSHA's view is that as rigorous a housekeeping program as practicable is necessary in many jobs to keep airborne lead levels below permissible limits. This contemplates a regular housekeeping schedule adapted to exposure conditions at a particular site.

Vacuuming is considered to be the most reliable method of cleaning surfaces on which dust accumulates, but equally effective methods may be used, for example, a wet floor scrubber. Where vacuuming methods are selected, the

vacuums must be equipped with HEPA filters. Dry or wet sweeping, shoveling, or brushing may not be used except where vacuuming or other equally effective methods have been tried and do not work.

Blowing with compressed air is generally prohibited as a cleaning method, unless the compressed air is used in conjunction with a ventilation system designed to capture the airborne dust created by the compressed air.

I. Hygiene Facilities: Paragraph (i)

This paragraph requires employers to provide hygiene facilities and to assure employee compliance with basic hygiene practices. These provisions are universally recognized industrial hygiene tools for minimizing additional sources of lead absorption from inhalation or ingestion of lead that accumulates on a worker's clothes or body. The employer must provide adequate shower facilities, if feasible, clean areas for changing clothes, and eating areas for employees who have exposure above the PEL. Hand washing facilities are to be provided for all employees occupationally exposed to lead in accordance with 29 CFR 1926.51(f). In addition, employers must assure that employees use the facilities as required by the standard as well as observe prohibitions on the use of tobacco, food, and cosmetics in contaminated areas. OSHA expects that strict compliance with these provisions will control several sources of lead exposure which substantially contribute to increased lead absorption.

The interim final standard requires employers to prohibit smoking, eating, applying cosmetics and the presence of tobacco products, food stuffs, or cosmetics in all work areas where employees are exposed to lead above the PEL. This prohibition will prevent unnecessary contamination of food or tobacco products caused by exposure to lead dust or fumes within the work area. It also decreases the likelihood of lead absorption in employees due to ingestion or inhalation of products contaminated with lead within the work environment.

The standard requires employers to provide separate storage facilities in change areas for street and work clothing to prevent cross-contamination between the two. This provision coupled with showering, where feasible, and the prohibition on wearing work clothing home will minimize employee exposure to lead after the work shift ends because it limits the period in which work clothes contaminated with lead dust may be worn.

Employers are also required to assure that employees exposed to lead during their work shift shower before leaving the workplace, where showers are provided, and do not leave wearing protective work clothing. Showering reduces the worker's period of exposure to lead and removes lead particles which accumulate on the skin and hair. Employees are not permitted to leave the worksite wearing any protective work clothes or equipment required to be provided by the employer.

The interim final standard also requires employers to provide employees working in lead areas where their airborne exposures exceed the PEL with lunchroom facilities or eating areas which are as free as practicable from lead contamination and are readily accessible to employees. Employers must also assure that employees wash their hands and face prior to eating or smoking and do not enter the lunchroom facilities or eating area wearing protective clothing, unless properly cleaned beforehand. This is to further minimize the possibility of food contamination and reduce the likelihood of additional lead absorption from contaminated food, beverages or tobacco.

J. Medical Surveillance: Paragraph (j)

The medical surveillance provisions are part of this standard's comprehensive approach to prevention of lead-related disease. Its purpose is to supplement the standard's primary mechanisms of disease prevention, the elimination or reduction of airborne concentrations of lead and sources of ingestion, by facilitating the early detection of medical effects associated with exposure to lead. These provisions in most respect are very similar to parallel provisions in the HUD Guidelines and lead standard for general industry.

All medical examinations and procedures are to be performed by or under the supervision of a licensed physician and are to be provided without cost to employees at a reasonable time and place. The standard does not make participation in the medical surveillance program mandatory for the employee. The employer's obligation is to "provide" and "make available" the medical tests and procedures as required. Where employee confidence in the medical program exists, refusal to participate should be minimal.

The medical surveillance provisions contemplate two phases of medical surveillance: one is initial medical surveillance, the other is a medical surveillance program. The employer is required to provide initial medical surveillance to employees occupationally exposed to airborne concentration of lead on any one day at or above the action level, consisting of biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels. Where this initial biological monitoring indicates that an employee's blood lead level is at or above 40 μg/dl, the employer must continue to provide biological monitoring at least every two months. The frequency is to continue until two consecutive blood samples and analyses indicate that the employee's blood lead level is below 40 μg/dl.

If an employee's airborne lead exposure is at or above the action level for more than 30 days a year, the employer shall provide a medical surveillance program to the employee consisting of routine monitoring of an employee's blood lead and ZPP levels, made available at least every 2 months for the first 6 months in the exposed job and every 6 months thereafter. If an employees PbB exceeds 40 μg/dl, the monitoring frequency must be increased to at least every 2 months and not reduced until two consecutive PbB's are below 40 μg/dl. If PbB levels exceed the removal criteria under paragraph (k)(1)(i), a second PbB must be provided within 2 weeks after the employer receives the results of the first blood test to confirm the accuracy of the results. This follow-up is intended to assure that no unnecessary removals occur. If the second test exceeds the removal criteria then the employee must be removed. Blood lead level sampling and analysis must have an accuracy (to a confidence level of 95 percent) within plus or minus 15 percent or 6 μg/dl, whichever is greater, and must be conducted by a laboratory approved by OSHA.

Within five working days after the receipt of biological monitoring results, the employer is to notify each employee in writing of his or her blood lead level. The employer must notify each employee who underwent biological monitoring whose blood lead level exceeds 40 μg/dl, that the standard requires temporary medical removal with Medical Removal Protection benefits when an employee's blood lead level exceeds the numerical criterion for medical removal.

The employer's obligation to provide a full medical surveillance program to an employee, including annual medical exams, is triggered by a determination that the employee's blood lead level exceeds 40 μg/dl if the employee's airborne exposure is or may be at or

above the action level for more than 30 days a year.

The required examination includes a work history and medical history; a physical examination; determinations of blood lead level (PbB), hematocrit, hemoglobin, peripheral smear morphology and red cell indices; levels of zinc protoporphyrin (ZPP), routine urinalysis (specific gravity, sugar, protein determinations, and microscopic examination), blood urea nitrogen (BUN), and serum creatinine (S-Creat).

Medical consultations, with examinations as appropriate, are required to be provided upon notification by an employee (1) that the employee has developed symptoms commonly associated with lead-related disease, (2) that the employee desires advice concerning the effects of lead on reproductive capacity, and (3) that the employee has demonstrated difficulty in breathing during fit testing or use of a respirator. Additional examinations must be made available when an employee is removed from exposure or otherwise limited under paragraph (k) of the regulation. The content and frequency of these examinations is to be at the discretion of the physician. Upon request of an employee, however, a pregnancy test or male fertility test (at a minimum analyzing sperm number, motility, and morphology) must be provided. These tests will facilitate the protection of reproductive capacity.

The employer must make medical examinations and consultations available to each employee exposed to lead at or above the action level for more than 30 days per year on the following schedule: at least annually for those employees for whom a blood sampling test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 μg/dl; as soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to lead on the employee's ability to procreate a healthy child, that the employee is pregnant, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during use; and as medically appropriate for each employee either removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited pursuant to a final medical determination.

The medical surveillance provisions of the final standard contain a multiple physician review mechanism which gives workers an opportunity to obtain a second and possibly third opinion regarding the medical determinations made pursuant to the standard. An employee may designate a second physician to review any findings, determinations or recommendations of an initial physician chosen by the employer. Efforts are to be made to resolve any disagreement which may arise between the two physicians. Should they be unable to agree, a third physician they select will resolve the disagreement.

OSHA's reasons for the provision of this review process are twofold; first, to broaden and strengthen the basis for medical determinations in situations where a worker questions the results of the initial examination or consultation provided by the employer; and second, to assure employee confidence in the soundness of medical determinations made pursuant to the standard. OSHA views the multiple physician review mechanism as an important element of the lead standard's medical surveillance program both due to the importance attached to medical surveillance by the Act, and due to the crucial role medical surveillance will play in the operation of the standard's medical removal protection program.

Medical surveillance, as under the HUD Guidelines and OSHA lead standard, must be provided by employers without cost to employees. Since the multiple physician review mechanism will be one means by which medical surveillance is provided to an employee, employers must bear the expense of this mechanism when it is used. In practice, the costs of this mechanism should not be burdensome, particularly since employers will have substantial control over the frequency of its use. Where employers carefully structure and administer medical surveillance programs which engender, merit and maintain worker confidence, workers will see no need to seek a second medical opinion.

The multiple physician review mechanism commences after an initial medical examination or consultation provided by a physician chosen by the employer. OSHA recognizes the value to employers and employees alike of having the mechanism operate in an expeditious fashion, and thus has established explicit criteria for the beginning of the process. After an initial physician conducts an examination or consultation pursuant to the standard, the employer must promptly notify the employee of his or her right to seek a second medical opinion. This notification need be no more than an oral reminder of the existence and content of this multiple physician review mechanism. After this notification has been given, an employer may condition employee participation in, and payment for, the mechanism upon the employee acting within 15 days after receipt of the foregoing notification, or receipt of the physician's written opinion, whichever is later. Before or within this 15-day period the employee must inform the employer (orally or otherwise) that the employee intends to seek a second medical opinion. The employee must also initiate steps within this time to make an appointment with a second physician. These steps would include actually making an appointment or contacting a physician with the request that a referral to a specialist be arranged.

The standard contains no more limitation upon an employee's choice of a second physician than the standard places on an employer's choice of the initial physician. The second physician, like the initial physician, need only be licensed to practice medicine. There is no subspecialty of medicine solely concerned with lead-related diseases, and since lead-related diseases affect numerous systems of the body, it would not be appropriate to limit the choice of doctors to any one specialty. It is certainly to an employee's advantage to choose a competent physician, thus OSHA relies on this self-interest to assure the value of the second opinion. For example, where an employee's difference with the initial physician revolves around a particular body system—e.g., nervous system—it is likely that the employee will choose a specialist in that body system—e.g., a neurologist. Where, however, the dispute revolves around several body systems, or the employee cannot identify one specific system, the employee will likely choose the general practitioner or internist most familiar with the employee's medical history or current health status.

The standard provides that the second physician shall review any findings, determinations or recommendations of the initial physician, and may conduct such examinations, consultations and laboratory tests as the second physician deems necessary to facilitate this review. An additional provision in the standard requires the employer to supply the same information to the second physician upon request that must be supplied to an initial physician. The second physician, therefore, is provided an opportunity to fully assess the employee's health status with access to the same background information supplied to the initial physician.

If the second physician's findings, determinations and recommendations are the same as those of the initial physician, then the multiple physician review process comes to an end. If, however, the opinions of the two physicians are in conflict, then the standard provides that the employer and the employee shall assure that efforts are made for the two physicians to communicate with each other to resolve their differences. This professional interaction among peers should in most cases resolve any differences between the two physicians. The preceding elements of the multiple physician review mechanism assure that if differences of opinion remain, these differences are likely to be genuine and substantial.

Where the first two physicians have been unable to quickly resolve any differences of opinion with respect to an employee, then it is necessary for a third qualified physician to resolve the dispute. It is important that this third physician be competent to resolve the dispute, thus the standard provides that the third physician shall be designated by the employer and the employee jointly through their respective physicians. It is the responsibility of the employer and the employee to assure that a third physician is selected, but the selection is to be made by the two prior physicians.

The standard provides the third physician with full opportunity to review the findings, determinations, and recommendations of the prior physicians by conducting such examinations, consultations, and laboratory tests as the third physician deems necessary. The standard incorporates the expectation that the third physician will consult with the two prior physician, and upon request, the employer must supply the same information to the third physician given to the initial physicians. The third physician is required to provide a written medical opinion to the employer, which will operate to resolve the disagreement between the earlier physicians. The standard finally requires the employer to act in a manner consistent with the findings, determinations, and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

The medical surveillance section of the standard includes a provision stating that the employer and employee or authorized employee representative may agree upon the use of any alternate physician determination mechanism in lieu of the multiple physician review mechanism. The only conditions are that the alternate mechanism be as expeditious and protective as the multiple physician review mechanism. For example, the parties might decide, in cases of dispute, for an employee to go directly from an initial physician chosen by the employer to an agreed upon final physician—thus dispensing with the need for a second physician. Alternately, a mutually agreed upon physician might be used in the first instance without recourse to other physicians. Or, an employee might be given the opportunity to choose this final physician. OSHA desires to encourage employers and employees to adopt medical determination procedures in which all parties have trust and confidence.

The interim final standard prohibits prophylactic chelation of any employee by any person the employer employs, retains, supervises, or controls, and requires the employer to assure that any therapeutic or diagnostic chelation, if administered, is done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring. In cases where the examining physician determines that chelation is appropriate, the employee must be notified of this fact before such treatment. This is to inform the employee that chelation can be a potentially harmful treatment, and will afford the employee the opportunity to seek the review of this determination by another physician.

K. Medical Removal Protection: Paragraph (k)

The employer is required to remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test indicate that the employee's blood lead level is at or above 50 μg/dl. Although OSHA's General Industry Standard (1910.1025) requires removal based on the average of three blood tests indicating blood leads in excess of 50 μg/dl, OSHA believes that the length of time associated with taking these three tests (up to four months) would not be appropriate for activities in construction which often will not last 4 months. The provisions for blood testing under this construction standard to determine whether removal is necessary, would be accomplished within a much shorter period (e.g., a periodic test revealing blood lead above 50 μg/dl requires a follow-up test within 2-weeks). OSHA further believes that this more stringent requirement for removal based on fewer blood tests is warranted in view of the high airborne lead exposures that construction workers have been permissibly exposed to (e.g., 200 μg/m^3).

The employer must also remove an employee from work having an exposure to lead at or above the action level on each occasion that a final medical determination results in a medical finding, determination, or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead. The phrase "final medical determination" means the written medical opinion on the employee's health status by the examining physician or, where relevant, the outcome of the multiple physician review mechanism or alternate medical determination mechanism.

Where a final medical determination results in any recommended special protective measures for an employee, or limitations on an employee's exposure to lead, the employer must implement and act consistent with the recommendation.

For an employee removed from exposure to lead at or above the action level due to a blood lead level at or above 50 μg/dl the employer may return that employee to former job status when two consecutive blood sampling tests indicate that the employee's blood level is at or below 40 μg/dl. For an employee removed from exposure to lead due to a final medical determination, the employee must be returned when a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

The requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

Thus, for example, where an employee's job is concluded while the employee is on medical removal, the employee is not entitled to continuing MRP benefits or to the job since, if the employee had not been removed, the employment would have ended in any case.

The employer shall remove any limitations placed on an employee or end any special protective measures provided to an employee pursuant to a final medical determination when a

subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

Where the multiple physician review mechanism, or alternate medical determination mechanism used pursuant to the medical surveillance provisions has not yet resulted in a final medical determination with respect to an employee, the employer may either remove the employee from exposure to lead, provide special protective measures to the employee, or place limitations upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status. In such circumstances, the employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, unless the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician or the employee has been on removal status for the preceding eighteen months due to an elevated blood lead level.

If a removed employee files a claim for workers' compensation payments for a lead-related disability, then the employer must continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation may be reduced by such amount. The employer may not receive credit for workers' compensation payments received by the employee for treatment related expenses. The employer's obligation to provide medical removal protection benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer made possible by virtue of the employee's removal.

For employees removed from exposure to lead due to an elevated blood lead level whose blood lead level has not declined within the past eighteen (18) months of removal to allow the employee to be returned to his or her former job status, the employer must make available to the employee a medical examination to obtain a final medical determination with respect to the employee. The employer must also assure that the final medical determination obtained indicates whether or not the employee may be returned to his or her former job status, and if not, what steps would be taken to protect the employee's health. Further, where the final medical determination has not yet been obtained, or once obtained indicates that the employee may not yet be returned to his or her former job status, the employer must continue to provide medical removal protection benefits to the employee until either the employee is returned to former job status, or a final medical determination is made that the employee is incapable of ever safely returning to his or her former job status.

Finally, where the employer acts pursuant to a final medical determination which permits the return of the employee to his or her former job status despite what would otherwise be an unacceptable blood lead level, later questions concerning removing the employee again must be decided by a final medical determination. The employer, however, need not automatically remove such an employee pursuant to the blood lead level removal criteria provided in the standard.

Where an employer, although not required by this section to do so, removes an employee from exposure to lead or otherwise places limitations on an employee due to the effects of lead exposure on the employee's medical condition, the employee is entitled to full medical removal protection benefits as provided for under the standard.

L. Employee Information and Training: Paragraph (l)

The final standard requires the employer to provide an information and training program for all employees exposed to lead at or above the action level. Information and training are an essential aspect of the overall protection of employees who can do much to protect themselves if they are informed of the nature of the hazards in the workplace. To be effective, an employee education system must apprise the employee of the specific hazards associated with his work environment, protective measures which can be taken, and his rights under the standard.

The provisions under this paragraph also alert employers of their existing obligation to comply with provisions under OSHA's Hazard Communication Standard (20 CFR 1926.59), which currently applies to construction activities. Under the Hazard Communication Standard (HCS) all chemical manufacturers and importers are to assess the hazards of the chemicals they produce or import and are to develop appropriate information about those hazards, which they are required to communicate in various ways to their own exposed employees and to relevant downstream employers, as specified under paragraphs (d)–(h) of the standard. Downstream employers, in turn, are required to communicate the information concerning the hazards of such chemicals in various ways to their own employees. The transmittal of hazard information to employees is to be accomplished by means of comprehensive hazard communication programs, which must include container labeling and other forms of warning, material safety data sheets and employee training.

Employers are also obligated to comply with existing training requirements set forth in 29 CFR 1926.21, Employee training and education.

In paragraph (l)(2), OSHA includes additional particular requirements that are needed to protect employees specifically exposed to lead at or above the action level. The training program required under paragraph (l)(2) must be provided prior to the time of initial job assignment or prior to the startup date for this requirement, whichever comes last, and must be repeated at least annually for covered employees unless exposure at or above the action level will no longer occur.

Paragraph (l)(2) requires that the employer assure that each employee who is exposed at or above the action level is trained in the following:

The content of the standard and its appendices: The specific nature of the operations which could result in exposure to lead above the action level; the purpose, proper selection, fitting, use, and limitations of respirators; the purpose and a description of the medical surveillance program, and the medical removal protection program including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females and hazards to the fetus and additional precautions for employees who are pregnant); the engineering controls and work practices associated with the employee's job assignment including training of employees to follow relevant good work practices

described in Appendix B of this section; the contents of any compliance plan in effect; instructions to employees that chelating agents should not routinely be used to remove lead from their bodies and should not be used at all except under the direction of a licensed physician; and the employee's right of access to records under 29 CFR 1910.20.

In addition, the employer is required to make available to all affected employees a copy of this standard and its appendices and must provide, upon request, all materials relating to the employee information and training program to affected employees and their designated representatives, and to the Assistant Secretary and the Director.

M. Signs: Paragraph (M)

The standard requires warning signs to be posted in each work area where employee lead exposure exceeds the PEL.

In light of the serious nature of the hazard of exposure to lead, OSHA believes that sign posting is needed, as well as periodic training, to adequately inform employees of the presence of high levels of lead and the possible need to utilize respirators and other protective equipment when entering the area. Phrases to be placed on the sign include "Warning", "Lead Work Area," "Poison," and "No Smoking or Eating." Signs are to be illuminated and cleaned as necessary so that the legend is readily visible.

N. Recordkeeping: Paragraph (n)

The HUD Guidelines and OSHA's general industry standard mandate the inclusion of provisions requiring employers to maintain accurate biological and environmental monitoring records of employee exposures to potentially toxic materials. It also provides that employees or their representatives have access to such records.

The interim final standard requires records of all exposure monitoring and other data used in conducting the employee exposure assessment to be established and maintained. The records must include the name and job classification of employees monitored, details of the sampling and analytic techniques, results, and type of respiratory protection worn. These records must be kept for 30 years in accordance with OSHA's standard 29 CFR 1910.20, Access to Exposure and Medical records. The standard also requires employers to establish and maintain records of medical surveillance (biological monitoring and medical examination results). These include names of employees, the physician's written opinion, exposure data provided to the physician, and any employee medical complaints associated with lead exposure. In addition, the employer is required to keep or must assure that the examining physician keeps a record of the results of medical examinations, a description of laboratory procedures and a copy of the results of biological monitoring. These records must be kept for at least duration of employment plus 30 years, except that medical records of employees who have worked for less than one (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon termination of employment. These retention requirements are in accordance with § 1910.20

The interim standard contains a limited recordkeeping requirement concerning temporary medical removals effected pursuant to the medical removal protection program. The employer must establish and maintain an accurate record for each employee removed from current exposure to lead. The record is to contain four entries each time an employee is removed. First, the employee must be identified by name and social security number. Second, the date of removal and return must be stated. Third, the employer must briefly explain how each removal was or is being accomplished. This description need be no more detailed than such statements as "Employee X was transferred from position A to position B during the entire period of removal," or "Employee X was laid off for the entire period of removal," or "Employee X is currently working half shifts until a transfer opportunity becomes available." Fourth, the record must indicate whether or not the reason for the removal was an elevated blood lead level. If removal is due to a reason other than an elevated blood lead level, this precise reason should not be stated, so as to prevent disclosure of confidential medical information about the employee. Medical removal records are to be maintained for at least the duration of employment.

The purpose of the foregoing recordkeeping requirement is to enable employees and their authorized representatives, and the Secretary to assess the operation of, and an employer's compliance with the medical removal protection program. The limited but pertinent information contained in these records will, in most cases, enable these assessments to be made without interviewing large numbers of employees or placing undue burdens on employers by requiring further time consuming and burdensome examinations of payroll, production, or confidential medical records—examinations which likely would be necessary in the absence of the standard's limited recordkeeping requirement. Due to the limited purposes to be served by these records, the standard requires an employer to maintain each medical removal record only for so long as the duration of an employee's employment.

A provision for the use of objective data in lieu of initial monitoring for the purpose of assessing employee exposure is included in this standard in paragraph (d)(3)(iv). Objective data are defined in paragraph (n)(4) as information demonstrating that a particular product or material containing lead cannot release dust or fumes in concentrations at or above the action level under any expected conditions of use. Employers might use data from an industry-wide survey to estimate maximum exposure levels that could occur if that survey pertains to workplace conditions that, to the extent relevant and significant, are all very similar to those in the employer's worksite. Employers may also use laboratory product test results to demonstrate that airborne concentrations must be below the action level.

A record documenting the relevance of the objective data in assessing employee exposure is required to be established, and maintained for at least 30 years of the objective data relied on. This retention period is consistent with OSHA's Access standard (29 CFR 1910.20) that requires retention of exposure records for at least 30 years.

The interim final standard requires that records be made available to employees and their authorized representatives, physician or other person designated by an employee or former employee in accordance with 29 CFR 1910.20, and to the Director and Assistant Secretary.

The records described above are to be transferred to a successor employer whenever the employer ceases to do business. When there is no successor employer to receive and retain the records these records must be transmitted to the Director of NIOSH.

Upon expiration of the retention period for required records, the employer must notify the Director of NIOSH at least 3 months prior to disposal of such records and must transmit those records to the Director if so requested.

O. Observation of Monitoring: Paragraph (o)

The lead standard for general industry of the Act requires that employers provide employees or their representatives with the opportunity to observe monitoring of employee exposures to toxic materials or harmful physical agents. In accordance with this section and consistent with other OSHA standards, the standard contains provisions for such observation. To insure that this right is meaningful, observers are entitled to an explanation of the measurement procedure, to observe all steps related to the measurement procedure, and to record the results obtained. Since results will not normally be available at the time of monitoring, the standard entitles the observers to receive the results of the monitoring when returned by the laboratory. The observer, whether an employee or designated representative, must be provided with, and is required to use, any personal protective devices required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

P. Effective Dates: Paragraph (p)

The effective date is June 3, 1993. Congress in section 1031 of the Housing and Community Development Act directs that this interim final regulation take effect on issuance, but also expressly authorizes OSHA to reasonably delay the effective date. OSHA, therefore sets the effective date 30 days from publication in the **Federal Register**, which is the shortest time period allowed under the Administrative Procedures Act. Consequently, the regulation becomes effective 30 days after publication in the **Federal Register**. However, implementation of many provisions of the standard does not appear to be feasible so quickly. Thus, OSHA provides a minimal additional time period before the start-up dates for these provisions. OSHA believes that this is consistent with Congress' intent.

Q. Appendices: Paragraph (q)

The appendices included with the regulation are intended to be purely informational and, unless otherwise expressly stated in this section, are not intended to create any additional obligations not otherwise imposed or to detract or reduce any existing obligations. Appendix D provides mandatory procedures for fit testing of respirators.

R. Startup Dates: Paragraph (r)

All requirements of the interim final rule, except for engineering controls specified in paragraph (e)(1) of the standard, must be complied with as soon as possible, but no later than 60 days from the effective date of this section. Feasible engineering controls specified under paragraph (e)(1) shall also be implemented as soon as possible, but no later than 120 days from the effective date of this section.

OSHA believes that expeditious action by employers to achieve compliance with the provisions of this standard is warranted. Construction employees under the current standard are being exposed to lead at concentrations that present significant risk of adverse health impairment.

Employers must install feasible engineering controls as required under this standard within four (4) months from the effective date of this standard. Compliance with all other provisions of the standard must be accomplished within two (2) months of the effective date of the standard.

Employers performing lead operations in construction to some extent have already instituted protective measures voluntarily or in response to existing OSHA or other regulations, regarding training, engineering controls, compliance plans, respirators, exposure monitoring, work practices, recordkeeping, signs, protective clothing, and hygiene facilities. In addition, the Act of 1992 put the industry on notice that protective requirements like those, would be promptly imposed on employers to protect lead exposed employees in the construction industry. Thus, OSHA believes that it is a reasonable and appropriate judgment that compliance with the new burdens imposed under this interim rule in the time-frames specified is achievable.

IV. Regulatory Impact and Regulatory Flexibility Analysis

A. Executive Summary

Industry Profile

Construction projects involving lead or lead-containing materials occur throughout the entire construction industry as well as in several non-construction industries. Eighteen construction industry SICs and five non-construction industry SICs (involving construction activity) are expected to be affected by the Interim Final Standard. OSHA estimates that approximately 936,000 employees in 147,000 establishments are exposed to at least some level of lead during construction work.

Technological Feasibility

Compliance with the PEL and ancillary provisions of the Interim Final Standard is technologically feasible for all affected industries. Existing engineering control types, including mechanical ventilation, local exhaust ventilation, shrouded tools, HEPA vacuums, and wetting agents are already in use in the construction industry. Due to the nature of the activities in which high exposures to lead are generated, OSHA assumes that supplemental respirator use will be necessary for most activities in which engineering controls will be used.

Benefits

Benefits of the Interim Final Standard include decreases in the annual number of expected cases of: reduced nerve conduction velocity; reduced blood ALA-D levels; increased urinary ALA; gastrointestinal disturbances; and blood-lead levels above the medical removal trigger level. Long-term effects avoided over a ten-year period include cases of fatal/non-fatal infarction; fatal/non-fatal stroke; and renal disease.

Costs of Compliance

The annual recurring cost of the Interim Final Standard is expected to range between $365 million to $445 million. Additional start-up costs will be incurred during the first year for worker training, biological monitoring, medical examinations, and medical removal protection benefits.

Economic Impacts

The most impacted SICs, as measured by compliance costs per worker and compliance costs per establishment, are expected to include: SIC 1611, Highway and Street Construction Contractors; SIC 1622, Bridge, Tunnel and Elevated Highway Contractors; SIC 1721, Painting Contractors; SIC 1791, Structural Steel Erection Contractors; SIC 1795, Wrecking and Demolition Contractors; and SIC 3231, Glass Products Manufacturers. OSHA has concluded that it will be economically feasible to achieve compliance for all affected sectors.

B. Industry Profile

This industry profile describes the industries identified as potentially affected by the Interim Final Standard for Lead in Construction. Information is also presented on the twenty-two types of construction projects expected to be affected by the standard. Project type is often a better indicator of the likelihood

of lead exposure than the industry classification of the firm performing the work.

The definition of "construction" includes the categories of new construction (relatively little exposure to lead will be encountered in new construction); additions, alterations, and reconstruction (including remodeling and renovation); installation; demolition; repairs and maintenance. In this profile, the three major divisions of the construction industry are identified by two-digit Standard Industrial Classification (SIC) codes: SIC 15, General Building Contractors; SIC 16, Heavy Construction Contractors, Excluding Building Contractors; and SIC 17, Special Trade Contractors.

Subsectors of each industry division are identified by four-digit SIC codes. Because an establishment's SIC classification is based solely on the primary activities of the firm, contractors from different two-digit and four-digit SIC codes are often identified as working on the same project type. Construction projects involving contact with lead or lead-containing materials occur throughout the entire construction industry as well as in several non-construction SICs. Table 1 shows the eighteen construction industry SICs and five non-construction industry SICs (involving construction activity) expected to be affected by the Interim Final Standard and the affected construction project types associated with each SIC.[1] Table 2 lists the industries affected and shows the estimated total number of affected establishments and estimated total number of workers exposed by industry sector.

TABLE 1.—SICs AFFECTED BY THE INTERIM FINAL STANDARD AND ASSOCIATED PROJECT TYPES

SIC	Industry title	Project type
1521	General Contractors, Single Family Housing	In-Place Management (Private Housing). Residential Remodeling.
1522	General Contractors, Other Residential Buildings	Residential Remodeling.
1531	Operative Builders	In-Place Management (Private Housing). Residential Remodeling.
1541	General Contractors, Industrial Buildings and Warehouses	Petroleum Tank Repainting. Indoor Industrial Facility Maintenance and Renovation. Outdoor Industrial Facility Maintenance and Renovation. Commercial and Institutional Remodeling.
1542	General Contractors, Other Non-Residential Construction	Commercial and Institutional Remodeling.
1611	Highway and Street Construction Contractors	Highway and Railroad Bridge Repainting. Highway and Railroad Bridge Rehabilitation.
1622	Bridge, Tunnel and Elevated Highway Contractors	Highway and Railroad Bridge Repainting. Highway and Railroad Bridge Rehabilitation.
1711	Plumbing Contractors	Lead Joint Work on Cast Iron Soil Pipes. Repair and Removal of Water Lines.
1721	Painting Contractors	Highway and Railroad Bridge Repainting. Water Tank Repainting. Petroleum Tank Repainting. Housing Lead Abatement (Public Housing). Housing Lead Abatement (Private Housing). In-Place Management (Public Housing). In-Place Management (Private Housing). Indoor Industrial Facility Maintenance and Renovation. Outdoor Industrial Facility Maintenance and Renovation. Commercial and Institutional Remodeling. Residential Remodeling. Electric Transmission and Communication Tower Maintenance.
1731	Electrical Work Contractors	Commercial and Institutional Remodeling. Residential Remodeling. Electrical Cable Splicing.
1742	Plastering, Drywall, and Insulation Work Contractors	In-Place Management (Public Housing). In-Place Management (Private Housing). Commercial and Institutional Remodeling. Residential Remodeling. Reinsulation over Existing Mineral Wool.
1751	Carpentry Work Contractors	Commercial and Institutional Remodeling. Residential Remodeling.
1752	Floor Layers and Other Floor Work Contractors	Commercial and Institutional Remodeling. Residential Remodeling.
1761	Roofing and Siding Contractors	Commercial and Institutional Remodeling. Residential Remodeling. Installation of Terne Roofing.
1791	Structural Steel Erection Contractors	Highway and Railroad Bridge Rehabilitation. Indoor Industrial Facility Maintenance and Renovation. Outdoor Industrial Facility Maintenance and Renovation.
1795	Wrecking and Demolition Contractors	Underground Storage Tank Demolition. Commercial and Industrial Demolition.

[1] Three of the 22 basic project types were split into two sub-categories for costing purposes. These project types are Housing Lead Abatement (Public and Private Housing), In-Place Management (Public and Private Housing) and Industrial Facility Maintenance and Renovation (Indoor and Outdoor Work).

TABLE 1.—SICs AFFECTED BY THE INTERIM FINAL STANDARD AND ASSOCIATED PROJECT TYPES—Continued

SIC	Industry title	Project type
1796	Building Equipment Contractors	Elevator Cable Babbitting.
1799	Miscellaneous Special Trade Contractors, NEC	Underground Storage Tank Demolition.
		Housing Lead Abatement (Public Housing).
		Housing Lead Abatement (Private Housing).
		In-Place Management (Public Housing).
		In-Place Management (Private Housing).
		Indoor Industrial Facility Maintenance and Renovation.
		Outdoor Industrial Facility Maintenance and Renovation.
		Industrial Process Equipment Maintenance and Repair.
		Industrial Vacuuming.
		Installation of Radiation Shielding.
		Commercial and Institutional Remodeling.
		Residential Remodeling.
		Reinsulation Over Existing Mineral Wool.
3231	Glass Products Manufacturers	Stained Glass Window Removal.
4911	Electric Utilities	Electrical Cable Splicing.
6513	Operators of Apartment Buildings	In-Place Management (Private Housing).
6514	Operators of Other Dwellings	In-Place Management (Private Housing).
9999	State and Municipal Governments	Highway and Railroad Bridge Repainting.
		Water Tank Repainting.
		In-Place Management (Public Housing).

Source: OSHA, Office of Regulatory Analysis.

TABLE 2.—ESTIMATED TOTAL NUMBER OF AFFECTED ESTABLISHMENTS AND ESTIMATED TOTAL NUMBER OF WORKERS EXPOSED BY STANDARD INDUSTRIAL CLASSIFICATION (SIC) CODE

SIC	Industry title	Estimated total number of affected establishments	Estimated total number of workers exposed
1521	General Contractors, Single Family Housing	16,742	67,716
1522	General Contractors, Other Residential Buildings	2,204	8,927
1531	Operative Builders	5,285	21,360
1541	General Contractors, Ind. Buildings and Warehouses	3,674	66,242
1542	General Contractors, Other Non-Res. Construction	5,089	92,956
1611	Highway and Street Construction Contractors	481	8,178
1622	Bridge, Tunnel and Elevated Highway Contractors	744	15,900
1711	Plumbing Contractors	43,598	56,378
1721	Painting Contractors	13,874	139,473
1731	Electrical Work Contractors	6,072	46,194
1742	Plastering, Drywall, and Insulation Work Contractors	11,746	103,638
1751	Carpentry Work Contractors	10,395	127,214
1752	Floor Layers and Other Floor Work Contractors	740	7,253
1761	Roofing and Siding Contractors	5,264	64,183
1791	Structural Steel Erection Contractors	568	11,097
1795	Wrecking and Demolition Work Contractors	685	7,699
1796	Building Equipment Contractors	2,250	4,500
1799	Miscellaneous Special Trade Contractors, NEC	14,105	71,168
3231	Glass Products Manufacturers	104	208
4911	Electric Utilities	667	4,000
6513	Operators of Apartment Buildings	1,753	7,011
6514	Operators of Other Dwellings	876	3,506
9999	State and Municipal Governments	159	1,869
	Total for All SICs	147,075	936,670

Source: OSHA, Office of Regulatory Analysis.

Lead exposure is most common among project types that involve the disturbance of lead or lead-containing materials during additions, alterations, reconstruction, demolition, repairs and maintenance. Some examples of potential sources of exposure in these project types include lead-based paint (LBP) and paint dust, lead pipes, leaded solder, the leaded support rods in stained glass windows, and some mineral wool insulation.

In contrast, project types involving exposure to lead during new construction are comparatively rare. This is in part due to government regulations that have banned specific uses of once common lead-containing construction materials. An example is the Consumer Product Safety Commission's 1977 ban on "lead containing paint" prohibiting the use of such paint on products to which consumers are exposed after sale (42 FR 44199). Another example is the Environmental Protection Agency's 1986 ban on further use of lead pipes and solder in residential plumbing. In most new construction projects involving lead use, lead and lead-

containing materials are used in limited quantities for specialized applications. Examples include terne (leaded-steel) roofing and the use of lead foil sheet in the walls of hospital x-ray suites.

Table 3 shows preliminary estimates of the number of lead-exposed projects occurring each year, the estimated total number of workers exposed, and the primary sources of lead exposure by project type. The estimated number of employees differs from those originally reported in the draft CONSAD report of July, 1991; this earlier draft did not include workers involved in commercial and residential remodeling project types. For these and other reasons, the draft CONSAD report of July, 1991 is superseded by CONSAD's final report of April, 1993, which contains more complete and accurate information. The final CONSAD report is consistent with the scope and provisions of OSHA's Interim Final Rule.

TABLE 3.—ESTIMATED TOTAL NUMBER OF CONSTRUCTION PROJECTS INVOLVING LEAD PER YEAR, ESTIMATED TOTAL NUMBER OF WORKERS EXPOSED, AND PRIMARY SOURCE(S) OF LEAD EXPOSURE BY PROJECT TYPE

Project type	Estimated number of projects involving lead per year	Estimated total number of workers exposed	Primary source(s) of lead exposure
Highway and Railroad Bridge Repainting	3,721	18,419	Lead-Based Paint and Paint Debris.
Highway and Railroad Bridge Rehabilitation	2,157	29,958	Lead-Based Paint and Paint Debris.
Water Tank Repainting	1,994	5,113	Lead-Based Paint and Paint Debris.
Petroleum Tank Repainting	3,491	4,364	Lead-Based Paint and Paint Debris.
Underground Storage Tank Demolition	648	288	Lead-Based Paint and Paint Debris.
Housing Lead Abatement (Public Housing)	900	2,893	Lead-Based Paint and Paint Debris.
Housing Lead Abatement (Private Housing)	62,300	9,345	Lead-Based Paint and Paint Debris.
In-place Management (Public Housing)	3,150	188	Lead-Based Paint and Paint Debris.
In-place Management (Private Housing)	631,000	35,056	Lead-Based Paint and Paint Debris.
Commercial and Industrial Demolition	1,240	7,440	Lead-Based Paint and Metallic Lead Residues.
Indoor Industrial Facility Maint./Renovation	280	2,113	Lead-Based Paint and Paint Debris.
Outdoor Industrial Facility Maint./Renovation	1,584	2,981	Lead-Based Paint and Paint Debris.
Lead Joint Work on Cast Iron Soil Pipes	9,438	15,337	Lead-Oakum Pipe Joint Material.
Ind. Process Equipment Mfg./Maint./Repair	982	409	Lead Bricks, Lead Mortar, and Lead Sheets.
Industrial Vacuuming	784	392	Metallic Lead Dust in Metal Processing Plants.
Stained Glass Window Removal	2,500	208	Lead Support Rods.
Installation of Radiation Shielding	100	40	Lead-Containing Construction Materials.
Commercial and Institutional Remodeling	546,000	546,798	Lead-Based Paint and Paint Debris.
Residential Remodeling	2,698,000	178,544	Lead-Based Paint and Paint Debris.
Elevator Cable Babbitting	5,400	4,500	Tin-Base Babbit Containing Lead.
Electrical Cable Splicing	100,000	5,000	Lead Splicing Material.
Reinsulation Over Existing Mineral Wool	22,000	18,333	Mineral Wool Insulation With Lead Contaminants.
Repair and Removal of Water Lines	197,000	41,042	Lead Pipes and Lead Solder.
Transmission and Communication Tower Maint	880	7,333	Lead-Based Paint and Paint Debris.
Installation of Terne Roofing	40	576	Leaded Steel Roofing Materials and Lead Solder.
Total For All Project Types	4,295,589	936,670	

Source: OSHA, Office of Regulatory Analysis.

C. Technological Feasibility

Compliance with the Interim Final Standard is considered technologically feasible for each of the affected industries. OSHA has identified several categories of engineering controls that are technologically feasible and appropriate for use in the construction industry. Due to the nature of the activities in which high exposures to lead are generated, OSHA assumes that supplemental respirator use will be necessary for most activities in which engineering controls will be used. Based on the currently available evidence in the record, OSHA has not been able to conclude that the PEL is achievable in most of the operations most of the time by engineering and work practice controls alone in the construction industry. Currently available respirators are capable of providing the supplemental protection necessary to achieve the PEL all of the time in all construction activities with the exception of abrasive blasting as described below.

In order to analyze the technological feasibility of the standard, data on lead exposures were examined by the type of activity generating the potential for exposure to lead. The exposure data reviewed by OSHA were obtained from the following sources: OSHA IMIS; various NIOSH Health Hazard Evaluation reports; various Department of Housing and Urban Development (HUD) Lead Abatement Demonstration Projects; Maryland's Department of Occupational Safety and Health; site visits conducted by CONSAD Research for OSHA and other published reports and studies. The exposure data obtained from each of these sources are believed to be representative and reliable exposure estimates for the construction activities being examined.

Table 4 summarizes exposure data by construction activity. The table shows personal TWA(8) exposure levels (in micrograms per cubic meter of air), in the absence of reduction factors from engineering controls and respirators. For several of the activities presented, statistics were calculated for small groups of data. Despite the potential weaknesses of these small samples, the data were used as the best available evidence about exposure levels in these activities.

The wide variations in the exposure data for certain construction activities accurately reflect the nature of construction work. Analogous construction work sites, even where the same types of activities are performed, can produce very different exposure levels. Sources of variability in exposure

levels for the same activity include the concentration of lead in the paint or other materials being removed; the total quantity of lead-containing materials being removed; work practices used and weather conditions on outdoor projects.

Because OSHA was unable to allow the public the opportunity to comment on the data used in this analysis, OSHA is taking a very conservative approach in the use of this data. As shown in Table 4, OSHA calculated a 95 percent confidence level for the mean exposure level in each activity and used this value to assign appropriate engineering controls and respirators.[2] (Where this statistic exceeded the maximum observed level for an activity, the maximum observed level was used to specify controls.) This methodology was used in order to ensure a consistent approach to control assignment across activities. The appropriateness of control assignments was then confirmed by examination of the actual exposure level distributions for each activity. Table 5 shows the controls assigned to each activity.

TABLE 4.—REPRESENTATIVE TWA(8) EXPOSURE LEVELS IN μG/M³ ABSENT ENGINEERING CONTROLS AND RESPIRATORY PROTECTION BY CONSTRUCTION ACTIVITY

Construction activity key	Number of observations	Minimum value	Maximum value	Arithmetic mean	Standard deviation	Exposure level used to specify controls [a]
1.0 Open abrasive blasting	26	1,352	58,700	17,315	19,001	23,680
1.1 Open abrasive blasting in full containment	13	2,188	58,700	26,673	21,502	37,300
1.2 Vacuum blasting	4	2	665	169	331	558
2.1 Welding, cutting, and burning on bridges	90	1	10,320	1,230	1,897	1,564
2.2 Other welding, cutting, and burning	152	1	28,000	615	2,681	973
2.3 Lead burning	19	33	2,557	451	533	[b]663
3.0 Spray painting lead-based paint	37	1	460	74	95	101
4.0 Hand scraping	6	6	167	45	63	96
5.1 Removal and replacement of building components	113	0.4	121	7	15	9
5.2 Manual demolition of building components	15	1	168	50	59	77
6.0 Heat gun use	380	0.4	916	26	71	32
7.0 Chemical stripping	296	0.4	476	11	35	15
8.0 Encapsulation	86	0.4	26	3	4	4
9.1 Power tool use (housing abatement projects)	28	0.2	1,596	185	347	[c]296
9.2 Power tool use (other paint removal projects)	65	1	20,600	735	2,794	1,314
10.0 Use of lead pots	10	1	19	4	5	8
11.0 Soldering and brazing	1	9	9	9	—	9
12.0 Use of lead mortar	—	—	—	—	—	[d]663
13.0 Stained glass removal	3	10	79	43	35	[e]79
14.0 Handling lead shot, bricks, or sheet	132	0.1	224	12	30	16
15.0 Industrial vacuuming	9	8	2,900	404	951	994
16.0 Cutting lead foil panels	—	—	—	—	—	[f]1
17.0 Reinsulation over existing mineral wool	3	1	90	34	49	[e]90
18.1 Miscellaneous enclosure movement	6	13	2,100	504	792	1,156
18.2 Miscellaneous abrasive blasting/repainting	30	4	9,580	1,147	2,441	1,904
18.3 Miscellaneous remodeling related	8	0.4	207	27	73	76
18.4 Miscellaneous lead abatement	442	0.4	588	6	31	8
18.5 Miscellaneous steel structure rehabilitation	54	0.2	4,100	145	601	282
19.1 Spray painting non-lead-based paint	1	26	26	26	—	26
19.2 Brush painting non-lead-based paint	13	0.4	6	2	2	3
(A) Combined lead abatement activities (4, 5.1, 6, 7, 8, 18.4)	1,323	0.4	916	13	47	15
(B) Combined in-place management activities (4, 5.1, 6, 7, 18.4, 19.2)	954	0.4	916	14	51	17
(C) Combined commercial remodeling activities (4, 5.1, 18.3, 19.1)	128	0.4	207	10	27	14
(D) Combined residential remodeling activities (4, 5.1, 18.3, 19.2)	140	0.4	207	9	26	13

[a] Represents the average exposure level that, statistically, would only be exceeded five percent of the time the activity was monitored.
[b] Control specification level is based on data collected during work performed without ventilation.
[c] Data shown were collected during use of shrouded equipment. Control specification level assumes shrouds are not being used.
[d] Activity 12 exposure levels are assumed to be similar to data from Activity 2.3.
[e] Maximum observed value used as the control specification level.
[f] Activity 16 exposure levels were assumed to be minimal due to nature of activity.

Sources: OSHA IMIS; Selected NIOSH Health Hazard Evaluation Reports; Selected HUD Lead Abatement Demonstration Projects; Maryland OSH Data; CONSAD Site Visits for Lead in Construction and Construction PELS Projects; Other Miscellaneous Reports and Studies.

[2] In no way does OSHA mean to imply that to prove feasibility, it must show that a PEL is capable of being achieved 95 percent of the time by engineering and work practice controls.

TABLE 5.—ANALYSIS OF ENGINEERING CONTROLS AND RESPIRATORS NEEDED TO ACHIEVE COMPLIANCE WITH THE 50 μG/M³ PEL

Project type activity	Exposure level used to specify controls (μg/m3)	Type of ventilation controls specified (by activity)	Other types of controls specified (by project)	Exposure level after control application (μg/m³)	Respirator type specified
Highway and railroad bridge repairing			HV, WA		
1.1 Abrasive blasting in full containment	37,300	MV		18,650	10
3.0 Spray painting with LBP	101	MV		51	5
19.1 Spray painting with non-LBP	26	MV		13	
18.1 Enclosure movement	1,156	—		1,156	4
18.5 Associated miscellaneous activities	1,904	—		1,904	4
Highway and railroad bridge rehabilitation			HV, WA		
2.1 Welding, cutting, burning on bridges	1,564	—		1,564	4
18.5 Associated miscellaneous activities	282	—		282	4
Water Tank Repainting			HV, WA		
1.1 Abrasive blasting in full containment	37,300	MV		18,650	10
3.0 Spray painting with LBP	101	MV		51	5
19.1 Spray painting with non-LBP	26	MV		13	—
18.1 Enclosure movement	1,156	—		1,156	4
18.5 Associated miscellaneous activities	1,904	—		1,904	4
Petroleum tank repainting			HV, WA		
1.1 Abrasive blasting in full containment	37,300	MV		18,650	10
3.0 Spray painting with LBP	101	MV		51	5
19.1 Spray painting with non-LBP	26	MV		13	—
18.1 Enclosure movement	1,156	—		1,156	4
18.5 Associated miscellaneous activities	1,904	—		1,904	4
Underground storage tank demolition			HV		
2.2 Other welding, cutting, burning	973	—		973	4
Housing lead abatement (public housing)			HV, WA		
(a) Combined lead abatement activities	15	—		15	—
9.1 Power tool use (housing)	296	ST		74	5
Housing lead abatement (private housing)			HV, WA		
(A) Combined lead abatement activities	15	—		15	—
In-place management (public housing)			HV, WA		
(B) Combined in-place mgmt. activities	17	—		17	—
In-place management (private housing)			HV, WA		
(B) Combined in-place mgmt. activities	17	—		17	—
Commercial and industrial demolition			HV		
2.2 Other welding, cutting, burning	973	—	HV	973	5
Indoor industrial facility maint./renovation			HV, WA		
1.1 Abrasive blasting	37,300	MV		18,650	10
9.2 Power tool use (other)	1,314	ST		329	5
2.2 Other welding, cutting, burning	973	LEV		243	5
19.1 Spray painting with non-LBP	26	MV		13	—
18.1 Enclosure movement	1,156	—		1,156	4
18.5 Associated miscellaneous activities	282	—		282	4
Outdoor industrial facility maint./renovation			HV, WA		
1.1 Abrasive blasting	37,300	MV		18,650	10
9.2 Power tool use (other)	1,314	ST		329	5
2.2 Other welding, cutting, burning	973	—		973	5
19.1 Spray painting with non-LBP	26	MV		13	—
18.1 Enclosure movement	1,156	—		1,156	4
18.5 Associated miscellaneous activities	282	—		282	4
Lead joint work on cast iron soil pipes			HV		
10.0 Use of lead pots	1	—		1	—
Ind. process equipment mfg./maint./repair			HV		
2.3 Lead burning	663	MV		332	5
Industrial vacuuming			HV		
15.0 Industrial vacuuming	994	—		994	4
Stained glass window removal			HV		
13.0 Removal of stained glass	79	—		79	4
Installation of radiation shielding			HV		
14.0 Handling of lead shot/bricks/sheets	16	—		16	—
16.0 Cutting of lead foil panels	1	—		1	—
Commercial and institutional remodeling			HV, WA		
(C) Combined comm./inst. remodeling activities	14	—		14	—
5.2 Manual demolition	77	—		77	4
9.2 Power tool use (other)	1,314	ST		329	5
2.2 Other welding, cutting, burning	973	LEV		243	5
Residential remodeling			HV, WA		
(D) Combined res. remodeling activities	13	—		13	—
5.2 Manual demolition	77	—		77	4
Elevator cable babbitting			HV		

TABLE 5.—ANALYSIS OF ENGINEERING CONTROLS AND RESPIRATORS NEEDED TO ACHIEVE COMPLIANCE WITH THE 50 μG/M³ PEL—Continued

Project type activity	Exposure level used to specify controls (μg/m3)	Type of ventilation controls specified (by activity)	Other types of controls specified (by project)	Exposure level after control application (μg/m³)	Respirator type specified
10.0 Use of lead pots	1	—		1	—
Electrical cable splicing			HV		
10.0 Use of lead pots	1	—		1	—
Reinsulation over existing mineral wool			HV		
17.0 Reinsulation over existing mineral wool	90	—		90	1
Repair/removal of water lines containing lead			HV		
11.0 Soldering, brazing	9	—		9	—
Transmission and communication tower maint.			HV, WA		
4.0 Hand scraping	96	—		96	4
9.2 Other power tool cleaning	1,314	ST		329	5
19.2 Brush painting with non-LBP	3	—		3	—
18.5 Associated miscellaneous activities	282	—		282	4
Installation of terne roofing			HV		
11.0 Soldering, brazing	9	—		9	—
14.0 Handling of lead shot, bricks, or sheet	16	—		16	—

Engineering control key: MV—Mechanical ventilation [50% exposure reduction factor]; LEV—Local exhaust ventilation [75% exposure reduction factor]; ST—Shrouded tools [75% exposure reduction factor]; HV—HEPA vacuums; WA—Wetting agents.

Respirator type key: Type 1: Half mask cartridge respirator; Type 2: Full facepiece cartridge respirator; Type 3: Loose fitting hood or helmet powered air purifying respirator; Type 4: Tight fitting powered air purifying respirator; Type 5: Half mask supplied air respirator; Type 6: Full facepiece supplied air respirator; Type 7: Loose-Fitting supplied air blasting helmet; Type 8: Full facepiece SCBA; Type 9: Supplied air welding helmet; Type 10: Abrasive blasting helmet with tight fitting facepiece.

Associated protection factor: Protection factor=10 x PEL; protection factor=50 x PEL; protection factor=25 x PEL; protection factor=50 x PEL; protection factor=10 x PEL, 50 x PEL, or 1,000 x PEL depending on operating mode; protection factor=50 x PEL or 2,000 x PEL depending on operating mode; protection factor=25 x PEL; protection factor=50 x or 2,000 x PEL depending on operating mode; protection factor=25 x PEL; protection factor=2,000 x PEL.

Source: OSHA, Office of Regulatory Analysis

The hierarchy of controls requires employers to first apply all feasible engineering controls. OSHA concluded that ventilation controls are an appropriate means of exposure reduction in lead-exposed construction activities. The two categories of ventilation controls considered especially appropriate were mechanical ventilation systems used in conjunction with enclosures or containments (MV) and local exhaust ventilation (LEV). Local exhaust ventilation includes both portable ventilation systems and shrouded tools with ventilation (ST).

CONSAD assigned a 30 percent reduction factor to mechanical ventilation systems and a 75 percent reduction factor for portable local exhaust ventilation and shrouded tools. Based upon OSHA's judgement and experience, the 30 percent exposure reduction factor is an underestimate and does not take into account technological advances in construction and design of containment systems. According to John Peart, Director of Research on Bridge Coatings for the Federal Highway Administration, the current state of industry use of mechanical ventilation controls is improving. Industry and establishment experience continues to develop as contractors steadily move towards more use of full containment with ventilation systems. Continuing research into proper containment and ventilation for activities involving steel structures painting is resulting in increased efficiency ratings being attained by these large mechanical ventilation systems. OSHA therefore believes that an exposure reduction factor of 50 percent will be achievable for mechanical ventilation systems.

Two other categories of engineering controls were assumed to be required, where appropriate, in accordance with the hierarchy of controls. These control categories were HEPA vacuums (HV) and wetting agents (WA). HEPA vacuums are used to prevent exposure before it occurs by reducing the amount of lead-contaminated debris in the work environment. HEPA vacuums are also used to clean personal protective equipment and work clothes to limit worker exposure to lead. Wetting agents prevent lead-based paint dust and lead-contaminated debris from becoming airborne. These controls are considered technologically feasible for all affected activities where their use is appropriate.

When all feasible engineering controls have been added and personal exposures have not been reduced below the PEL, respiratory protection, as specified in Table I of the Interim Final Standard, must be used. Currently available respirators provide sufficient levels of protection for all activities except for abrasive blasting. The loose-fitting, continuous-flow abrasive blasting helmet currently used in the construction industry has been assigned a protection factor of 25xPEL (1,250 μg/m³). Because exposures during abrasive blasting inside pollution containment setups often exceed this level, this type of respirator is no longer considered adequate. At present, no manufacturer makes a Type CE abrasive blasting respirator with both a helmet and the tight-fitting facepiece needed to achieve an acceptable protection factor. However, the technology for producing such a respirator is already known to exist and a Type CE respirator with a hood is already available on the market.

OSHA assumes that a type CE abrasive blasting helmet can be designed and be certified for use in environments of up to 2,000xPEL within one to two years following promulgation of the standard. Until such a respirator is developed, workers may have to wear a respirator type that provides an acceptable protection factor but lacks integral head protection.

OSHA has assumed for costing purposes that workers will be supplied with respirators providing at least the minimum protection sufficient to meet the requirements of the interim final standard. (These respirator selections are shown in Table 5.) For most construction activities, the supplied-air respirators were found to be more cost-effective than cartridge respirators

because cartridge replacement would produce ongoing costs outweighing the "up-front" costs of purchasing supplied air respirators.

Other regulatory provisions requiring employer action under OSHA's Interim Final Lead Standard include (depending upon the construction activity):

- Initial determination of the presence of lead.
- Competent persons.
- Exposure monitoring and associated recordkeeping.
- Written compliance programs.
- Warning signs.
- Worker training.
- Notification of other employers.
- Protective work clothing and equipment.
- Hygiene facilities (hand washing, changing and decontamination facilities)
- Eating areas and facilities.
- Biological monitoring, medical examinations, and medical removal protection (including associated recordkeeping)

All of these provisions were deemed technologically feasible for the affected construction activities. These requirements can be satisfied by work practice modifications and/or conventional, off-the-shelf items, most of which have already been implemented or introduced in well-maintained workplaces.

D. Benefits

This section presents an analysis of the potential benefits associated with the reduction of the permissible exposure limit for lead to 50 μg/m³. The avoidable adverse health effects of lead are described in detail in the Preamble and Supplements to OSHA's 1978 Lead Standard. In addition, OSHA relied upon the technical expertise of Meridian Research, Inc. in the development and formulation of the benefit model and estimates presented in this section.

Because exposure to lead causes a number of different adverse health effects, the potential benefits associated with this requirement of the Interim Final Standard are varied and include benefits that will accrue during the first year following the effective date, as well as benefits that accrue over longer time horizons (separately identified). Some of the near-term benefits that are expected to accrue include reductions in the incidence of acute lead poisoning and adverse neurologic and biochemical effects, and reductions in the incidence of blood lead levels above 50 μg/m³. Benefits that accrue over longer time horizons include reductions in the incidence of lead-induced hypertension, which may increase the risk of myocardial infarction or stroke, and renal disease. Other potential benefits that are expected to accrue, but which are not specifically discussed below, are reductions in the incidence of lead-induced male and female reproductive effects.

This analysis estimates benefits associated with reducing exposures to airborne lead. Additional benefits are likely to be realized as a result of reductions in worker blood-lead levels due to improved hygiene practices. The general approach taken to evaluate the quantitative benefits was as follows:

- For each construction project and activity, available exposure data were used to develop a profile of worker exposures to airborne lead;
- The exposure profiles were used as inputs for a compartmentalized kinetic lead model to generate a blood-lead profile for each group of workers engaged in a particular construction activity;
- The resulting blood-lead profiles were used to predict the frequency with which blood-lead values were likely to exceed the medical removal trigger of 50 μg/dl, and to calculate an average blood-lead level for each group of workers; and
- The average and peak blood-lead levels were used along with risk estimates contained in Meridian's Peer-Review Draft Risk Assessment report to estimate the number of lead-related illness cases that might potentially be avoided as a result of reducing the PEL to 50 μg/m³ for construction.

For each construction activity, airborne exposures to lead were characterized using statistics to reflect that worker exposures to lead may vary considerably from one day to the next. For all of the construction activities shown in Table 4, exposure profiles were calculated using the full set of available exposure data. However, for the benefits analysis, additional exposure profiles were created by combining data from different activities to recognize that some construction workers may typically be engaged in more than one activity. For example, the abrasive blasting exposure data were combined with painting exposure data to create an exposure profile for workers performing both tasks on a regular basis. In addition, a supplementary baseline exposure profile was created for project types involving lead abatement, in-place management and remodeling activities, in order to obtain a blood-lead level profile for workers currently using poor work practices. This profile was generated to yield a blood-lead profile consistent with blood-lead levels reported in the state of Massachusetts. (One of the few states with useful construction industry data in their blood lead registry.)

For each construction activity and operation, the exposure profile data were used to generate numerical sets that matched the parametric distributions of the exposure profiles. These figures were used to represent daily air-lead levels to which workers engaged in each activity are believed to be exposed during a one-year period. Blood-lead levels likely to result from these exposures were estimated using the compartmentalized kinetic lead distribution/excretion model contained in Meridian's Peer-Review Draft Risk Assessment Report. Table 6 presents the results of this analysis, and includes the average blood-lead levels expected to result over a year of performing each construction activity under baseline exposure conditions. These conditions are based upon the exposure levels shown in Table 4 and the wearing of respirators with the estimated protection factors specified in column one of Table 6.

A similar analysis was performed to evaluate likely blood-lead levels that would result from complying with the 50 μg/m³ PEL. For this analysis, OSHA's consultant, Meridian, assumed that air lead exposures would be reduced in accordance with the same engineering and respiratory protection assumptions used in the cost analysis. Table 7 presents the blood-lead profiles associated with compliance with the 50 μg/m³ PEL. Given the implementation of the control strategies required by the rule, blood-lead levels are not expected to exceed 25 μg/dl among construction workers.

TABLE 6.—BASELINE BLOOD-LEAD PROFILE, BY CONSTRUCTION ACTIVITY

Construction project activity	Assumed baseline factor of respiratory protection	Percent of time that blood-lead level (µg/dl) is within stated range						Average blood-lead level (µg/dl)
		<=15	>15–25	>25–30	>30–40	>40–50	>50	
Highway and Railroad Bridge Repainting:								
1.1 Abrasive Blasting	100–600	34.8	19.5	10.7	11.1	7.4	16.4	32.1
3.0 Spray Painting with LBP	1	33.4	11.8	12.3	35.3	7.1	0.0	24.2
19.1 Spray Painting with Non-LBP	1	13.4	86.6	0.0	0.0	0.0	0.0	16.9
—Combined Blasting/Painting	—	40.5	23.8	28.2	7.4	0.0	0.0	18.4
18.1 Enclosure Movement	10	51.8	12.9	17.0	18.4	0.0	0.0	17.9
18.2 Associated Miscellaneous Activities	10	35.1	17.5	8.8	16.2	6.6	15.9	28.0
Highway and Railroad Bridge Rehabilitation								
2.1 Welding, Cutting, Burning on Bridges	10	26.6	10.7	7.1	5.5	3.8	46.3	43.8
18.5 Associated Miscellaneous Activities	1	51.0	13.7	3.8	4.9	7.4	19.2	26.6
Water Tank Repainting:								
1.1 Abrasive Blasting	100–600	28.9	31.5	9.5	10.5	6.3	13.4	28.9
3.0 Spray Painting with LBP	1	29.6	31.2	25.8	13.4	0.0	0.0	20.5
19.1 Spray Painting with Non-LBP	1	80.8	19.2	0.0	0.0	0.0	0.0	11.5
—Combined Blasting/Painting	—	17.8	66.3	12.9	3.0	0.0	0.0	20.1
18.1 Enclosure Movement	10	44.4	34.2	10.7	10.7	0.0	0.0	17.6
18.2 Associated Miscellaneous Activities	10	23.8	32.6	10.4	10.1	9.9	13.2	27.6
Petroleum Tank Repainting:								
1.1 Abrasive Blasting	100–600	34.8	19.5	10.7	11.1	7.4	16.4	32.1
3.0 Spray Painting with LBP	1	33.4	11.8	12.3	35.3	7.1	0.0	24.2
19.1 Spray Painting with Non-LBP	1	13.4	86.6	0.0	0.0	0.0	0.0	16.9
—Combined Blasting/Painting	—	40.5	23.8	28.2	7.4	0.0	0.0	18.4
18.1 Enclosure Movement	10	51.8	12.9	17.0	18.4	0.0	0.0	17.9
18.2 Associated Miscellaneous Activities	10	35.1	17.5	8.8	16.2	6.6	15.9	28.0
Underground Storage Tank Demolition:								
2.2 Other Welding, Cutting, Burning	10	100.0	0.0	0.0	0.0	0.0	0.0	5.2
Housing Lead Abatement (Public):								
(A) Combined Abatement Activities-HUD Practice	1	100.0	0.0	0.0	0.0	0.0	0.0	7.9
—Combined Abatement Activities-Poor Practice	1	20.8	42.7	14.5	14.5	4.4	3.0	33.8
9.1 Power Tool Use (Housing)	1	31.2	35.3	15.3	16.7	1.4	0.0	21.4
Housing Lead Abatement (Private):								
(A) Combined Abatement Activities-HUD Practice	1	100.0	0.0	0.0	0.0	0.0	0.0	7.2
—Combined Abatement Activities-Poor Practice	1	20.8	42.7	14.5	14.5	4.4	3.0	33.8
In-Place Management (Public):								
(B) Combined In-Place Mgmt. Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	8.6
—Comb. In-Place Mgmt. Activities-Poor Practice	1	20.8	42.7	14.5	14.5	4.4	3.0	33.8
In-Place Management (Private):								
(B) Combined In-Place Mgmt. Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	9.2
—Comb. In-Place Mgmt. Activities-Poor Practice	1	20.8	42.7	14.5	14.5	4.4	3.0	33.8
Commercial and Industrial Demolition:								
2.2 Other Welding, Cutting, Burning	10	58.1	35.9	5.5	0.5	0.0	0.0	14.0
Indoor Industrial Facility Maintenance/Renovation:								
1.1 Abrasive Blasting	100–600	77.5	11.8	2.9	2.7	2.1	3.0	15.0
9.2 Power Tool Use (Other)	10	81.1	7.9	3.8	4.7	2.5	0.0	10.8
2.2 Other Welding, Cutting, Burning	10	94.0	6.0	0.0	0.0	0.0	0.0	7.6
19.1 Spray Painting with Non-LBP	1	95.9	4.1	0.0	0.0	0.0	0.0	7.3
—Combined Blasting/Painting	—	82.2	13.2	4.7	0.0	0.0	0.0	9.3
—Combined Power Tool Use/Painting	—	84.7	14.8	0.5	0.0	0.0	0.0	8.7
18.1 Enclosure Movement	10	100.0	0.0	0.0	0.0	0.0	0.0	7.5
18.5 Associated Miscellaneous Activities	1	94.8	5.2	0.0	0.0	0.0	0.0	7.4
Outdoor Industrial Facility Maintenance/Renovation:								
1.1 Abrasive Blasting	100–600	34.8	19.5	10.7	11.1	7.4	16.4	32.1

TABLE 6.—BASELINE BLOOD-LEAD PROFILE, BY CONSTRUCTION ACTIVITY—Continued

Construction project activity	Assumed baseline factor of respiratory protection	Percent of time that blood-lead level (µg/dl) is within stated range						Average blood-lead level (µg/dl)
		<=15	>15–25	>25–30	>30–40	>40–50	>50	
9.2 Power Tool Use (Other)	10	35.9	10.1	10.7	16.2	15.3	11.8	27.8
2.2 Other Welding, Cutting, Burning	10	55.6	44.4	0.0	0.0	0.0	0.0	13.1
19.1 Spray Painting with Non-LBP	1	13.4	86.6	0.0	0.0	0.0	0.0	16.9
—Combined Blasting/Painting	—	41.4	14.2	18.4	26.0	0.0	0.0	19.7
—Combined Power Tool Use/Painting	—	44.1	34.5	18.1	3.3	0.0	0.0	16.8
18.1 Enclosure Movement	10	51.8	12.9	17.0	18.4	0.0	0.0	17.9
18.5 Associated Miscellaneous Activities	1	51.0	13.7	3.8	4.9	7.4	19.2	26.6
Lead Joint Work on Cast Iron Soil Pipes:								
10.0 Use of Lead Pots	1	100.0	0.0	0.0	0.0	0.0	0.0	5.4
Ind. Process Equipment Mfg./Maint. Repair:								
2.3 Lead Burning	10	3.8	95.1	1.1	0.0	0.0	0.0	20.2
Industrial Vacuuming:								
15.0 Industrial Vacuuming	1	100.0	0.0	0.0	0.0	0.0	0.0	6.1
Stained Glass Window Removal:								
13.1 Removal of Stained Glass Windows	1	8.5	66.6	24.9	0.0	0.0	0.0	22.2
Installation of Radiation Shielding:								
14.0 Handling Lead Shot, Bricks, or Sheet	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
16.0 Cutting of Lead Foil Panels.								
Commercial and Institutional Remodeling:								
(C) Combined Comm./Inst. Remodeling Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	7.0
—Combined Remodeling Activities-Poor Practice	1	20.8	42.7	14.5	14.5	4.4	3.0	33.8
5.2 Manual Demolition	1	34.0	53.4	11.2	1.4	0.0	0.0	17.9
9.2 Power Tool Use (Other)	10	32.3	40.0	6.0	13.2	4.4	4.1	22.0
2.2 Other Welding, Cutting, Burning	10	63.6	35.9	0.5	0.0	0.0	0.0	14.2
Residential Remodeling:								
(D) Combined Res. Remodeling Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	7.6
—Combined Remodeling Activities-Poor Practice	1	20.8	42.7	14.5	14.5	4.4	3.0	33.8
5.2 Manual Demolition	1	34.0	53.4	11.2	1.4	0.0	0.0	17.9
Elevator Cable Babbitting:								
10.0 Use of Lead Pots	1	100.0	0.0	0.0	0.0	0.0	0.0	5.0
Electrical Cable Splicing:								
10.0 Use of Lead Pots	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
Reinsulation over Existing Mineral Wool:								
17.0 Reinsulation over Existing Mineral Wool	1	100.0	0.0	0.0	0.0	0.0	0.0	5.2
Repair/Removal of Water Lines Containing Lead:								
11.0 Soldering, Brazing	1	100.0	0.0	0.0	0.0	0.0	0.0	5.1
Transmission Communication Tower Maint.:								
4.0 Hand Scraping	1	74.2	25.8	0.0	0.0	0.0	0.0	9.7
9.2 Power Tool Use (Other)	10	73.4	8.5	6.8	7.9	3.3	0.0	12.9
19.2 Brush Painting with Non-LBP	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
—Combined Hand Scraping/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	6.4
—Combined Power Tool Use/Painting	—	86.3	12.3	1.4	0.0	0.0	0.0	9.0
18.5 Associated Miscellaneous Activities	1	71.0	13.4	2.2	3.0	4.9	5.5	15.1
Installation of Terne Roofing:								
11.0 Soldering, Brazing	1	100.0	0.0	0.0	0.0	0.0	0.0	6.3
14.0 Handling Lead Shot, Bricks, or Sheet	1	100.0	0.0	0.0	0.0	0.0	0.0	5.6

Source: OSHA, Office of Regulatory Analysis.

TABLE 7.—PROJECTED BLOOD-LEAD PROFILE ASSOCIATED WITH THE 50 µG/M³ PEL, BY CONSTRUCTION ACTIVITY

Construction project activity	Assumed factor of exposure reduction	Percent of time that blood-lead level (µg/dl) is within stated range						Average blood-lead level (µg/dl)
		<=15	>15–25	>25–30	>30–40	>40–50	>50	
Highway and Railroad Bridge Repainting:								
1.1 Abrasive Blasting	4000	100.0	0.0	0.0	0.0	0.0	0.0	6.6
3.0 Spray Painting with LBP	20	100.0	0.0	0.0	0.0	0.0	0.0	6.0
19.1 Spray Painting with Non-LBP	2	100.0	0.0	0.0	0.0	0.0	0.0	8.6
—Combined Blasting/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	7.1
18.1 Enclosure Movement	50	100.0	0.0	0.0	0.0	0.0	0.0	7.6
18.2 Associated Miscellaneous Activities	50	86.0	14.0	0.0	0.0	0.0	0.0	9.6
Highway and Railroad Bridge Rehabilitation:								
2.1 Welding, Cutting, Burning on Bridges	50	59.2	40.8	0.0	0.0	0.0	0.0	12.8
18.5 Associated Miscellaneous Activities	50	100.0	0.0	0.0	0.0	0.0	0.0	5.4
Water Tank Repainting:								
1.1 Abrasive Blasting	4000	100.0	0.0	0.0	0.0	0.0	0.0	6.6
3.0 Spray Painting with LBP	20	100.0	0.0	0.0	0.0	0.0	0.0	5.9
19.1 Spray Painting with Non-LBP	2	100.0	0.0	0.0	0.0	0.0	0.0	8.6
—Combined Blasting/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	8.5
18.1 Enclosure Movement	50	100.0	0.0	0.0	0.0	0.0	0.0	7.5
18.2 Associated Miscellaneous Activities	50	92.3	7.7	0.0	0.0	0.0	0.0	9.5
Petroleum Tank Repainting:								
1.1 Abrasive Blasting	4000	100.0	0.0	0.0	0.0	0.0	0.0	6.6
3.0 Spray Painting with LBP	20	100.0	0.0	0.0	0.0	0.0	0.0	6.0
19.1 Spray Painting with Non-LBP	2	100.0	0.0	0.0	0.0	0.0	0.0	8.6
—Combined Blasting/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	7.1
18.1 Enclosure Movement	50	100.0	0.0	0.0	0.0	0.0	0.0	7.6
18.2 Associated Miscellaneous Activities	50	86.0	14.0	0.0	0.0	0.0	0.0	9.6
Underground Storage Tank Demolition:								
2.2 Other Welding, Cutting, Burning	50	100.0	0.0	0.0	0.0	0.0	0.0	5.0
Housing Lead Abatement (Public):								
(A) Combined Abatement Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
9.1 Power Tool Use (Housing)	40	100.0	0.0	0.0	0.0	0.0	0.0	9.1
Housing Lead Abatement (Private):								
(A) Combined Abatement Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	5.1
In-Place Management (Public)								
(B) Combined In-Place Mgmt. Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	8.6
In-Place Management (Private):								
(B) Combined In-Place Mgmt. Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	9.2
Commercial and Industrial Demolition:								
2.2 Other Welding, Cutting, Burning	50	100.0	0.0	0.0	0.0	0.0	0.0	6.6
Indoor Industrial Facility Maintenance/Renovation:								
1.1 Abrasive Blasting	4000	100.0	0.0	0.0	0.0	0.0	0.0	5.5
9.2 Power Tool Use (Other)	40	99.2	0.8	0.0	0.0	0.0	0.0	6.5
2.2 Other Welding, Cutting, Burning	50	100.0	0.0	0.0	0.0	0.0	0.0	5.5
19.1 Spray Painting with Non-LBP	2	100.0	0.0	0.0	0.0	0.0	0.0	6.1
—Combined Blasting/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	5.7
—Combined Power Tool Use/Painting	—	97.5	2.5	0.0	0.0	0.0	0.0	6.7
18.1 Enclosure Movement	50	100.0	0.0	0.0	0.0	0.0	0.0	5.7
18.5 Associated Miscellaneous Activities	50	100.0	0.0	0.0	0.0	0.0	0.0	5.1
Outdoor Industrial Facility Maintenance/Renovation:								
1.1 Abrasive Blasting	4000	100.0	0.0	0.0	0.0	0.0	0.0	6.6
9.2 Power Tool Use (Other)	40	81.92	18.1	0.0	0.0	0.0	0.0	10.7
2.2 Other Welding, Cutting, Burning	50	100.0	0.0	0.0	0.0	0.0	0.0	6.6
19.1 Spray Painting with Non-LBP	2	100.0	0.0	0.0	0.0	0.0	0.0	8.6
—Combined Blasting/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	6.9
—Combined Power Tool Use/Painting	—	74.52	25.5	0.0	0.0	0.0	0.0	10.2
18.1 Enclosure Movement	50	100.0	0.0	0.0	0.0	0.0	0.0	7.6
18.5 Associated Miscellaneous Activities	50	100.0	0.0	0.0	0.0	0.0	0.0	5.4
Lead Joint Work on Cast Iron Soil Pipes:								
10.0 Use of Lead Pots	1	100.0	0.0	0.0	0.0	0.0	0.0	5.4

TABLE 7.—PROJECTED BLOOD-LEAD PROFILE ASSOCIATED WITH THE 50 μG/M³ PEL, BY CONSTRUCTION ACTIVITY—Continued

Construction project activity	Assumed factor of exposure reduction	Percent of time that blood-lead level (μg/dl) is within stated range						Average blood-lead level (μg/dl)
		<=15	>15–25	>25–30	>30–40	>40–50	>50	
Ind. Process Equipment Mfg./Maint./Repair:								
2.3 Lead Burning	20	98.90	1.1	0.0	0.0	0.0	0.0	12.6
Industrial Vacuuming:								
15.0 Industrial Vacuuming	50	100.0	0.0	0.0	0.0	0.0	0.0	5.0
Stained Glass Window Removal:								
13.1 Removal of Stained Glass Windows	50	100.0	0.0	0.0	0.0	0.0	0.0	5.3
Installation of Radiation Shielding:								
14.0 Handling Lead Shot, Bricks, or Sheet	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
16.0 Cutting of Lead Foil Panels	1							
Commercial and Institutional Remodeling:								
(C) Combined Comm./Inst. Remodeling Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	7.0
5.2 Manual Demolition	50	100.0	0.0	0.0	0.0	0.0	0.0	5.3
9.2 Power Tool Use (Other)	40	94.79	5.2	0.0	0.0	0.0	0.0	9.2
2.2 Other Welding, Cutting, Burning	50	100.0	0.0	0.0	0.0	0.0	0.0	6.8
Residential Remodeling:								
(D) Combined Res. Remodeling Activities	1	100.0	0.0	0.0	0.0	0.0	0.0	7.6
5.2 Manual Demolition	50	100.0	0.0	0.0	0.0	0.0	0.0	5.3
Elevator Cable Babbitting:								
10.0 Use of Lead Pots	1	100.0	0.0	0.0	0.0	0.0	0.0	5.0
Electrical Cable Splicing:								
10 Use of Lead Pots	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
Reinsulation over Existing Mineral Wool:								
17.0 Reinsulation over Existing Mineral Wool	10	100.0	0.0	0.0	0.0	0.0	0.0	5.0
Repair/Removal of Water Lines Containing Lead:								
11.0 Soldering, Brazing	1	100.0	0.0	0.0	0.0	0.0	0.0	5.1
Transmission and Communication Tower Maint.:								
4.0 Hand Scraping	50	100.0	0.0	0.0	0.0	0.0	0.0	5.0
9.2 Power Tool Use (Other)	40	99.18	0.8	0.0	0.0	0.0	0.0	7.0
19.2 Brush Painting with Non-LBP	1	100.0	0.0	0.0	0.0	0.0	0.0	5.3
—Combined Hand Scraping/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	6.4
—Combined Power Tool Use/Painting	—	100.0	0.0	0.0	0.0	0.0	0.0	5.8
18.5 Associated Miscellaneous Activities	50	100.0	0.0	0.0	0.0	0.0	0.0	5.2
Installation of Terne Roofing:								
11.0 Soldering, Brazing	1	100.0	0.0	0.0	0.0	0.0	0.0	6.3
14.0 Handling Lead Shot, Bricks, or Sheet	1	100.0	0.0	0.0	0.0	0.0	0.0	5.6

Source: OSHA, Office of Regulatory Analysis.

Table 8 presents the analysis of the number of potential medical removal protection (MRP) cases expected to occur during the first year that the Interim Final Standard is in effect. The estimates shown are based on the assumptions that initial monitoring is administered to all workers in activities with exposures at or above the 30 μg/m³ action level and that medical surveillance program monitoring is administered to all workers in activities with exposures at or above the 30 μg/m³ action level for more than 30 days per year. These estimates were prepared to support the analysis of potential costs of medical removal protection benefits and increased medical surveillance for workers with detected and confirmed blood leads over 50 μg/dl. Because measurements of blood-lead levels are to be taken at fixed intervals under the Interim Final Standard, and because a worker's blood-lead level changes in response to variations in air lead exposures, there is a determinable probability that a blood-lead level above the 50 μg/dl medical removal trigger will be detected on any particular test. To estimate the number of MRP cases that would likely be identified, two alternative assumptions were made. First, it was assumed that blood-lead levels above the MRP trigger occur irregularly during the year. Under this assumption, the probability of detecting a blood-lead level above the MRP trigger can be described using binomial statistics, and the result represents a minimum estimate of the true probability. Alternatively, it was assumed that all blood-lead levels above the MRP trigger occur on consecutive days (i.e., blood-lead levels are highly autocorrelated), and that blood-lead measurements will be taken at 60-day intervals. Under this assumption, the probability of detecting a blood-lead level above the MRP trigger can be described by the ratio of the number of days that blood-lead levels are above the

MRP trigger divided by 60. This approach was assumed to yield the maximum probability of detecting a blood-lead level above 50 µg/dl. Multiplying the minimum and maximum probabilities of detecting a blood-lead level above the MRP trigger by the estimated number of employees engaged in each construction activity yields estimates of the annual number of employees that will be detected with blood-lead levels above the MRP trigger under baseline exposure conditions.

TABLE 8.—PREVALENCE OF MEDICAL REMOVAL CASES UNDER BASELINE EXPOSURE ASSUMPTIONS BY PROJECT TYPE

Project type	Total number of workers exposed	Initial biological monitoring**	Medical surveillance program monitoring***	Number of MRP cases per year (minimum)	Number of MRP cases per year (maximum)
Highway and Railroad Bridge Repainting	18,419	X	X	2,419	4,697
Highway and Railroad Bridge Rehabilitation	29,958	X	X	11,733	15,053
Water Tank Repainting	5,113	X	X	579	1,077
Petroleum Tank Repainting	4,364	X	X	565	1,067
Underground Storage Tank Demolition	288	X		0	0
Housing Lead Abatement (Public Housing)*	2,893	X	X	0	0
Housing Lead Abatement (Private Housing)*	9,345			0	0
In-place Management (Public Housing)*	188			0	0
In-place Management (Private Housing)*	35,056			0	0
Commercial and Industrial Demolition	7,440	X	X	0	0
Indoor Industrial Facility Maint./Renovation	2,113	X	X	0	14
Outdoor Industrial Facility Maint./Renovation	2,981	X	X	393	706
Lead Joint Work on Cast Iron Soil Pipes	15,337			0	0
Ind. Process Equipment Mfg./Maint./Repair	409	X	X	0	0
Industrial Vacuuming	392	X		0	0
Stained Glass Window Removal	208	X	X	0	0
Installation of Radiation Shielding	40			0	0
Commercial and Institutional Remodeling*	546,798	X		166	384
Residential Remodeling*	178,544	X		0	0
Elevator Cable Babbitting	4,500			0	0
Electrical Cable Splicing	5,000			0	0
Reinsulation Over Existing Mineral Wool	18,333	X		0	0
Repair/Removal of Water Lines	41,042			0	0
Transmission & Comm. Tower Maint.	7,333	X	X	372	614
Installation of Terne Roofing	576			0	0
Total for all project types	986,670			16,256	29,559

* OSHA's analysis shows that in some activities in these project types, poor work practices can result in blood-lead levels that would require medical removal. However, once the standard is in effect, and good work practices are implemented, none of these workers in these activities will be exposed above the action level.

** Initial monitoring is triggered by a single day of exposure above the action level of 30 µg/m³.

*** Medical surveillance program monitoring is triggered by exposure above the action level for more than 30 days and for all workers with blood-lead levels above 40 µg/dl.

Source: OSHA, Office of Regulatory Analysis.

However, not all of these employees will be medically removed. The interim final standard mandates that employees be removed from exposure only after a follow-up blood-lead test taken two weeks after a periodic test confirms the blood-lead level to be above 50 µg/dl. Of the number of employees found to have a blood-lead level above the MRP trigger, Meridian assumed that two-thirds will require medical removal as a result of a confirming follow-up blood-lead test.

In addition, it can reasonably be expected that blood-lead levels will fall during the first year that the standard is in effect, due to the requirement to reduce employee exposures during that year. Therefore, the number of employees having blood-lead levels above 50 µg/dl will likely decline during the first year. For this analysis, it was assumed that the number of employees requiring medical removal will decline by half after the first four months following the effective date, and should approach zero at the end of the first year following the effective date of the standard. (The number of MRP cases expected to be identified during the first year was reduced, in accordance with this assumption, for purposes of the cost analysis.)

Table 9 contains estimates of the number of illness and MRP cases expected to be avoided following promulgation of the 50 µg/m³ PEL for construction. (About half of these benefits would have been achieved if there had been full compliance with the existing OSHA PEL of 200 µg/m³.) Except for cases of gastrointestinal disturbances, detected blood-leads above the 50 µg/dl medical removal trigger, and medical removal, estimates of the numbers of cases avoided were derived using average baseline blood-lead levels predicted for each group of workers (see Table 6) and corresponding risk estimates contained in Meridian's Peer-Review Draft Risk Assessment. For gastrointestinal disturbances, a minimum estimate of cases avoided was derived by assuming that all workers predicted to have blood-lead levels exceeding 99 µg/dl at least five percent of the time (i.e., about three weeks) were at risk of acute lead poisoning. The maximum estimate was derived by assuming that all workers with blood-lead levels exceeding 70 µg/dl are at risk. The number of cases of detected

blood-leads above the MRP trigger level and number of cases of medical removals comes from the analysis summarized in Table 8.

The number of illness and MRP cases avoided for near-term effects listed in Table 9 are expected to accrue during or shortly after the first year following promulgation of the Interim Final Standard. These near-term effects have generally been found to be reversible upon reduction or cessation of exposure to lead. The number of illness cases avoided for long-term effects are expected to accrue over at least a 10-year period of time.

TABLE 9.—SUMMARY OF POTENTIAL BENEFITS ASSOCIATED WITH A REDUCTION OF THE LEAD PEL TO 50 μG/M³ for Construction

Effect avoided	Number of cases	
	Minimum	Maximum
Near-Term Effects Avoided Annually:		
Reduced Nerve Conduction Velocity	16,199	22,831
Reduced Blood ALA–D Levels	130,056	164,044
Increased Urinary ALA	60,389	78,676
Gastrointestinal Disturbances	1,135	4,413
Detected Blood-Lead Levels Above MRP Trigger**	24,262	35,163
Long-Term Effects Avoided Over A Ten-Year Period:		
Fatal/Nonfatal Infarctions	2,164	2,322
Fatal/Nonfatal Stroke	698	644
Renal Disease	1,258	2,157

**Note: The minimum estimate of expected medical removal cases is 16,256. The maximum estimate of expected medical removal cases is 23,559.

Source: OSHA, Office of Regulatory Analysis.

E. Costs of Compliance

This section describes the costs of compliance expected to be incurred by the industries affected by the Interim Final Standard for Lead in Construction. The cost estimates presented in this section are based on the preliminary findings of OSHA's research into current compliance, costs and economic impact issues related to lead exposure reduction efforts in the construction industry.

As described in the technological feasibility section above, there are several general approaches for controlling exposure to airborne lead. The existing OSHA lead standard, 29 CFR 1926.55, requires engineering controls, work practices, and respirators to be used to meet a PEL of 200 μg/m³ for lead exposure in the construction industry.[3] The Interim Final Standard reduces the lead PEL to 50 μg/m³ and requires additional safeguards in the form of ancillary provisions intended to prevent overexposure to lead. These ancillary provisions include requirements for competent person supervision, exposure monitoring, protective clothing and equipment, biological monitoring, and recordkeeping. The costs of meeting these additional requirements are attributable to the Interim Final Standard. Table 10 summarizes information on the regulatory provisions of the existing standard, the Interim Final Standard, and the exposure levels at which required controls must be employed.

TABLE 10.—SUMMARY OF CONTROL PRACTICE REQUIREMENTS ASSOCIATED WITH OSHA'S EXISTING AND INTERIM FINAL LEAD STANDARDS

Control practice	Existing standard: 200 μg/m³ PEL		Interim final standard		
	Exposure below PEL	Exposure above PEL	Exposure below 30 μg/m³ AL	Exposure between AL and PEL	Exposure above 50 μg/m³ PEL
Determination of the Presence of Lead[a]			X	X	X
Competent Person					X
Exposure Monitoring and Assoc. Recordkeeping[a]			X	X	X
Mechanical Ventilation		X			X
Local exhaust Ventilaiton		X			X
Enclosures/Containment Systems[b]		X			X
HEPA Vacumms	X[c]	X[c]	X	X	X
Wetting Agents	X	X	X	X	X
Written Compliance Program					X
Warning Signs					X
Worker Training				X	X
Notification of Other Employers			X	X	X
Respiratory Protection		X			X

[3] Thus the capital costs of mechanical ventilation, local exhaust ventilation, HEPA vacuums, wetting agents, and respiratory protection for projects with exposures over 200 μg/m³ are already required under 29 CFR 1926.55.

TABLE 10.—SUMMARY OF CONTROL PRACTICE REQUIREMENTS ASSOCIATED WITH OSHA'S EXISTING AND INTERIM FINAL LEAD STANDARDS—Continued

Control practice	Existing standard: 200 μg/m³ PEL		Interim final standard		
	Exposure below PEL	Exposure above PEL	Exposure below 30 μg/m³ AL	Exposure between AL and PEL	Exposure above 50 μg/m³ PEL
Protective Clothing/Gloves/Shoe Covers					X
Handwashing Facilities Only[d]			X	X	X
Change Areas with Storage Facilities					X
Decontamination Facilities Including Showers					X
Eating Areas and Facilities					X
Biological Monitoring and Assoc. Recordkeeping				X	X
Medical Examinations and Assoc. Recordkeeping				X	X
Medical Removal Protection Requirements[e]			X	X	X

[a] Exemption is possible if objective data shows that exposures are below the action level or if the employer has relevant data from the past 12 months.
[b] Enclosures are only assumed to be needed in conjunction with indoor projects using mechanical ventilation. Outdoor enclosures are required by EPA regulations concerning environmental release of lead.
[c] For this standard, vacuums are only needed for worksite clean-up.
[d] Hand washing facilities for activities below the PEL are required by 29 CFR 1926.51(f).
[e] Medical removal is dependent on worker blood-lead level.
Source: OSHA, Office of Regulatory Analysis.

In order to develop the cost estimates associated with achieving full compliance with OSHA's Interim Final Standard, unit cost estimates were obtained for the control practices and ancillary measures required for each of the project types and activities covered by the rule. The appropriate control practices required to achieve compliance were identified for each project type and construction activity in accordance with the exposure data presented in the technological feasibility section above. The unit cost data used in this analysis were obtained from published price lists of equipment suppliers and from other information collected and developed by OSHA's consultant, CONSAD Research.

The control practices costed in the analysis of the Interim Final Standard included: Determination of the presence of lead; exposure monitoring; competent person labor time; written compliance programs; warning signs; worker training; respirators for activities with exposures below the old PEL of 200 μg/m³ but above the new PEL of 50 μg/m³ (including the respirator unit, accessories, fit testing, cleaning, and training); disposable and reusable protective clothing, shoe covers and gloves; handwashing facilities; decontamination facilities; clean change areas with storage facilities; eating facilities; biological monitoring (blood lead and ZPP testing); medical examinations; medical removal protection; recordkeeping; and employee notification of monitoring data, blood lead analysis, and medical exam results.[4]

Estimates of the annual need for or use of each control practice were calculated using the following bases for costing purposes: Establishments, projects,[5] crews, workers, project-days, crew-days, or worker-days. Estimates for the other parameters in the cost analyses were calculated based upon estimates of the types and frequency of construction activities performed within each project type, project and activity durations, average number of crews per construction activity, crew size, hours of exposure per day, the percentage of projects performed per year involving lead, and the number of available work-days per year. These estimates were developed by OSHA's consultant, CONSAD Research, based on data obtained from industry and labor experts, site visits conducted to support this analysis, CONSAD's PELs in Construction Study, and the 1991 Steel Structures Painting Council (SSPC) Survey of Facility Owners.

Annual compliance costs for each project type and associated activities were developed by combining the unit cost data with estimates of the number of units of each type of control practice needed per year to achieve compliance with the Interim Final Standard. Estimated costs for hygiene facilities, respirators and other capital goods were annualized based on assumptions about the expected useful life of the equipment. The resulting gross annual cost estimates were then adjusted to reflect existing use of specific control practices in order to develop net annual compliance cost estimates.

OSHA's preliminary estimates of current compliance with lead exposure control requirements were used to determine current expenditures on control practices for each project type. These compliance estimates were based upon information obtained from industry and labor experts, CONSAD site visits, CONSAD's PELs in Construction Study, and reports from various HUD Lead Abatement Demonstration Projects.

The cost estimates discussed in this section are the estimated incremental costs to the affected industries of achieving full compliance with the requirements of the Interim Final Standard. These incremental costs are those costs which must be expended to achieve full compliance with OSHA's new requirements in excess of amounts currently being spent by industry.

The annual recurring costs of achieving compliance with a 50 μg/m³ PEL and the ancillary requirements of the Interim Final Standard are estimated to range between $365 million to $445 million dollars.[6] During the first year following the standard's implementation, additional "one-time" start-up costs are expected to be incurred for worker training, biological monitoring, medical examinations, and

[4] Costs of complying with the requirement for handwashing facilities are attributed to the existing OSHA construction sanitation standard: 29 CFR 1926.51(f).

[5] Multiple pieces of equipment were costed where firms were assumed to perform more than one project at a time.

[6] Additional costs will be borne by those firms not currently in compliance with the existing 200 μg/m³ PEL.

medical removal protection benefits.[7] These costs are estimated to range between $150 million and $183 million. Start-up costs for worker training and biological monitoring are based on the need to train and monitor all current employees exposed above the trigger levels for these provisions during the first year after the standard becomes effective. Costs for medical examinations and medical removal protection benefits should not persist beyond the first year; compliance with the 50 μg/m³ PEL is expected to reduce worker blood leads below the trigger levels for these provisions.

Tables 11 and 12 present point estimates of the annual recurring cost of the Interim Final Standard to illustrate the relative magnitude of costs by project type and by provision. The figures shown in Tables 11 and 12 suggest the relative importance of each cost element.

TABLE 11.—POINT-ESTIMATE SUMMARY OF ANNUAL RECURRING COMPLIANCE COSTS FOR OSHA'S INTERIM FINAL LEAD STANDARD BY PROJECT TYPE

Project type	Total annual recurring compliance costs	Project cost as a percentage of total
Highway and railroad bridge repainting	56,742,000	13.99
Highway and railroad bridge rehabilitation	109,593,000	27.02
Water tank repainting	14,797,000	3.65
Petroleum tank repainting	16,125,000	3.98
Underground storage tank demolition	443,000	0.11
Housing lead abatement (public housing)	5,473,000	1.35
Housing lead abatement (private housing)	[1] 0	0.00
In-place management (public housing)	[1] 0	0.00

[7] Cost estimates for medical removal benefits were based on an average removal duration of 100 work days and an average medical removal benefit per case of $74 per day. This estimate is based on OSHA's assumptions about the likelihood of removed workers: finding non-lead exposed jobs with a different employer; moving to a job with the same employer at the same wage rate; moving to a lower-paying job with the same employer; receiving worker compensation; or being removed for fewer than 100 work days.

TABLE 11.—POINT-ESTIMATE SUMMARY OF ANNUAL RECURRING COMPLIANCE COSTS FOR OSHA'S INTERIM FINAL LEAD STANDARD BY PROJECT TYPE—Continued

Project type	Total annual recurring compliance costs	Project cost as a percentage of total
In-place management (private housing)	[1] 0	0.00
Commercial and industrial demolition	16,445,000	4.05
Indoor industrial facility maintenance/renovation	3,739,000	0.92
Outdoor industrial facility maintenance/renovation	10,152,000	2.50
Lead joint work on cast iron soil pipes	[1] 0	0.00
Industrial process equipment manufacturing/maintenance/repair	2,285,000	0.56
Industrial vacuuming	394,000	0.10
Stained glass window removal	1,046,000	0.26
Installation of radiation shielding	[1] 0	0.00
Commercial and institutional remodeling	76,746,000	18.92
Residential remodeling	59,163,000	14.59
Elevator cable babbitting	[1] 0	0.00
Electrical cable splicing	[1] 0	0.00
Reinsulation over existing mineral wool	18,580,000	4.58
Repair/removal of water lines	[1] 0	0.00
Transmission and commercial tower maintenance	13,827,000	3.41
Installation of terne roofing	[1] 0	0.00
Total for all project types	405,550,000	100.000

[1] Lead exposure levels on these projects are not expected to exceed the action level of 30 μg/m.

Source: OSHA, Office of Regulatory Analysis.

TABLE 12.—POINT-ESTIMATE SUMMARY OF ANNUAL RECURRING COMPLIANCE COSTS FOR OSHA'S INTERIM FINAL LEAD STANDARD BY CONTROL PRACTICE

Control practice	Total annual recurring compliance costs	Control practice percentage of total
Determination of the presence of lead	1,413,000	0.35
Competent person labor time	18,610,000	4.59
Exposure monitoring and association recordkeeping	121,617,000	29.99
Written compliance program	15,179,000	3.74
Warning signs	7,036,000	1.73
Worker training	11,118,000	2.74
Respiratory protection	4,714,000	1.16
Protective work clothing	89,325,000	22.03
Hand washing facilities only	[1] 0	0.00
Change areas with storage facilities	2,108,000	0.52
Decontamination facilities and shower time labor cost	111,510,000	27.50
Eating facilities	419,000	0.10
Biological monitoring and association recordkeeping	22,500,000	5.55
Total	405,550,000	100.00

[1] Costs of hand washing facilities were attributed to 29 CFR 1926.51(f).

Source: OSHA, Office of Regulatory Analysis.

As shown in Table 11, the project types expected to account for the largest share of annual costs are Highway and Railroad Bridge Rehabilitation (27%); Commercial and Institutional Remodeling (19%); Residential Remodeling (15%); and Highway and Railroad Bridge Repainting (14%). It should be noted that although lead exposures associated with remodeling project types are generally low, and less than 20 percent of commercial and 5 percent of residential remodeling jobs involving lead exposure are expected to be exposed over the PEL, the large number of remodeling projects estimated to occur annually results in significant total costs for these project types. As shown above in Table 3, the annual numbers of lead-exposed projects for Commercial and Institutional Remodeling and

Residential Remodeling are 546,000 and 2,698,000, respectively.

Table 12 shows the annual recurring costs by control practice in order to indicate the relative magnitude of costs associated with specific regulatory provisions. In descending order of importance, the most costly provisions are exposure monitoring and associated recordkeeping (30%); hygiene facilities, including change areas and decontamination facilities with associated showering labor time costs (28%); and protective work clothing and equipment, including both reusable and disposable protective clothing (22%).

F. Economic Impacts

This chapter examines the economic impacts associated with OSHA's Interim Final Standard for Lead in Construction. The economic impact analysis presented below is based on those costs attributable to the Interim Final Standard as described in the cost section above.

The economic impacts in this section are presented on both a "per worker" and a "per establishment" basis. The bases for estimating these impacts were derived from data on each SIC obtained from the 1987 Census of Construction Industries, the 1989 County Business Patterns, and the Dun & Bradstreet Insight Database. The following data were used to construct this analysis:

- The total number of establishments;
- The total number of employees and the total number of construction workers;
- The average number of employees and the average number of construction workers per establishment;
- The annual payroll for all employees and for construction workers;
- The net dollar value of construction work for construction SICs or sales for non-construction SICs; and
- The pre-tax profit ratio.

These data were used to derive the annual payroll and net value of construction work per establishment and per construction worker. To obtain pre-tax profits per establishment, pre-tax profit ratios derived from Dun & Bradstreet data were multiplied by the net value of construction work or sales per establishment.

Across all the affected SICs, the annual payroll per establishment ranges from $48,000 for SIC 1521, Single Family Housing to $3.4 million for SIC 4911, Electric Utilities. The net value of construction work or sales per establishment ranges from $15,300 in sales for SIC 6514, Operators of Other Dwellings to $7 million in sales for SIC 4911, Electric Utilities. Across all the affected SICs, pre-tax profits per establishment range from $1,300 for SIC 6514, Operators of Other Dwellings to $676,000 for SIC 4911, Electric Utilities.

Several different cost-related impact measures were calculated for each of the 18 construction SICs and four of the five non-construction SICs identified as affected by OSHA's Interim Final Standard.[8] These impact measures are:

- The ratio of the average annual compliance costs per affected establishment (or per exposed construction worker) to an estimate of the annual payroll for an average establishment (or per construction worker) in the specific SIC. This measure compares the projected compliance costs to labor costs normally incurred by the establishment. It can be interpreted as the cost of providing a mandated occupational safety and health "benefit" relative to existing payroll expenses.
- A comparison of the average annual compliance costs per affected establishment (or per exposed construction worker) to an estimate of the net dollar value of construction work or sales for an average establishment (or per construction worker) in the specific SIC. This ratio indicates the relationship of the compliance costs to an establishment's output.
- The average annual compliance cost per affected establishment as a percentage of pre-tax profits for an average establishment in the specific SIC. This measure is particularly meaningful when establishments face highly competitive conditions which prevent the pass through of compliance costs to customers.

The impact measures described above were calculated for the annual recurring costs of the Interim Final Standard as shown in Table 11 above. Table 13 presents estimates of the annual recurring compliance costs per exposed worker and per establishment for each affected SIC. These estimates are an average of costs across the mix of different project types assumed to be performed by each construction or non-construction industry SIC.

Table 13 shows these average costs as a percentage of construction payroll and net value of construction work or sales, on both a per worker and per establishment basis for affected industries. The last column of Table 13 presents the compliance costs per establishment as a percentage of pre-tax profits per establishment. These average percentages are shown to illustrate the relative magnitude of impacts on specific SICs; they should not be interpreted as indicative of the cost impacts on specific project types or on firms within an SIC which specialize in only one of the associated project types.

As shown in Table 13, using annual compliance costs per worker as a measure of impact, the most impacted SICs are expected to include SIC 1791, Structural Steel Erection Contractors; SIC 1795, Wrecking and Demolition Contractors; SIC 1622, Bridge, Tunnel and Elevated Highway Contractors; SIC 1611, Highway and Street Construction Contractors; SIC 1721, Painting Contractors; and SIC 3231, Glass Products Manufacturers.

[8] Impact estimates were not made for SIC 9999, State and Municipal Governments since the relevant revenue and profit data are not applicable.

TABLE 13.—SUMMARY ECONOMIC IMPACT MEASURES FOR OSHA'S INTERIM FINAL STANDARD IMPACT MEASURES CALCULATED USING ESTIMATES OF ANNUAL RECURRING COSTS

SIC	Industry title	Compliance cost per worker ($)	Compliance cost per worker as a percentage of—		Compliance cost per establishment ($)	Compliance cost per establishment as a percentage of—		
			Construction payroll per worker (percent)	Net value of construction work/sales per worker (percent)		Construction worker payroll per establishment (percent)	Net value of construction work/sales per establishment (percent)	Pre-tax profits per establishment (percent)
1521	Single family housing	297	2.1	0.3	1,202	2.5	0.4	6.9
1522	Other residential buildings	331	1.8	0.3	1,342	1.0	0.2	3.2
1531	Operative builders	277	1.5	0.1	1,119	1.6	0.1	1.6
1541	Industrial buildings and warehouses.	168	0.7	0.2	3,028	0.9	0.2	4.8
1542	Other non-resident construction.	140	0.7	0.1	2,564	1.0	0.2	5.0
1611	Highway and street contractors	3,398	15.1	2.9	57,735	11.8	2.3	44.4
1622	Bridge, tunnel and el. highway contractors.	3,625	16.0	3.5	77,482	9.9	2.1	47.7
1711	Plumbing contractors	0	0.0	0.0	0	0.0	0.0	0.0
1721	Painting contractors	775	4.7	1.5	7,792	9.8	3.1	42.2
1731	Electrical work contractors	211	0.9	0.2	1,606	0.8	0.2	3.6
1742	Plastering, drywall, and ins. contractors.	229	1.1	0.3	2,023	0.8	0.2	4.8
1751	Carpentry work contractors	167	1.1	0.3	2,046	2.8	0.7	10.8
1752	Floor work contractors	187	1.0	0.2	1,836	2.3	0.4	6.7
1761	Roofing and siding contractors	166	1.0	0.2	2,020	1.7	0.4	7.0
1791	Structural steel erection contractors.	3,607	16.0	4.4	70,485	23.0	6.3	99.6
1795	Wrecking and demolition work contractors.	2,188	13.1	3.0	24,596	15.6	3.6	62.3
1796	Building equipment contractors	0	0.0	0.0	0	0.0	0.0	0.0
1799	Miscellaneous special trade contractors, NEC.	402	2.5	0.6	2,027	2.1	0.5	7.2
3231	Glass products manufacturers	5,019	29.7	1.8	10,038	14.0	0.9	14.6
4911	Electric utilities	0	0.0	0.0	0	0.0	0.0	0.0
6513	Operators of apartment buildings.	0	0.0	0.0	0	0.0	0.0	0.0
6514	Operators of other dwellings	0	0.0	0.0	0	0.0	0.0	0.0

Source: OSHA, Office of Regulatory Analysis.

If compliance costs per establishment are used as a measure of impact, the most impacted SICs during subsequent years are expected to include: SIC 1791, Structural Steel Erection Contractors; SIC 1795, Wrecking and Demolition Contractors; SIC 1622, Bridge, Tunnel and Elevated Highway Contractors; SIC 1611, Highway and Street Construction Contractors; SIC 1721, Painting Contractors; and SIC 3231, Glass Products Manufacturers.

Impact measures calculated on the basis of percent of net value of construction work and sales suggest the magnitude of cost increases that may potentially be passed through to consumers of construction. (The very high impact on pre-tax profits found in SICs 1791 and 1795 would only be realized if no costs were passed through to buyers of construction. Since cost pass through of most costs is likely, the impact shown in Table 13 represents a hypothetical extreme.)

Existing federal, state and local regulations have already established some obligations for owners and contractors concerning abatement practices on construction projects that supplement and reinforce the requirements of OSHA's Interim Final Lead Standard. These regulations, in conjunction with forthcoming lead regulations from the Federal Highway Administration, the Environmental Protection Agency and the Department of Housing and Urban Development, are expected to ensure a level playing field for contractors bidding on work involving lead exposure.

For many project types involving high exposures to lead, and especially those involving abrasive blasting, small contractors have traditionally made up most of the industry. In recent years, construction industry compliance with environmental regulations has resulted in large capital expenditures and additional worker skill training requirements. These requirements are bringing about some restructuring in this industry with a progressively larger share of work involving lead exposure being performed by larger, better capitalized contractors. OSHA does not anticipate that these changes will result in massive dislocations, undue concentration or any threat to the competitive structure of the industry.

Where OSHA compliance costs significantly increase costs to the buyers of construction, some projects may be delayed in order to compensate for the increased cost of existing work. This may occur in the case of infrastructure projects such as bridge repainting and bridge rehabilitation. However, OSHA cannot state with certainty whether or not this will actually occur or whether new levels of infrastructure spending will more than compensate for new costs of the interim final rule.

G. Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980 (Pub.L. 96–353, 94 Stat. 1164 (5 U.S.C. et seq.)), OSHA has assessed the impact of the Interim Final Standard on small businesses, defined as establishments with fewer than 20

employees. The impacts were evaluated for potential adverse impacts on small firms and their relative consequences compared with large firms. Of the estimated 147,000 affected establishments, approximately 132,000 (90%), are small businesses. Thus, the impacts shown above for all establishments are also illustrative of the expected impacts on small businesses.

In general, the costs of compliance for any firm will depend on the extent of worker exposures, the extent of current engineering control, work practice and respirator use, and the amount of lead-exposed work being done. For any given lead-exposed activity, work is likely to be done in a similar manner by both large and small firms, with costs proportional to the scale of the project. As noted above, in response to environmental regulations regarding lead removal, larger capital requirements are bringing about some industry rationalization and concentration. However, this development is not threatening the overall competitive structure of the industry. Estimated compliance costs are feasible for both large and small establishments in each affected industry sector.

V. Environmental Impact Analysis

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 at seq.), as implemented by the regulations (40 CFR part 1500) of the Council on Environmental Quality (CEQ), requires that federal agencies assess their regulatory actions to determine if there is a potential for a significant impact on the quality of the human environment and, if necessary, to prepare an environmental impact statement.

In accordance with these requirements and DOL NEPA Compliance Procedures (29 CFR part 11, subpart B, § 11.10(a)(4)), OSHA has determined that this standard will not have any appreciable negative environmental impact. In any event, OSHA also believes that due to the compressed rulemaking schedule imposed by the Congress in issuing the interim regulation, no environmental impact statement will be prepared for this interim rule.

In similar situations, for example, when an emergency temporary standard (ETS) has been issued, the courts have held that NEPA does not require advance preparation of an environmental statement for an ETS (*Dry Color Manufacturing Association* v. *U.S. Department of Labor*; 486 F. 2d 98, 107 [3rd Cir. 1973]). This interim final standard is similar in nature to an ETS, which is issued on an abbreviated schedule and for a relatively brief period. The DOL NEPA regulations set forth in 29 CFR part 11, subpart B, section 11, 10(s)(4), provide that in these situations the regulations set forth in 40 CFR parts 1500 et seq may not be strictly observable.

VI. Federalism and State Plan Applicability

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

In short, there is a clear national problem related to occupational safety and health for employees exposed to lead in the construction industry. Those States which have elected to participate under section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard.

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of publication of a final rule. The States are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. For New York and Connecticut, plans cover only state and local government employees. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these States.

VII. Date of Effectiveness and Absence of Notice and Comment

Section 1031 of the Housing and Community Development Act specifically provides that the "not later than 180 days after enactment of this Act, the Secretary of Labor shall issue an interim final regulation regulating occupational exposure to lead."

The express use of the phrase "interim final regulation," which in the rulemaking context commonly describes a rule issued without notice and comment, in connection with the extremely limited time frame provided by this section, makes clear that Congress intended this rule to be issued without the time-consuming process of notice and comment. The Agency, therefore, concludes that neither the notice and comment rulemaking provisions of the OSH Act nor those of the Administrative Procedures Act are applicable to the issuance of this interim final rule. This view is further supported in the Act's Legislative Committee report which states that "* * * the procedural requirements of section 6 of the OSH Act do not apply to the promulgation of the interim final regulation," [n]or * * * do the notice and comment provisions of the Administrative procedures Act apply."

VIII. Clearance of Information Collection Requirements

5 CFR part 1320 sets forth procedures for agencies to follow in obtaining OMB clearances for information collection requirements under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. The lead in construction interim rule requires the employer to allow OSHA access to various records including the employers' compliance and training plans; and the employees' exposure monitoring, medical and training records. In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it has submitted the information collection requirements of this standard to OMB for review under section 3504(h) of that Act.

Public reporting burden for this collection of information is estimated to average 5 minutes to allow OSHA compliance officers access to the employer's records. Send comments

regarding this burden estimate, or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, Department of Labor, room N–1301, 200 Constitution Avenue NW., Washington DC, 20210: and to the Office of Management and Budget, Paperwork Reduction Project (Lead Interim Final Rule), Washington, DC, 20503.

IX. Signature

Signed at Washington, DC, this 26 day of April, 1993.

David C. Zeigler,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

Accordingly, 29 CFR part 1926 is amended as follows:

PART 1926—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for subpart D of 29 CFR part 1926 is amended by adding the following:

Authority: * * * Section 1926.62 issued under sec. 1031 of the Housing and Community Development Act of 1992 (sec. 1031, title X, 106 Stat. 3924 (42 U.S.C. 4853)).

2. By adding a new § 1926.62, with Appendices A, B, C, and D to subpart D to read as follows:

§ 1926.62 Lead

(a) *Scope.* This section applies to all construction work where an employee may be occupationally exposed to lead. All construction work excluded from coverage in the general industry standard for lead by 29 CFR 1910.1025(a)(2) is covered by this standard. Construction work is defined as work for construction, alteration and/or repair, including painting and decorating. It includes but is not limited to the following:

(1) Demolition or salvage of structures where lead or materials containing lead are present;
(2) Removal or encapsulation of materials containing lead;
(3) New construction, alteration, repair, or renovation of structures, substrates, or portions thereof, that contain lead, or materials containing lead;
(4) Installation of products containing lead;
(5) Lead contamination/emergency cleanup;
(6) Transportation, disposal, storage, or containment of lead or materials containing lead on the site or location at which construction activities are performed, and
(7) Maintenance operations associated with the construction activities described in this paragraph.

(b) *Definitions.*

Action level means employee exposure, without regard to the use of respirators, to an airborne concentration of lead of 30 micrograms per cubic meter of air (30 μg/m³) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Competent person means one who is capable of identifying existing and predictable lead hazards in the surroundings or working conditions and who has authorization to take prompt corrective measures to eliminate them.

Director means the Director, National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Lead means metallic lead, all inorganic lead compounds, and organic lead soaps. Excluded from this definition are all other organic lead compounds.

This section means this standard.

(c) *Permissible exposure limit.* (1) The employer shall assure that no employee is exposed to lead at concentrations greater than fifty micrograms per cubic meter of air (50 μg/m³) averaged over an 8-hour period.

(2) If an employee is exposed to lead for more than 8 hours in any work day the employees' allowable exposure, as a time weighted average (TWA) for that day, shall be reduced according to the following formula:

Allowable employee exposure (in μg/m³)=400 divided by hours worked in the day.

(3) When respirators are used to limit employee exposure as required under paragraph (c) of this section and all the requirements of paragraphs (e)(1) and (f) of this section have been met, employee exposure may be considered to be at the level provided by the protection factor of the respirator for those periods the respirator is worn. Those periods may be averaged with exposure levels during periods when respirators are not worn to determine the employee's daily TWA exposure.

(d) *Exposure assessment—(1) General.* (i) Each employer who has a workplace or operation covered by this standard shall initially determine if any employee may be exposed to lead at or above the action level.

(ii) For the purposes of paragraph (d) of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(iii) With the exception of monitoring under paragraph (d)(3), where monitoring is required under this section, the employer shall collect personal samples representative of a full shift including at least one sample for each job classification in each work area either for each shift or for the shift with the highest exposure level.

(iv) Full shift personal samples shall be representative of the monitored employee's regular, daily exposure to lead.

(2) *Protection of employees during assessment of exposure.*

(i) With respect to the lead related tasks listed in paragraph (d)(2)(i) of this section, where lead is present, until the employer performs an employee exposure assessment as required in paragraph (d) of this section and documents that the employee performing any of the listed tasks is not exposed above the PEL, the employer shall treat the employee as if the employee were exposed above the PEL, and not in excess of ten (10) times the PEL, and shall implement employee protective measures prescribed in paragraph (d)(2)(v) of this section. The tasks covered by this requirement are:

(A) Where lead containing coatings or paint are present: Manual demolition of structures (e.g. dry wall), manual scraping, manual sanding, heat gun applications, and power tool cleaning with dust collection systems;

(B) Spray painting with lead paint

(ii) In addition, with regard to tasks not listed in paragraph (d)(2)(i), where the employee has any reason to believe that an employee performing the task may be exposed to lead in excess of the PEL, until the employer performs an employee exposure assessment as required by paragraph (d) of this section and documents that the employee's lead exposure is not above the PEL the employer shall treat the employee as if the employee were exposed above the PEL and shall implememt employee protective measures as prescribed in paragraph (d)(2)(v) of this section.

(iii) With respect to the tasks listed in paragraph (d)(2)(iii) of this section, where lead is present, until the employer performs an employee exposure assessment as required in paragraph (d) of this section, and documents that the employee performing any of the listed tasks is not exposed in excess of 500 μg/m³, the employer shall treat the employee as if the employee were exposed to lead in excess of 500 μg/m³ and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section. Where the employer does establish that the employee is exposed to levels of lead below 500 μg/m³, the employer may

provide the exposed employee with the appropriate respirator prescribed for such use at such lower exposures, in accordance with Table 1 of this section. The tasks covered by this requirement are:

(A) Using lead containing mortar; lead burning

(B) Where lead containing coatings or paint are present: rivet busting; power tool cleaning without dust collection systems; cleanup activities where dry expendable abrasives are used; and abrasive blasting enclosure movement and removal.

(iv) With respect to the tasks listed in paragraph (d)(2)(iv) of this section, where lead is present, until the employer performs an employee exposure assessment as required in paragraph (d) of this section and documents that the employee performing any of the listed tasks is not exposed to lead in excess of 2,500 μg/m^3 (50×PEL), the employer shall treat the employee as if the employee were exposed to lead in excess of 2,500 μg/m^3 and shall implement employee protective measures as prescribed in paragraph (d)(2)(v) of this section. Where the employer does establish that the employee is exposed to levels of lead below 2,500 μg/m3, the employer may provide the exposed employee with the appropriate respirator prescribed for use at such lower exposures, in accordance with Table I of this section. Interim protection as described in this paragaraph is required where lead containing coatings or paint are present on structures when performing:

(A) Abrasive blasting,

(B) Welding,

(C) Cutting, and

(D) Torch burning.

(v) Until the employer performs an employee exposure assessment as required under paragraph (d) of this section and determines actual employee exposure, the employer shall provide to employees performing the tasks described in paragraphs (d)(2)(i), (d)(2)(ii), (d)(2)(iii), and (d)(2)(iv) of this section with interim protection as follows:

(A) Appropriate respiratory protection in accordance with paragraph (f) of this section.

(B) Appropriate personal protective clothing and equipment in accordance with paragraph (g) of this section.

(C) Change areas in accordance with paragraph (i)(2) of this section.

(D) Hand washing facilities in accordance with paragraph (i)(5) of this section.

(E) Biological monitoring in accordance with paragraph (j)(1)(i) of this section, to consist of blood sampling and analysis for lead and zinc protoporphyrin levels, and

(F) Training as required under paragraph (l)(1)(i) of this section regarding 29 CFR 1926.59, Hazard Communication; training as required under paragraph (l)(2)(ii)(C) of this section, regarding use of respirators; and training in accordance with 29 CFR 1926.21, Safety training and education.

(3) *Basis of initial determination.* (i) Except as provided under paragraphs (d)(3)(iii) and (d)(3)(iv) of this section the employer shall monitor employee exposures and shall base initial determinations on the employee exposure monitoring results and any of the following, relevant considerations:

(A) Any information, observations, or calculations which would indicate employee exposure to lead;

(B) Any previous measurements of airborne lead; and

(C) Any employee complaints of symptoms which may be attributable to exposure to lead.

(ii) Monitoring for the initial determination where performed may be limited to a representative sample of the exposed employees who the employer reasonably believes are exposed to the greatest airborne concentrations of lead in the workplace.

(iii) Where the employer has previously monitored for lead exposures, and the data were obtained within the past 12 months during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraphs (d)(3)(i) and (d)(6) of this section if the sampling and analytical methods meet the accuracy and confidence levels of paragraph (d)(10) of this section.

(iv) Where the employer has objective data, demonstrating that a particular product or material containing lead or a specific process, operation or activity involving lead cannot result in employee exposure to lead at or above the action level during processing, use, or handling, the employer may rely upon such data instead of implementing initial monitoring.

(A) The employer shall establish and maintain an accurate record documenting the nature and relevancy of objective data as specified in paragraph (n)(4) of this section, where used in assessing employee exposure in lieu of exposure monitoring.

(B) Objective data, as described in paragraph (d)(3)(iv) of this section, is not permitted to be used for exposure assessment in connection with paragraph (d)(2) of this section.

(4) *Positive initial determination and initial monitoring.*

(i) Where a determination conducted under paragraphs (d) (1), (2) and (3) of this section shows the possibility of any employee exposure at or above the action level the employer shall conduct monitoring which is representative of the exposure for each employee in the workplace who is exposed to lead.

(ii) Where the employer has previously monitored for lead exposure, and the data were obtained within the past 12 months during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(4)(i) of this section if the sampling and analytical methods meet the accuracy and confidence levels of paragraph (d)(10) of this section.

(5) *Negative initial determination.* Where a determination, conducted under paragraphs (d) (1), (2), and (3) of this section is made that no employee is exposed to airborne concentrations of lead at or above the action level the employer shall make a written record of such determination. The record shall include at least the information specified in paragraph (d)(3)(i) of this section and shall also include the date of determination, location within the worksite, and the name and social security number of each employee monitored.

(6) *Frequency.* (i) If the initial determination reveals employee exposure to be below the action level further exposure determination need not be repeated except as otherwise provided in paragraph (d)(7) of this section.

(ii) If the initial determination or subsequent determination reveals employee exposure to be at or above the action level but at or below the PEL the employer shall perform monitoring in accordance with this paragraph at least every 6 months. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee except as otherwise provided in paragraph (d)(7) of this section.

(iii) If the initial determination reveals that employee exposure is above the PEL the employer shall perform

monitoring quarterly. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are at or below the PEL but at or above the action level at which time the employer shall repeat monitoring for that employee at the frequency specified in paragraph (d)(6)(ii) of this section, except as otherwise provided in paragraph (d)(7) of this section. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee except as otherwise provided in paragraph (d)(7) of this section.

(7) *Additional exposure assessments.* Whenever there has been a change of equipment, process, control, personnel or a new task has been initiated that may result in additional employees being exposed to lead at or above the action level or may result in employees already exposed at or above the action level being exposed above the PEL, the employer shall conduct additional monitoring in accordance with this paragraph.

(8) *Employee notification.* (i) Within 5 working days after completion of the exposure assessment the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure, without regard to respirators, is at or above the PEL the employer shall include in the written notice a statement that the employees exposure was at or above that level and a description of the corrective action taken or to be taken to reduce exposure to below that level.

(9) *Accuracy of measurement.* The employer shall use a method of monitoring and analysis which has an accuracy (to a confidence level of 95%) of not less than plus or minus 25 percent for airborne concentrations of lead equal to or greater than 30$\mu g/m^3$.

(e) *Methods of compliance* (1) *Engineering and work practice controls.* The employer shall implement engineering and work practice controls, including administrative controls, to reduce and maintain employee exposure to lead to or below the permissible exposure limit to the extent that such controls are feasible. Wherever all feasible engineering and work practices controls that can be instituted are not sufficient to reduce employee exposure to or below the permissible exposure limit prescribed in paragraph (c) of this section, the employer shall nonetheless use them to reduce employee exposure to the lowest feasible level and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (f) of this section.

(2) *Compliance program.* (i) Prior to commencement of the job each employer shall establish and implement a written compliance program to achieve compliance with paragraph (c) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each activity in which lead is emitted; e.g. equipment used, material involved, controls in place, crew size, employee job responsibilities, operating procedures and maintenance practices;

(B) A description of the specific means that will be employed to achieve compliance and, where engineering controls are required engineering plans and studies used to determine methods selected for controlling exposure to lead;

(C) A report of the technology considered in meeting the PEL;

(D) Air monitoring data which documents the source of lead emissions;

(E) A detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.;

(F) A work practice program which includes items required under paragraphs (g), (h) and (i) of this section and incorporates other relevant work practices such as those specified in paragraph (e)(5) of this section;

(G) An administrative control schedule required by paragraph (e)(4) of this section, if applicable;

(H) A description of arrangements made among contractors on multi-contractor sites with respect to informing affected employees of potential exposure to lead and with respect to responsibility for compliance with this section as set-forth in § 1926.16.

(I) Other relevant information.

(iii) The compliance program shall provide for frequent and regular inspections of job sites, materials, and equipment to be made by a competent person.

(iv) Written programs shall be submitted upon request to any affected employee or authorized employee representatives, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary and the Director.

(v) Written programs shall be revised and updated at least every 6 months to reflect the current status of the program.

(3) *Mechanical ventilation.* When ventilation is used to control lead exposure, the employer shall evaluate the mechanical performance of the system in controlling exposure as necessary to maintain its effectiveness.

(4) *Administrative controls.* If administrative controls are used as a means of reducing employees TWA exposure to lead, the employer shall establish and implement a job rotation schedule which includes:

(i) Name or identification number of each affected employee;

(ii) Duration and exposure levels at each job or work station where each affected employee is located; and

(iii) Any other information which may be useful in assessing the reliability of administrative controls to reduce exposure to lead.

(5) The employer shall ensure that, to the extent relevant, employees follow good work practices such as described in Appendix B of this section.

(f) *Respiratory protection*—(1) *General.* Where the use of respirators is required under this section the employer shall provide, at no cost to the employee, and assure the use of respirators which comply with the requirements of this paragraph. Respirators shall be used in the following circumstances:

(i) Whenever an employee's exposure to lead exceeds the PEL;

(ii) In work situations in which engineering controls and work practices are not sufficient to reduce exposures to or below the PEL;

(iii) Whenever an employee requests a respirator; and

(iv) An interim protection for employees performing tasks as specified in paragraph (d)(2) of this section.

(2) *Respirator selection.* (i) Where respirators are used under this section the employer shall select the appropriate respirator or combination of respirators from Table I below.

(ii) The employer shall provide a powered, air-purifying respirator in lieu of the respirator specified in Table I whenever:

(A) An employee chooses to use this type of respirator; and (B) This respirator will provide adequate protection to the employee.

(iii) The employer shall select respirators from among those approved for protection against lead dust, fume, and mist by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11.

TABLE I.—RESPIRATORY PROTECTION FOR LEAD AEROSOLS

Airborne concentration of lead or condition of use	Required respirator [1]
Not in excess of 500 μg/m³.	• ½ mask air purifying respirator with high efficiency filters.[2, 3] • ½ mask supplied air respirator operated in demand (negative pressure) mode.
Not in excess of 1,250 μg/m³.	• Loose fitting hood or helmet powered air purifying respirator with high efficiency filters.[3] • Hood or helmet supplied air respirator operated in a continuous-flow mode—e.g., type CE abrasive blasting respirators operated in a continuous-flow mode.
Not in excess of 2,500 μg/m³.	• Full facepiece air purifying respirator with high efficiency filters.[3] • Tight fitting powered air purifying respirator with high efficiency filters.[3] • Full facepiece supplied air respirator operated in demand mode. • ½ mask or full facepiece supplied air respirator operated in a continuous-flow mode. • Full facepiece self-contained breathing apparatus (SCBA) operated in demand mode.
Not in excess of 50,000 μg/m³.	• ½ mask supplied air respirator operated in pressure demand or other positive-pressure mode.
Not in excess of 100,000 μg/m³.	• Full facepiece supplied air respirator operated in pressure demand or other positive-pressure mode—e.g., type CE abrasive blasting respirators operated in a positive-pressure mode.
Greater than 100,000 μg/m³ unknown concentration, or fire fighting.	• Full facepiece SCBA operated in pressure demand or other positive-pressure mode.

[1] Respirators specified for higher concentrations can be used at lower concentrations of lead.
[2] Full facepiece is required if the lead aerosols cause eye or skin irritation at the use concentrations.
[3] A high efficiency particulate filter (HEPA) means a filter that is 99.97 percent efficient against particles of 0.3 micron size or larger.

(3) *Respirator usage.* (i) The employer shall assure that the respirator issued to the employee exhibits minimum facepiece leakage and that the respirator is fitted properly.

(ii) Employers shall perform either quantitative or qualitative face fit tests at the time of initial fitting and at least every six months thereafter for each employee wearing negative pressure respirators. The qualitative fit tests may be used only for testing the fit of half-mask respirators where they are permitted to be worn, and shall be conducted in accordance with appendix D of this section. The tests shall be used to select facepieces that provide the required protection as prescribed in Table I.

(iii) If an employee exhibits difficulty in breathing during the fitting test or during use, the employer shall make available to the employee an examination in accordance with paragraph (j)(3)(i)(B) of this section to determine whether the employee can wear a respirator while performing the required duty.

(4) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e) and (f).

(ii) The employer shall permit each employee who uses a filter respirator to change the filter elements whenever an increase in breathing resistance is detected and shall maintain an adequate supply of filter elements for this purpose.

(iii) Employees who wear respirators shall be permitted to leave work areas to wash their face and respirator facepiece whenever necessary to prevent skin irritation associated with respirator use.

(g) *Protective work clothing and equipment*—(1) *Provision and use.* Where an employee is exposed to lead above the PEL without regard to the use of respirators, where employees are exposed to lead compounds which may cause skin or eye irritation (e.g. lead arsenate, lead azide), and as interim protection for employees performing tasks as specified in paragraph (d)(2) of this section, the employer shall provide at no cost to the employee and assure that the employee uses appropriate protective work clothing and equipment that prevents contamination of the employee and the employee's garments such as, but not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, hats, and shoes or disposable shoe coverlets; and

(iii) Face shields, vented goggles, or other appropriate protective equipment which complies with § 1910.133 of this chapter.

(2) *Cleaning and replacement.* (i) The employer shall provide the protective clothing required in paragraph (g)(1) of this section in a clean and dry condition at least weekly, and daily to employees whose exposure levels without regard to a respirator are over 200 μg/m³ of lead as an 8-hour TWA.

(ii) The employer shall provide for the cleaning, laundering, and disposal of protective clothing and equipment required by paragraph (g)(1) of this section.

(iii) The employer shall repair or replace required protective clothing and equipment as needed to maintain their effectiveness.

(iv) The employer shall assure that all protective clothing is removed at the completion of a work shift only in change areas provided for that purpose as prescribed in paragraph (i)(2) of this section.

(v) The employer shall assure that contaminated protective clothing which is to be cleaned, laundered, or disposed of, is placed in a closed container in the change area which prevents dispersion of lead outside the container.

(vi) The employer shall inform in writing any person who cleans or launders protective clothing or equipment of the potentially harmful effects of exposure to lead.

(vii) The employer shall assure that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) of this section are labelled as follows:

Caution: Clothing contaminated with lead. Do not remove dust by blowing or shaking. Dispose of lead contaminated wash water in accordance with applicable local, state, or federal regulations.

(viii) The employer shall prohibit the removal of lead from protective clothing or equipment by blowing, shaking, or

any other means which disperses lead into the air.

(h) *Housekeeping*—(1) All surfaces shall be maintained as free as practicable of accumulations of lead.

(2) Clean-up of floors and other surfaces where lead accumulates shall wherever possible, be cleaned by vacuuming or other methods that minimize the likelihood of lead becoming airborne.

(3) Shoveling, dry or wet sweeping, and brushing may be used only where vacuuming or other equally effective methods have been tried and found not to be effective.

(4) Where vacuuming methods are selected, the vacuums shall be equipped with HEPA filters and used and emptied in a manner which minimizes the reentry of lead into the workplace.

(5) Compressed air shall not be used to remove lead from any surface unless the compressed air is used in conjunction with a ventilation system designed to capture the airborne dust created by the compressed air.

(i) *Hygiene facilities and practices.* (1) The employer shall assure that in areas where employees are exposed to lead above the PEL without regard to the use of respirators, food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied.

(2) *Change areas.* (i) The employer shall provide clean change areas for employees whose airborne exposure to lead is above the PEL, and as interim protection for employees performing tasks as specified in paragraph (d)(2) of this section, without regard to the use of respirators.

(ii) The employer shall assure that change areas are equipped with separate storage facilities for protective work clothing and equipment and for street clothes which prevent cross-contamination.

(iii) The employer shall assure that employees do not leave the workplace wearing any protective clothing or equipment that is required to be worn during the work shift.

(3) *Showers.* (i) The employer shall provide shower facilities, where feasible, for use by employees whose airborne exposure to lead is above the PEL.

(ii) The employer shall assure, where shower facilities are available, that employees shower at the end of the work shift and shall provide an adequate supply of cleansing agents and towels for use by affected employees.

(4) *Eating facilities.* (i) The employer shall provide lunchroom facilities or eating areas for employees whose airborne exposure to lead is above the PEL, without regard to the use of respirators.

(ii) The employer shall assure that lunchroom facilities or eating areas are as free as practicable from lead contamination and are readily accessible to employees.

(iii) The employer shall assure that employees whose airborne exposure to lead is above the PEL, without regard to the use of a respirator, wash their hands and face prior to eating, drinking, smoking or applying cosmetics.

(iv) The employer shall assure that employees do not enter lunchroom facilities or eating areas with protective work clothing or equipment unless surface lead dust has been removed by vacuuming, downdraft booth, or other cleaning method that limits dispersion of lead dust.

(5) *Hand washing facilities.* (i) The employer shall provide adequate handwashing facilities for use by employees exposed to lead in accordance with 29 CFR 1926.51(f).

(ii) Where showers are not provided the employer shall assure that employees wash their hands and face at the end of the work-shift.

(j) *Medical surveillance*—(1) *General.* (i) The employer shall make available initial medical surveillance to employees occupationally exposed on any day to lead at or above the action level. Initial medical surveillance consists of biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels.

(ii) The employer shall institute a medical surveillance program in accordance with paragraphs (j)(2) and (j)(3) of this section for all employees who are or may be exposed by the employer at or above the action level for more than 30 days in any consecutive 12 months;

(iii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician.

(iv) The employer shall make available the required medical surveillance including multiple physician review under paragraph (j)(3)(iii) without cost to employees and at a reasonable time and place.

(2) *Biological monitoring*—(i) *Blood lead and ZPP level sampling and analysis.* The employer shall make available biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels to each employee covered under paragraphs (j)(1)(i) and (ii) of this section on the following schedule:

(A) For each employee covered under paragraph (j)(1)(ii) of this section, at least every 2 months for the first 6 months and every 6 months thereafter;

(B) For each employee covered under paragraphs (j)(1) (i) or (ii) of this section whose last blood sampling and analysis indicated a blood lead level at or above 40 μg/dl, at least every two months. This frequency shall continue until two consecutive blood samples and analyses indicate a blood lead level below 40 μg/dl; and

(C) For each employee who is removed from exposure to lead due to an elevated blood lead level at least monthly during the removal period.

(ii) *Follow-up blood sampling tests.* Whenever the results of a blood lead level test indicate that an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i) of this section, the employer shall provide a second (follow-up) blood sampling test within two weeks after the employer receives the results of the first blood sampling test.

(iii) *Accuracy of blood lead level sampling and analysis.* Blood lead level sampling and analysis provided pursuant to this section shall have an accuracy (to a confidence level of 95 percent) within plus or minus 15 percent or 6 μg/dl, whichever is greater, and shall be conducted by a laboratory approved by OSHA.

(iv) *Employee notification.* (A) Within five working days after the receipt of biological monitoring results, the employer shall notify each employee in writing of his or her blood lead level; and

(B) the employer shall notify each employee whose blood lead level exceeds 40 μg/dl that the standard requires temporary medical removal with Medical Removal Protection benefits when an employee's blood lead level exceeds the numerical criterion for medical removal under paragraph (k)(1)(i) of this section.

(3) *Medical examinations and consultations*—(i) *Frequency.* The employer shall make available medical examinations and consultations to each employee covered under paragraph (j)(1)(ii) of this section on the following schedule:

(A) At least annually for each employee for whom a blood sampling test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 μg/dl;

(B) As soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to

lead on the employee's ability to procreate a healthy child, that the employee is pregnant, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during use; and

(C) As medically appropriate for each employee either removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited pursuant to a final medical determination.

(ii) *Content.* The content of medical examinations made available pursuant to paragraph (j)(3)(i)(B)–(C) of this section shall be determined by an examining physician and, if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility. Medical examinations made available pursuant to paragraph (j)(3)(i)(A) of this section shall include the following elements:

(A) A detailed work history and a medical history, with particular attention to past lead exposure (occupational and non-occupational), personal habits (smoking, hygiene), and past gastrointestinal, hematologic, renal, cardiovascular, reproductive and neurological problems;

(B) A thorough physical examination, with particular attention to teeth, gums, hematologic, gastrointestinal, renal, cardiovascular, and neurological systems. Pulmonary status should be evaluated if respiratory protection will be used;

(C) A blood pressure measurement;

(D) A blood sample and analysis which determines:

(*1*) Blood lead level;

(*2*) Hemoglobin and hematocrit determinations, red cell indices, and examination of peripheral smear morphology;

(*3*) Zinc protoporphyrin;

(*4*) Blood urea nitrogen; and,

(*5*) Serum creatinine;

(E) A routine urinalysis with microscopic examination; and

(F) Any laboratory or other test relevant to lead exposure which the examining physician deems necessary by sound medical practice.

(iii) *Multiple physician review mechanism.* (A) If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, the employee may designate a second physician:

(*1*) To review any findings, determinations or recommendations of the initial physician; and

(*2*) To conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

(B) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the foregoing notification, or receipt of the initial physician's written opinion, whichever is later:

(*1*) The employee informing the employer that he or she intends to seek a second medical opinion, and

(*2*) The employee initiating steps to make an appointment with a second physician.

(C) If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(D) If the two physicians have been unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician:

(*1*) To review any findings, determinations or recommendations of the prior physicians; and

(*2*) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(E) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(iv) *Information provided to examining and consulting physicians.* (A) The employer shall provide an initial physician conducting a medical examination or consultation under this section with the following information:

(*1*) A copy of this regulation for lead including all Appendices;

(*2*) A description of the affected employee's duties as they relate to the employee's exposure;

(*3*) The employee's exposure level or anticipated exposure level to lead and to any other toxic substance (if applicable);

(*4*) A description of any personal protective equipment used or to be used;

(*5*) Prior blood lead determinations; and

(*6*) All prior written medical opinions concerning the employee in the employer's possession or control.

(B) The employer shall provide the foregoing information to a second or third physician conducting a medical examination or consultation under this section upon request either by the second or third physician, or by the employee.

(v) *Written medical opinions.* (A) The employer shall obtain and furnish the employee with a copy of a written medical opinion from each examining or consulting physician which contains only the following information:

(*1*) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to lead;

(*2*) Any recommended special protective measures to be provided to the employee, or limitations to be placed upon the employee's exposure to lead;

(*3*) Any recommended limitation upon the employee's use of respirators, including a determination of whether the employee can wear a powered air purifying respirator if a physician determines that the employee cannot wear a negative pressure respirator; and

(*4*) The results of the blood lead determinations.

(B) The employer shall instruct each examining and consulting physician to:

(*1*) Not reveal either in the written opinion or orally, or in any other means of communication with the employer, findings, including laboratory results, or diagnoses unrelated to an employee's occupational exposure to lead; and

(*2*) Advise the employee of any medical condition, occupational or nonoccupational, which dictates further medical examination or treatment.

(vi) *Alternate physician determination mechanisms.* The employer and an employee or authorized employee representative may agree upon the use of any alternate physician determination mechanism in lieu of the multiple physician review mechanism provided by paragraph (j)(3)(iii) of this section so long as the alternate mechanism is as expeditious and protective as the requirements contained in this paragraph.

(4) *Chelation.* (i) The employer shall assure that any person whom he retains, employs, supervises or controls does not engage in prophylactic chelation of any employee at any time.

(ii) If therapeutic or diagnostic chelation is to be performed by any person in paragraph (j)(4)(i) of this section, the employer shall assure that

it be done under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring and that the employee is notified in writing prior to its occurrence.

(k) *Medical removal protection*—(1) *Temporary medical removal and return of an employee*—(i) *Temporary removal due to elevated blood lead level.* The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 50 μg/dl; and,

(ii) *Temporary removal due to a final medical determination.* (A) The employer shall remove an employee from work having an exposure to lead at or above the action level on each occasion that a final medical determination results in a medical finding, determination, or opinion that the employee has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

(B) For the purposes of this section, the phrase "final medical determination" means the written medical opinion on the employees' health status by the examining physician or, where relevant, the outcome of the multiple physician review mechanism or alternate medical determination mechanism used pursuant to the medical surveillance provisions of this section.

(C) Where a final medical determination results in any recommended special protective measures for an employee, or limitations on an employee's exposure to lead, the employer shall implement and act consistent with the recommendation.

(iii) *Return of the employee to former job status.* (A) The employer shall return an employee to his or her former job status:

(*1*) For an employee removed due to a blood lead level at or above 50 μg/dl when two consecutive blood sampling tests indicate that the employee's blood lead level is at or below 40 μg/dl;

(*2*) For an employee removed due to a final medical determination, when a subsequent final medical determination results in a medical finding, determination, or opinion that the employee no longer has a detected medical condition which places the employee at increased risk of material impairment to health from exposure to lead.

(B) For the purposes of this section, the requirement that an employer return an employee to his or her former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(iv) *Removal of other employee special protective measure or limitations.* The employer shall remove any limitations placed on an employee or end any special protective measures provided to an employee pursuant to a final medical determination when a subsequent final medical determination indicates that the limitations or special protective measures are no longer necessary.

(v) *Employer options pending a final medical determination.* Where the multiple physician review mechanism, or alternate medical determination mechanism used pursuant to the medical surveillance provisions of this section, has not yet resulted in a final medical determination with respect to an employee, the employer shall act as follows:

(A) *Removal.* The employer may remove the employee from exposure to lead, provide special protective measures to the employee, or place limitations upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status.

(B) *Return.* The employer may return the employee to his or her former job status, end any special protective measures provided to the employee, and remove any limitations placed upon the employee, consistent with the medical findings, determinations, or recommendations of any of the physicians who have reviewed the employee's health status, with two exceptions.

If (*1*) the initial removal, special protection, or limitation of the employee resulted from a final medical determination which differed from the findings, determinations, or recommendations of the initial physician or;

(*2*) If the employee has been on removal status for the preceding eighteen months due to an elevated blood lead level, then the employer shall await a final medical determination.

(2) *Medical removal protection benefits*—(i) *Provision of medical removal protection benefits.* The employer shall provide an employee up to eighteen (18) months of medical removal protection benefits on each occasion that an employee is removed from exposure to lead or otherwise limited pursuant to this section.

(ii) *Definition of medical removal protection benefits.* For the purposes of this section, the requirement that an employer provide medical removal protection benefits means that, as long as the job the employee was removed from continues, the employer shall maintain the total normal earnings, seniority and other employment rights and benefits of an employee, including the employee's right to his or her former job status as though the employee had not been medically removed from the employee's job or otherwise medically limited.

(iii) *Follow-up medical surveillance during the period of employee removal or limitation.* During the period of time that an employee is medically removed from his or her job or otherwise medically limited, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(iv) *Workers' compensation claims.* If a removed employee files a claim for workers' compensation payments for a lead-related disability, then the employer shall continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation shall be reduced by such amount. The employer shall receive no credit for workers' compensation payments received by the employee for treatment-related expenses.

(v) *Other credits.* The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer made possible by virtue of the employee's removal.

(vi) *Voluntary removal or restriction of an employee.* Where an employer, although not required by this section to do so, removes an employee from exposure to lead or otherwise places limitations on an employee due to the effects of lead exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee

equal to that required by paragraph (k)(2) (i) and (ii) of this section.

(l) *Employee information and training*—(1) *General* (i) The employer shall communicate information concerning lead hazards according to the requirements of OSHA's Hazard Communication Standard for the construction industry, 29 CFR 1926.59, including but not limited to the requirements concerning warning signs and labels, material safety data sheets (MSDS), and employee information and training. In addition, employers shall comply with the following requirements:

(ii) For all employees who are subject to exposure to lead at or above the action level on any day or who are subject to exposure to lead compounds which may cause skin or eye irritation (e.g. lead arsenate, lead azide), the employer shall provide a training program in accordance with paragraph (l)(2) of this section and assure employee participation.

(iii) The employer shall provide the training program as initial training prior to the time of job assignment or prior to the start up date for this requirement, whichever comes last.

(iv) The employer shall also provide the training program at least annually for each employee who is subject to lead exposure at or above the action level on any day.

(2) *Training program.* The employer shall assure that each employee is trained in the following:

(i) The content of this standard and its appendices;

(ii) The specific nature of the operations which could result in exposure to lead above the action level;

(iii) The purpose, proper selection, fitting, use, and limitations of respirators;

(iv) The purpose and a description of the medical surveillance program, and the medical removal protection program including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females and hazards to the fetus and additional precautions for employees who are pregnant);

(v) The engineering controls and work practices associated with the employee's job assignment including training of employees to follow relevant good work practices described in Appendix B of this section;

(vi) The contents of any compliance plan in effect;

(vii) Instructions to employees that chelating agents should not routinely be used to remove lead from their bodies and should not be used at all except under the direction of a licensed physician; and

(viii) The employee's right of access to records under 29 CFR 1910.20.

(3) *Access to information and training materials.* (i) The employer shall make readily available to all affected employees a copy of this standard and its appendices.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to affected employees and their designated representatives, and to the Assistant Secretary and the Director.

(m) *Signs*—(1) *General.* (i) The employer may use signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign required by this paragraph which contradicts or detracts from the meaning of the required sign.

(2) *Signs.* (i) The employer shall post the following warning signs in each work area where an employees exposure to lead is above the PEL.

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(n) *Recordkeeping*—(1) *Exposure assessment.* (i) The employer shall establish and maintain an accurate record of all monitoring and other data used in conducting employee exposure assessments as required in paragraph (d) of this section.

(ii) Exposure monitoring records shall include:

(A) The date(s), number, duration, location and results of each of the samples taken if any, including a description of the sampling procedure used to determine representative employee exposure where applicable;

(B) A description of the sampling and analytical methods used and evidence of their accuracy;

(C) The type of respiratory protective devices worn, if any;

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent; and

(E) The environmental variables that could affect the measurement of employee exposure.

(iii) The employer shall maintain monitoring and other exposure assessment records in accordance with the provisions of 29 CFR 1910.20.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (j) of this section.

(ii) This record shall include:

(A) The name, social security number, and description of the duties of the employee;

(B) A copy of the physician's written opinions;

(C) Results of any airborne exposure monitoring done on or for that employee and provided to the physician; and

(D) Any employee medical complaints related to exposure to lead.

(iii) The employer shall keep, or assure that the examining physician keeps, the following medical records:

(A) A copy of the medical examination results including medical and work history required under paragraph (j) of this section;

(B) A description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to that information;

(C) A copy of the results of biological monitoring.

(iv) The employer shall maintain or assure that the physician maintains medical records in accordance with the provisions of 29 CFR 1910.20.

(3) *Medical removals.* (i) The employer shall establish and maintain an accurate record for each employee removed from current exposure to lead pursuant to paragraph (k) of this section.

(ii) Each record shall include:

(A) The name and social security number of the employee;

(B) The date of each occasion that the employee was removed from current exposure to lead as well as the corresponding date on which the employee was returned to his or her former job status;

(C) A brief explanation of how each removal was or is being accomplished; and

(D) A statement with respect to each removal indicating whether or not the reason for the removal was an elevated blood lead level.

(iii) The employer shall maintain each medical removal record for at least the duration of an employee's employment.

(4) *Objective data for exemption from requirement for initial monitoring.* (i) For purposes of this section, objective data are information demonstrating that a particular product or material containing lead or a specific process, operation, or activity involving lead cannot release dust or fumes in concentrations at or above the action level under any expected conditions of

use. Objective data can be obtained from an industry-wide study or from laboratory product test results from manufacturers of lead containing products or materials. The data the employer uses from an industry-wide survey must be obtained under workplace conditions closely resembling the processes, types of material, control methods, work practices and environmental conditions in the employer's current operations.

(ii) The employer shall maintain the record of the objective data relied upon for at least 30 years.

(5) *Availability.* The employer shall make available upon request all records required to be maintained by paragraph (n) of this section to affected employees, former employees, and their designated representatives, and to the Assistant Secretary and the Director for examination and copying.

(6) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (n) of this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records required to be maintained by this section for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained by this section, the employer shall notify the Director at least 3 months prior to the disposal of such records and shall transmit those records to the Director if requested within the period.

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(o) *Observation of monitoring.* (1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to lead conducted pursuant to paragraph (d) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to lead requires entry into an area where the use of respirators, protective clothing or equipment is required, the employer shall provide the observer with and assure the use of such respirators, clothing and equipment, and shall require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the monitoring of lead performed at the place of exposure; and

(C) Record the results obtained or receive copies of the results when returned by the laboratory.

(p) *Effective date.* This standard (§ 1926.62) shall become effective June 3, 1993.

(q) *Appendices.* The information contained in the appendices to this section is not intended by itself, to create any additional obligations not otherwise imposed by this standard nor detract from any existing obligation.

(r) *Startup dates.* (1) The requirements of paragraphs (c) through (o) of this section, including administrative controls and feasible work practice controls, but not including engineering controls specified in paragraph (e)(1) of this section, shall be complied with as soon as possible, but no later than 60 days from the effective date of this section.

(2) Feasible engineering controls specified by paragraph (e)(1) of this section shall be implemented as soon as possible, but no later than 120 days from the effective date of this section.

Appendix A to § 1926.62—Substance Data Sheet for Occupational Exposure to Lead

I. Substance Identification

A. *Substance*: Pure lead (Pb) is a heavy metal at room temperature and pressure and is a basic chemical element. It can combine with various other substances to form numerous lead compounds.

B. *Compounds covered by the standard*: The word "lead" when used in this interim final standard means elemental lead, all inorganic lead compounds and a class of organic lead compounds called lead soaps. This standard does not apply to other organic lead compounds.

C. *Uses*: Exposure to lead occurs in several different occupations in the construction industry, including demolition or salvage of structures where lead or lead-containing materials are present; removal or encapsulation of lead-containing materials, new construction, alteration, repair, or renovation of structures that contain lead or materials containing lead; installation of products containing lead. In addition, there are construction related activities where exposure to lead may occur, including transportation, disposal, storage, or containment of lead or materials containing lead on construction sites, and maintenance operations associated with construction activities.

D. *Permissible exposure*: The permissible exposure limit (PEL) set by the standard is 50 micrograms of lead per cubic meter of air (50 $\mu g/m^3$), averaged over an 8-hour workday.

E. *Action level*: The interim final standard establishes an action level of 30 micrograms of lead per cubic meter of air (30 $\mu g/m^3$), averaged over an 8-hour workday. The action level triggers several ancillary provisions of the standard such as exposure monitoring, medical surveillance, and training.

II. Health Hazard Data

A. *Ways in which lead enters your body.* When absorbed into your body in certain doses, lead is a toxic substance. The object of the lead standard is to prevent absorption of harmful quantities of lead. The standard is intended to protect you not only from the immediate toxic effects of lead, but also from the serious toxic effects that may not become apparent until years of exposure have passed. Lead can be absorbed into your body by inhalation (breathing) and ingestion (eating). Lead (except for certain organic lead compounds not covered by the standard, such as tetraethyl lead) is not absorbed through your skin. When lead is scattered in the air as a dust, fume respiratory tract. Inhalation of airborne lead is generally the most important source of occupational lead absorption. You can also absorb lead through your digestive system if lead gets into your mouth and is swallowed. If you handle food, cigarettes, chewing tobacco, or make-up which have lead on them or handle them with hands contaminated with lead, this will contribute to ingestion. A significant portion of the lead that you inhale or ingest gets into your blood stream. Once in your blood stream, lead is circulated throughout your body and stored in various organs and body tissues. Some of this lead is quickly filtered out of your body and excreted, but some remains in the blood and other tissues. As exposure to lead continues, the amount stored in your body will increase if you are absorbing more lead than your body is excreting. Even though you may not be aware of any immediate symptoms of disease, this lead stored in your tissues can be slowly causing irreversible damage, first to individual cells, then to your organs and whole body systems.

B. *Effects of overexposure to lead*—(1) *Short term (acute) overexposure.* Lead is a potent, systemic poison that serves no known useful function once absorbed by your body. Taken in large enough doses, lead can kill you in a matter of days. A condition affecting the brain called acute encephalopathy may arise which develops quickly to seizures, coma, and death from cardiorespiratory arrest. A short term dose of lead can lead to acute encephalopathy. Short term occupational exposures of this magnitude are highly unusual, but not impossible. Similar forms of encephalopathy may, however, arise from extended, chronic exposure to lower doses of lead. There is no sharp dividing line between rapidly developing acute effects of lead, and chronic effects which take longer to acquire. Lead adversely affects numerous body systems, and causes forms of health impairment and disease which arise after periods of exposure as short as days or as long as several years.

(2) *Long-term (chronic) overexposure.* Chronic overexposure to lead may result in severe damage to your blood-forming,

nervous, urinary and reproductive systems. Some common symptoms of chronic overexposure include loss of appetite, metallic taste in the mouth, anxiety, constipation, nausea, pallor, excessive tiredness, weakness, insomnia, headache, nervous irritability, muscle and joint pain or soreness, fine tremors, numbness, dizziness, hyperactivity and colic. In lead colic there may be severe abdominal pain. Damage to the central nervous system in general and the brain (encephalopathy) in particular is one of the most severe forms of lead poisoning. The most severe, often fatal, form of encephalopathy may be preceded by vomiting, a feeling of dullness progressing to drowsiness and stupor, poor memory, restlessness, irritability, tremor, and convulsions. It may arise suddenly with the onset of seizures, followed by coma, and death. There is a tendency for muscular weakness to develop at the same time. This weakness may progress to paralysis often observed as a characteristic "wrist drop" or "foot drop" and is a manifestation of a disease to the nervous system called peripheral neuropathy. Chronic overexposure to lead also results in kidney disease with few, if any, symptoms appearing until extensive and most likely permanent kidney damage has occurred. Routine laboratory tests reveal the presence of this kidney disease only after about two-thirds of kidney function is lost. When overt symptoms of urinary dysfunction arise, it is often too late to correct or prevent worsening conditions, and progression to kidney dialysis or death is possible. Chronic overexposure to lead impairs the reproductive systems of both men and women. Overexposure to lead may result in decreased sex drive, impotence and sterility in men. Lead can alter the structure of sperm cells raising the risk of birth defects. There is evidence of miscarriage and stillbirth in women whose husbands were exposed to lead or who were exposed to lead themselves. Lead exposure also may result in decreased fertility, and abnormal menstrual cycles in women. The course of pregnancy may be adversely affected by exposure to lead since lead crosses the placental barrier and poses risks to developing fetuses. Children born of parents either one of whom were exposed to excess lead levels are more likely to have birth defects, mental retardation, behavioral disorders or die during the first year of childhood. Overexposure to lead also disrupts the blood-forming system resulting in decreased hemoglobin (the substance in the blood that carries oxygen to the cells) and ultimately anemia. Anemia is characterized by weakness, pallor and fatigability as a result of decreased oxygen carrying capacity in the blood.

(3) *Health protection goals of the standard.* Prevention of adverse health effects for most workers from exposure to lead throughout a working lifetime requires that a worker's blood lead level (BLL, also expressed as PbB) be maintained at or below forty micrograms per deciliter of whole blood (40 μg/dl). The blood lead levels of workers (both male and female workers) who intend to have children should be maintained below 30 μg/dl to minimize adverse reproductive health effects to the parents and to the developing fetus. The measurement of your blood lead level (BLL) is the most useful indicator of the amount of lead being absorbed by your body. Blood lead levels are most often reported in units of milligrams (mg) or micrograms (μg) of lead (1 mg=1000 μg) per 100 grams (100g), 100 milliliters (100 ml) or deciliter (dl) of blood. These three units are essentially the same. Sometime BLLs are expressed in the form of mg% or μg%. This is a shorthand notation for 100g, 100 ml, or dl. (References to BLL measurements in this standard are expressed in the form of μg/dl.)

BLL measurements show the amount of lead circulating in your blood stream, but do not give any information about the amount of lead stored in your various tissues. BLL measurements merely show current absorption of lead, not the effect that lead is having on your body or the effects that past lead exposure may have already caused. Past research into lead-related diseases, however, has focused heavily on associations between BLLs and various diseases. As a result, your BLL is an important indicator of the likelihood that you will gradually acquire a lead-related health impairment or disease.

Once your blood lead level climbs above 40 μg/dl, your risk of disease increases. There is a wide variability of individual response to lead, thus it is difficult to say that a particular BLL in a given person will cause a particular effect. Studies have associated fatal encephalopathy with BLLs as low as 150 μg/dl. Other studies have shown other forms of diseases in some workers with BLLs well below 80 μg/dl. Your BLL is a crucial indicator of the risks to your health, but one other factor is also extremely important. This factor is the length of time you have had elevated BLLs. The longer you have an elevated BLL, the greater the risk that large quantities of lead are being gradually stored in your organs and tissues (body burden). The greater your overall body burden, the greater the chances of substantial permanent damage. The best way to prevent all forms of lead-related impairments and diseases—both short term and long term—is to maintain your BLL below 40 μg/dl. The provisions of the standard are designed with this end in mind.

Your employer has prime responsibility to assure that the provisions of the standard are complied with both by the company and by individual workers. You, as a worker, however, also have a responsibility to assist your employer in complying with the standard. You can play a key role in protecting your own health by learning about the lead hazards and their control, learning what the standard requires, following the standard where it governs your own actions, and seeing that your employer complies with provisions governing his or her actions.

(4) *Reporting signs and symptoms of health problems.* You should immediately notify your employer if you develop signs or symptoms associated with lead poisoning or if you desire medical advice concerning the effects of current or past exposure to lead or your ability to have a healthy child. You should also notify your employer if you have difficulty breathing during a respirator fit test or while wearing a respirator. In each of these cases, your employer must make available to you appropriate medical examinations or consultations. These must be provided at no cost to you and at a reasonable time and place. The standard contains a procedure whereby you can obtain a second opinion by a physician of your choice if your employer selected the initial physician.

Appendix B to § 1926.62—Employee Standard Summary

This appendix summarizes key provisions of the interim final standard for lead in construction that you as a worker should become familiar with.

I. Permissible Exposure Limit (PEL)—Paragraph (C)

The standard sets a permissible exposure limit (PEL) of 50 micrograms of lead per cubic meter of air (50 μg/m³), averaged over an 8-hour workday which is referred to as a time-weighted average (TWA). This is the highest level of lead in air to which you may be permissibly exposed over an 8-hour workday. However, since this is an 8-hour average, short exposures above the PEL are permitted so long as for each 8-hour work day your average exposure does not exceed this level. This interim final standard, however, takes into account the fact that your daily exposure to lead can extend beyond a typical 8-hour workday as the result of overtime or other alterations in your work schedule. To deal with this situation, the standard contains a formula which reduces your permissible exposure when you are exposed more than 8 hours. For example, if you are exposed to lead for 10 hours a day, the maximum permitted average exposure would be 40 μg/m³.

II. Exposure Assessment—Paragraph (D)

If lead is present in your workplace in any quantity, your employer is required to make an initial determination of whether any employee's exposure to lead exceeds the action level (30 μg/m³ averaged over an 8-hour day). Employee exposure is that exposure which would occur if the employee were not using a respirator. This initial determination requires your employer to monitor workers' exposures unless he or she has objective data which can demonstrate conclusively that no employee will be exposed to lead in excess of the action level. Where objective data is used in lieu of actual monitoring the employer must establish and maintain an accurate record, documenting its relevancy in assessing exposure levels for current job conditions. If such objective data is available, the employer need proceed no further on employee exposure assessment until such time that conditions have changed and the determination is no longer valid.

Objective data may be compiled from various sources, e.g., insurance companies and trade associations and information from suppliers or exposure data collected from similar operations. Objective data may also comprise previously-collected sampling data including area monitoring. If it cannot be determined through using objective data that worker exposure is less than the action level, your employer must conduct monitoring or must rely on relevant previous personal sampling, if available. Where monitoring is

required for the initial determination, it may be limited to a representative number of employees who are reasonably expected to have the highest exposure levels. If your employer has conducted appropriate air sampling for lead in the past 12 months, he or she may use these results, provided they are applicable to the same employee tasks and exposure conditions and meet the requirements for accuracy as specified in the standard. As with objective data, if such results are relied upon for the initial determination, your employer must establish and maintain a record as to the relevancy of such data to current job conditions.

If there have been any employee complaints of symptoms which may be attributable to exposure to lead or if there is any other information or observations which would indicate employee exposure to lead, this must also be considered as part of the initial determination.

If this initial determination shows that a reasonable possibility exists that any employee may be exposed, without regard to respirators, over the action level, your employer must set up an air monitoring program to determine the exposure level representative of each employee exposed to lead at your workplace. In carrying out this air monitoring program, your employer is not required to monitor the exposure of every employee, but he or she must monitor a representative number of employees and job types. Enough sampling must be done to enable each employee's exposure level to be reasonably represent full shift exposure. In addition, these air samples must be taken under conditions which represent each employee's regular, daily exposure to lead. Sampling performed in the past 12 months may be used to determine exposures above the action level if such sampling was conducted during work activities essentially similar to present work conditions.

The standard lists certain tasks which may likely result in exposures to lead in excess of the PEL and, in some cases, exposures in excess of 50 times the PEL. If you are performing any of these tasks, your employer must provide you with appropriate respiratory protection, protective clothing and equipment, change areas, hand washing facilities, biological monitoring, and training until such time that an exposure assessment is conducted which demonstrates that your exposure level is below the PEL.

If you are exposed to lead and air sampling is performed; your employer is required to notify you in writing within 5 working days of the air monitoring results which represent your exposure. If the results indicate that your exposure exceeds the PEL (without regard to your use of a respirator), then your employer must also notify you of this in writing, and provide you with a description of the corrective action that has been taken or will be taken to reduce your exposure.

Your exposure must be rechecked by monitoring, at least every six months if your exposure is at or over the action level but below the PEL. Your employer may discontinue monitoring for you if 2 consecutive measurements, taken at least 7 days apart, are at or below the action level. Air monitoring must be repeated every 3 months if you are exposed over the PEL. Your employer must continue monitoring for you at this frequency until 2 consecutive measurements, taken at least 7 days apart, are below the PEL but above the action level, at which time your employer must repeat monitoring of your exposure every six months and may discontinue monitoring only after your exposure drops to or below the action level. However, whenever there is a change of equipment, process, control, or personnel or a new type of job is added at your workplace which may result in new or additional exposure to lead, your employer must perform additional monitoring.

III. Methods of Compliance—Paragraph (E)

Your employer is required to assure that no employee is exposed to lead in excess of the PEL as an 8-hour TWA. The interim final standard for lead in construction requires employers to institute engineering and work practice controls including administrative controls to the extent feasible to reduce employee exposure to lead. Where such controls are feasible but not adequate to reduce exposures below the PEL they must be used nonetheless to reduce exposures to the lowest level that can be accomplished by these means and then supplemented with appropriate respiratory protection.

Your employer is required to develop and implement a written compliance program prior to the commencement of any job where employee exposures may reach the PEL as an 8-hour TWA. The interim final standard identifies the various elements that must be included in the plan. For example, employers are required to include a description of operations in which lead is emitted, detailing other relevant information about the operation such as the type of equipment used, the type of material involved, employee job responsibilities, operating procedures and maintenance practices. In addition, your employer's compliance plan must specify the means that will be used to achieve compliance and, where engineering controls are required, include any engineering plans or studies that have been used to select the control methods. If administrative controls involving job rotation are used to reduce employee exposure to lead, the job rotation schedule must be included in the compliance plan. The plan must also detail the type of protective clothing and equipment, including respirators, housekeeping and hygiene practices that will be used to protect you from the adverse effects of exposure to lead.

The written compliance program must be made available, upon request, to affected employees and their designated representatives, the Assistant Secretary and the Director.

Finally, the plan must be reviewed and updated at least every 6 months to assure it reflects the current status in exposure control.

IV. Respiratory Protection—Paragraph (F)

Your employer is required to provide and assure your use of respirators when your exposure to lead is not controlled below the PEL by other means. The employer must pay the cost of the respirator. Whenever you request one, your employer is also required to provide you a respirator even if your air exposure level is not above the PEL. You might desire a respirator when, for example, you have received medical advice that your lead absorption should be decreased. Or, you may intend to have children in the near future, and want to reduce the level of lead in your body to minimize adverse reproductive effects. While respirators are the least satisfactory means of controlling your exposure, they are capable of providing significant protection if properly chosen, fitted, worn, cleaned, maintained, and replaced when they stop providing adequate protection.

Your employer is required to select respirators from the types listed in Table I of the Respiratory Protection section of the standard. Any respirator chosen must be approved by the Mine Safety and Health Administration (MSHA) or the National Institute for Occupational Safety and Health (NIOSH). This respirator selection table will enable your employer to choose a type of respirator which will give you a proper amount of protection based on your airborne lead exposure. Your employer may select a type of respirator that provides greater protection than that required by the standard; that is, one recommended for a higher concentration of lead than is present in your workplace. For example, a powered air purifying respirator (PAPR) is much more protective than a typical negative pressure respirator, and may also be more comfortable to wear. A PAPR has a filter, cartridge or canister to clean the air, and a power source which continuously blows filtered air into your breathing zone. Your employer might make a PAPR available to you to ease the burden of having to wear a respirator for long periods of time. The standard provides that you can obtain a PAPR upon request.

Your employer must also start a Respiratory Protection Program. This program must include written procedures for the proper selection, use, cleaning, storage, and maintenance of respirators.

Your employer must assure that your respirator facepiece fits properly. Proper fit of a respirator facepiece is critical. Obtaining a proper fit on each employee may require your employer to make available two or three different mask types. In order to assure that your respirator fits properly and that facepiece leakage is minimized, your employer must give you either a qualitative fit test or a quantitative fit test (if you use a negative pressure respirator) in accordance with appendix D. Any respirator which has a filter, cartridge or canister which cleans the work room air before you breathe it and which requires the force of your inhalation to draw air through the filtering element is a negative pressure respirator. A positive pressure respirator supplies air to you directly. A quantitative fit test uses a sophisticated machine to measure the amount, if any, of test material that leaks into the facepiece of your respirator.

You must also receive from your employer proper training in the use of respirators. Your employer is required to teach you how to wear a respirator, to know why it is needed, and to understand its limitations.

Your employer must test the effectiveness of your negative pressure respirator initially

and at least every six months thereafter with a "qualitative fit test." In this test, the fit of the facepiece is checked by seeing if you can smell a substance placed outside the respirator. If you can, there is appreciable leakage where the facepiece meets your face.

The standard provides that if your respirator uses filter elements, you must be given an opportunity to change the filter elements whenever an increase in breathing resistance is detected. You also must be permitted to periodically leave your work area to wash your face and respirator facepiece whenever necessary to prevent skin irritation. If you ever have difficulty in breathing during a fit test or while using a respirator, your employer must make a medical examination available to you to determine whether you can safely wear a respirator. The result of this examination may be to give you a positive pressure respirator (which reduces breathing resistance) or to provide alternative means of protection.

V. Protective Work Clothing and Equipment—Paragraph (G)

If you are exposed to lead above the PEL as an 8-hour TWA, without regard to your use of a respirator, or if you are exposed to lead compounds such as lead arsenate or lead azide which can cause skin and eye irritation, your employer must provide you with protective work clothing and equipment appropriate for the hazard. If work clothing is provided, it must be provided in a clean and dry condition at least weekly, and daily if your airborne exposure to lead is greater than 200 $\mu g/m^3$. Appropriate protective work clothing and equipment can include coveralls or similar full-body work clothing, gloves, hats, shoes or disposable shoe coverlets, and face shields or vented goggles. Your employer is required to provide all such equipment at no cost to you. In addition, your employer is responsible for providing repairs and replacement as necessary, and also is responsible for the cleaning, laundering or disposal of protective clothing and equipment.

The interim final standard requires that your employer assure that you follow good work practices when you are working in areas where your exposure to lead may exceed the PEL. With respect to protective clothing and equipment, where appropriate, the following procedures should be observed prior to beginning work:

1. Change into work clothing and shoe covers in the clean section of the designated changing areas;
2. Use work garments of appropriate protective gear, including respirators before entering the work area; and
3. Store any clothing not worn under protective clothing in the designated changing area.

Workers should follow these procedures upon leaving the work area:

1. HEPA vacuum heavily contaminated protective work clothing while it is still being worn. At no time may lead be removed from protective clothing by any means which result in uncontrolled dispersal of lead into the air;
2. Remove shoe covers and leave them in the work area;
3. Remove protective clothing and gear in the dirty area of the designated changing area. Remove protective coveralls by carefully rolling down the garment to reduce exposure to dust.
4. Remove respirators last; and
5. Wash hands and face.

Workers should follow these procedures upon finishing work for the day (in addition to procedures described above):

1. Where applicable, place disposal coveralls and shoe covers with the abatement waste;
2. Contaminated clothing which is to be cleaned, laundered or disposed of must be placed in closed containers in the change room.
3. Clean protective gear, including respirators, according to standard procedures;
4. Wash hands and face again. If showers are available, take a shower and wash hair. If shower facilities are not available at the work site, shower immediately at home and wash hair.

VI. Housekeeping—Paragraph (H)

Your employer must establish a housekeeping program sufficient to maintain all surfaces as free as practicable of accumulations of lead dust. Vacuuming is the preferred method of meeting this requirement, and the use of compressed air to clean floors and other surfaces is generally prohibited unless removal with compressed air is done in conjunction with ventilation systems designed to contain dispersal of the lead dust. Dry or wet sweeping, shoveling, or brushing may not be used except where vacuuming or other equally effective methods have been tried and do not work. Vacuums must be used equipped with a special filter called a high-efficiency particulate air (HEPA) filter and emptied in a manner which minimizes the reentry of lead into the workplace.

VII. Hygiene Facilities and Practices—Paragraph (I)

The standard requires that hand washing facilities be provided where occupational exposure to lead occurs. In addition, change areas, showers (where feasible), and lunchrooms or eating areas are to be made available to workers exposed to lead above the PEL. Your employer must assure that except in these facilities, food and beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied, where airborne exposures are above the PEL. Change rooms provided by your employer must be equipped with separate storage facilities for your protective clothing and equipment and street clothes to avoid cross-contamination. After showering, no required protective clothing or equipment worn during the shift may be worn home. It is important that contaminated clothing or equipment be removed in change areas and not be worn home or you will extend your exposure and expose your family since lead from your clothing can accumulate in your house, car, etc.

Lunchrooms or eating areas may not be entered with protective clothing or equipment unless surface dust has been removed by vacuuming, downdraft booth, or other cleaning method. Finally, workers exposed above the PEL must wash both their hands and faces prior to eating, drinking, smoking or applying cosmetics.

All of the facilities and hygiene practices just discussed are essential to minimize additional sources of lead absorption from inhalation or ingestion of lead that may accumulate on you, your clothes, or your possessions. Strict compliance with these provisions can virtually eliminate several sources of lead exposure which significantly contribute to excessive lead absorption.

VIII. Medical Surveillance—Paragraph (J)

The medical surveillance program is part of the standard's comprehensive approach to the prevention of lead-related disease. Its purpose is to supplement the main thrust of the standard which is aimed at minimizing airborne concentrations of lead and sources of ingestion. Only medical surveillance can determine if the other provisions of the standard have affectively protected you as an individual. Compliance with the standard's provision will protect most workers from the adverse effects of lead exposure, but may not be satisfactory to protect individual workers (1) who have high body burdens of lead acquired over past years, (2) who have additional uncontrolled sources of non-occupational lead exposure, (3) who exhibit unusual variations in lead absorption rates, or (4) who have specific non-work related medical conditions which could be aggravated by lead exposure (e.g., renal disease, anemia). In addition, control systems may fail, or hygiene and respirator programs may be inadequate. Periodic medical surveillance of individual workers will help detect those failures. Medical surveillance will also be important to protect your reproductive ability-regardless of whether you are a man or woman.

All medical surveillance required by the interim final standard must be performed by or under the supervision of a licensed physician. The employer must provide required medical surveillance without cost to employees and at a reasonable time and place. The standard's medical surveillance program has two parts—periodic biological monitoring and medical examinations. Your employer's obligation to offer you medical surveillance is triggered by the results of the air monitoring program. Full medical surveillance must be made available to all employees who are or may be exposed to lead in excess of the action level for more than 30 days a year and whose blood lead level exceeds 40 $\mu g/dl$. Initial medical surveillance consisting of blood sampling and analysis for lead and zinc protoporphyrin must be provided to all employees exposed at any time (1 day) above the action level.

Biological monitoring under the standard must be provided at least every 2 months for the first 6 months and every 6 months thereafter until your blood lead level is below 40 $\mu g/dl$. A zinc protoporphyrin (ZPP) test is a very useful blood test which measures an adverse metabolic effect of lead on your body and is therefore an indicator of lead toxicity.

If your BLL exceeds 40 $\mu g/dl$ the monitoring frequency must be increased from

every 6 months to at least every 2 months and not reduced until two consecutive BLLs indicate a blood lead level below 40 μg/dl. Each time your BLL is determined to be over 40 μg/dl, your employer must notify you of this in writing within five working days of his or her receipt of the test results. The employer must also inform you that the standard requires temporary medical removal with economic protection when your BLL exceeds 50 μg/dl. (See Discussion of Medical Removal Protection-Paragraph (k).) Anytime your BLL exceeds 50 μg/dl your employer must make available to you within two weeks of receipt of these test results a second follow-up BLL test to confirm your BLL. If the two tests both exceed 50 μg/dl, and you are temporarily removed, then your employer must make successive BLL tests available to you on a monthly basis during the period of your removal.

Medical examinations beyond the initial one must be made available on an annual basis if your blood lead level exceeds 40 μg/dl at any time during the preceding year and you are being exposed above the airborne action level of 30 μg/m^3 for 30 or more days per year. The initial examination will provide information to establish a baseline to which subsequent data can be compared.

An initial medical examination to consist of blood sampling and analysis for lead and zinc protoporphyrin must also be made available (prior to assignment) for each employee being assigned for the first time to an area where the airborne concentration of lead equals or exceeds the action level at any time. In addition, a medical examination or consultation must be made available as soon as possible if you notify your employer that you are experiencing signs or symptoms commonly associated with lead poisoning or that you have difficulty breathing while wearing a respirator or during a respirator fit test. You must also be provided a medical examination or consultation if you notify your employer that you desire medical advice concerning the effects of current or past exposure to lead on your ability to procreate a healthy child.

Finally, appropriate follow-up medical examinations or consultations may also be provided for employees who have been temporarily removed from exposure under the medical removal protection provisions of the standard. (See Part IX, below.)

The standard specifies the minimum content of pre-assignment and annual medical examinations. The content of other types of medical examinations and consultations is left up to the sound discretion of the examining physician. Pre-assignment and annual medical examinations must include (1) a detailed work history and medical history; (2) a thorough physical examination, including an evaluation of your pulmonary status if you will be required to use a respirator; (3) a blood pressure measurement; and (4) a series of laboratory tests designed to check your blood chemistry and your kidney function. In addition, at any time upon your request, a laboratory evaluation of male fertility will be made (microscopic examination of a sperm sample), or a pregnancy test will be given.

The standard does not require that you participate in any of the medical procedures, tests, etc. which your employer is required to make available to you. Medical surveillance can, however, play a very important role in protecting your health. You are strongly encouraged, therefore, to participate in a meaningful fashion. The standard contains a multiple physician review mechanism which will give you a chance to have a physician of your choice directly participate in the medical surveillance program. If you are dissatisfied with an examination by a physician chosen by your employer, you can select a second physician to conduct an independent analysis. The two doctors would attempt to resolve any differences of opinion, and select a third physician to resolve any firm dispute. Generally your employer will choose the physician who conducts medical surveillance under the lead standard-unless you and your employer can agree on the choice of a physician or physicians. Some companies and unions have agreed in advance, for example, to use certain independent medical laboratories or panels of physicians. Any of these arrangements are acceptable so long as required medical surveillance is made available to workers.

The standard requires your employer to provide certain information to a physician to aid in his or her examination of you. This information includes (1) the standard and its appendices, (2) a description of your duties as they relate to occupational lead exposure, (3) your exposure level or anticipated exposure level, (4) a description of any personal protective equipment you wear, (5) prior blood lead level results, and (6) prior written medical opinions concerning you that the employer has. After a medical examination or consultation the physician must prepare a written report which must contain (1) the physician's opinion as to whether you have any medical condition which places you at increased risk of material impairment to health from exposure to lead, (2) any recommended special protective measures to be provided to you, (3) any blood lead level determinations, and (4) any recommended limitation on your use of respirators. This last element must include a determination of whether you can wear a powered air purifying respirator (PAPR) if you are found unable to wear a negative pressure respirator.

The medical surveillance program of the interim lead standard may at some point in time serve to notify certain workers that they have acquired a disease or other adverse medical condition as a result of occupational lead exposure. If this is true, these workers might have legal rights to compensation from public agencies, their employers, firms that supply hazardous products to their employers, or other persons. Some states have laws, including worker compensation laws, that disallow a worker who learns of a job-related health impairment to sue, unless the worker sues within a short period of time after learning of the impairment. (This period of time may be a matter of months or years.) An attorney can be consulted about these possibilities. It should be stressed that OSHA is in no way trying to either encourage or discourage claims or lawsuits. However, since results of the standard's medical surveillance program can significantly affect the legal remedies of a worker who has acquired a job-related disease or impairment, it is proper for OSHA to make you aware of this.

The medical surveillance section of the standard also contains provisions dealing with chelation. Chelation is the use of certain drugs (administered in pill form or injected into the body) to reduce the amount of lead absorbed in body tissues. Experience accumulated by the medical and scientific communities has largely confirmed the effectiveness of this type of therapy for the treatment of very severe lead poisoning. On the other hand, it has also been established that there can be a long list of extremely harmful side effects associated with the use of chelating agents. The medical community has balanced the advantages and disadvantages resulting from the use of chelating agents in various circumstances and has established when the use of these agents is acceptable. The standard includes these accepted limitations due to a history of abuse of chelation therapy by some lead companies. The most widely used chelating agents are calcium disodium EDTA, (Ca Na2 EDTA), Calcium Disodium Versenate (Versenate), and d-penicillamine (pencillamine or Cupramine).

The standard prohibits "prophylactic chelation" of any employee by any person the employer retains, supervises or controls. "Prophylactic chelation" is the routine use of chelating or similarly acting drugs to prevent elevated blood levels in workers who are occupationally exposed to lead, or the use of these drugs to routinely lower blood lead levels to predesignated concentrations believed to be "safe". It should be emphasized that where an employer takes a worker who has no symptoms of lead poisoning and has chelation carried out by a physician (either inside or outside of a hospital) solely to reduce the worker's blood lead level, that will generally be considered prophylactic chelation. The use of a hospital and a physician does not mean that prophylactic chelation is not being performed. Routine chelation to prevent increased or reduce current blood lead levels is unacceptable whatever the setting.

The standard allows the use of "therapeutic" or "diagnostic" chelation if administered under the supervision of a licensed physician in a clinical setting with thorough and appropriate medical monitoring. Therapeutic chelation responds to severe lead poisoning where there are marked symptoms. Diagnostic chelation involved giving a patient a dose of the drug then collecting all urine excreted for some period of time as an aid to the diagnosis of lead poisoning.

In cases where the examining physician determines that chelation is appropriate, you must be notified in writing of this fact before such treatment. This will inform you of a potentially harmful treatment, and allow you to obtain a second opinion.

IX. Medical Removal Protection—Paragraph (K)

Excessive lead absorption subjects you to increased risk of disease. Medical removal

protection (MRP) is a means of protecting you when, for whatever reasons, other methods, such as engineering controls, work practices, and respirators, have failed to provide the protection you need. MRP involves the temporary removal of a worker from his or her regular job to a place of significantly lower exposure without any loss of earnings, seniority, or other employment rights or benefits. The purpose of this program is to cease further lead absorption and allow your body to naturally excrete lead which has previously been absorbed. Temporary medical removal can result from an elevated blood lead level, or a medical opinion. For up to 18 months, or for as long as the job the employee was removed from lasts, protection is provided as a result of either form of removal. The vast majority of removed workers, however, will return to their former jobs long before this eighteen month period expires.

You may also be removed from exposure even if your blood lead level is below 50 µg/dl if a final medical determination indicates that you temporarily need reduced lead exposure for medical reasons. If the physician who is implementing your employers medical program makes a final written opinion recommending your removal or other special protective measures, your employer must implement the physician's recommendation. If you are removed in this manner, you may only be returned when the doctor indicates that it is safe for you to do so.

The standard does not give specific instructions dealing with what an employer must do with a removed worker. Your job assignment upon removal is a matter for you, your employer and your union (if any) to work out consistent with existing procedures for job assignments. Each removal must be accomplished in a manner consistent with existing collective bargaining relationships. Your employer is given broad discretion to implement temporary removals so long as no attempt is made to override existing agreements. Similarly, a removed worker is provided no right to veto an employer's choice which satisfies the standard.

In most cases, employers will likely transfer removed employees to other jobs with sufficiently low lead exposure. Alternatively, a worker's hours may be reduced so that the time weighted average exposure is reduced, or he or she may be temporarily laid off if no other alternative is feasible.

In all of these situation, MRP benefits must be provided during the period of removal—i.e., you continue to receive the same earnings, seniority, and other rights and benefits you would have had if you had not been removed. Earnings includes more than just your base wage; it includes overtime, shift differentials, incentives, and other compensation you would have earned if you had not been removed. During the period of removal you must also be provided with appropriate follow-up medical surveillance. If you were removed because your blood lead level was too high, you must be provided with a monthly blood test. If a medical opinion caused your removal, you must be provided medical tests or examinations that the doctor believes to be appropriate. If you do not participate in this follow up medical surveillance, you may lose your eligibility for MRP benefits.

When you are medically eligible to return to your former job, your employer must return you to your "former job status." This means that you are entitled to the position, wages, benefits, etc., you would have had if you had not been removed. If you would still be in your old job if no removal had occurred that is where you go back. If not, you are returned consistent with whatever job assignment discretion your employer would have had if no removal had occurred. MRP only seeks to maintain your rights, not expand them or diminish them.

If you are removed under MRP and you are also eligible for worker compensation or other compensation for lost wages, your employer's MRP benefits obligation is reduced by the amount that you actually receive from these other sources. This is also true if you obtain other employment during the time you are laid off with MRP benefits.

The standard also covers situations where an employer voluntarily removes a worker from exposure to lead due to the effects of lead on the employee's medical condition, even though the standard does not require removal. In these situations MRP benefits must still be provided as though the standard required removal. Finally, it is important to note that in all cases where removal is required, respirators cannot be used as a substitute. Respirators may be used before removal becomes necessary, but not as an alternative to a transfer to a low exposure job, or to a lay-off with MRP benefits.

X. Employee Information and Training—Paragraph (L)

Your employer is required to provide an information and training program for all employees exposed to lead above the action level or who may suffer skin or eye irritation from lead compounds such as lead arsenate or lead azide. The program must train these employees regarding the specific hazards associated with their work environment, protective measures which can be taken, including the contents of any compliance plan in effect, the danger of lead to their bodies (including their reproductive systems), and their rights under the standard. All employees must be trained prior to initial assignment to areas where there is a possibility of exposure over the action level.

This training program must also be provided at least annually thereafter unless further exposure above the action level will not occur.

XI. Signs—Paragraph (M)

The standard requires that the following warning sign be posted in work areas where the exposure to lead exceeds the PEL:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

These signs are to be posted and maintained in a manner which assures that the legend is readily visible.

XII. Recordkeeping—Paragraph (N)

Your employer is required to keep all records of exposure monitoring for airborne lead. These records must include the name and job classification of employees measured, details of the sampling and analytical techniques, the results of this sampling, and the type of respiratory protection being worn by the person sampled. Such records are to be retained for at least 30 years. Your employer is also required to keep all records of biological monitoring and medical examination results. These records must include the names of the employees, the physician's written opinion, and a copy of the results of the examination. Medical records must be preserved and maintained for the duration of employment plus 30 years. However, if the employee's duration of employment is less than one year, the employer need not retain that employee's medical records beyond the period of employment if they are provided to the employee upon termination of employment.

Recordkeeping is also required if you are temporarily removed from your job under the medical removal protection program. This record must include your name and social security number, the date of your removal and return, how the removal was or is being accomplished, and whether or not the reason for the removal was an elevated blood lead level. Your employer is required to keep each medical removal record only for as long as the duration of an employee's employment.

The standard requires that if you request to see or copy environmental monitoring, blood lead level monitoring, or medical removal records, they must be made available to you or to a representative that you authorize. Your union also has access to these records. Medical records other than BLL's must also be provided upon request to you, to your physician or to any other person whom you may specifically designate. Your union does not have access to your personal medical records unless you authorize their access.

XIII. Observation of Monitoring—Paragraph (O)

When air monitoring for lead is performed at your workplace as required by this standard, your employer must allow you or someone you designate to act as an observer of the monitoring. Observers are entitled to an explanation of the measurement procedure, and to record the results obtained. Since results will not normally be available at the time of the monitoring, observers are entitled to record or receive the results of the monitoring when returned by the laboratory. Your employer is required to provide the observer with any personal protective devices required to be worn by employees working in the area that is being monitored. The employer must require the observer to wear all such equipment and to comply with all other applicable safety and health procedures.

XIV. Effective Date—Paragraph (P)

The standard's effective date is June 3, 1993. Employer obligations under the standard begin as of that date with full implementation of engineering controls as soon as possible but no later than within 4

months, and all other provisions completed as soon as possible, but no later than within 2 months from the effective date.

XV. For Additional Information

A. A copy of the interim standard for lead in construction can be obtained free of charge by calling or writing the OSHA Office of Publications, room N-3101, United States Department of Labor, Washington, DC 20210: Telephone (202) 219-4667.

B. Additional information about the standard, its enforcement, and your employer's compliance can be obtained from the nearest OSHA Area Office listed in your telephone directory under United States Government/Department of Labor.

Appendix C to § 1926.62—Medical Surveillance Guidelines

Introduction

The primary purpose of the Occupational Safety and Health Act of 1970 is to assure, so far as possible, safe and healthful working conditions for every working man and woman. The interim final occupational health standard for lead in construction is designed to protect workers exposed to inorganic lead including metallic lead, all inorganic lead compounds and organic lead soaps.

Under this interim final standard occupational exposure to inorganic lead is to be limited to 50 μg/m³ (micrograms per cubic meter) based on an 8 hour time-weighted average (TWA). This permissible exposure limit (PEL) must be achieved through a combination of engineering, work practice and administrative controls to the extent feasible. Where these controls are in place but are found not to reduce employee exposures to or below the PEL, they must be used nonetheless, and supplemented with respirators to meet the 50 μg/m³ exposure limit.

The standard also provides for a program of biological monitoring for employees exposed to lead above the action level at any time, and additional medical surveillance for all employees exposed to levels of inorganic lead above 30 μg/m³ (TWA) for more than 30 days per year and whose BLL exceeds 40 μg/dl.

The purpose of this document is to outline the medical surveillance provisions of the interim standard for inorganic lead in construction, and to provide further information to the physician regarding the examination and evaluation of workers exposed to inorganic lead.

Section 1 provides a detailed description of the monitoring procedure including the required frequency of blood testing for exposed workers, provisions for medical removal protection (MRP), the recommended right of the employee to a second medical opinion, and notification and recordkeeping requirements of the employer. A discussion of the requirements for respirator use and respirator monitoring and OSHA's position on prophylactic chelation therapy are also included in this section.

Section 2 discusses the toxic effects and clinical manifestations of lead poisoning and effects of lead intoxication on enzymatic pathways in heme synthesis. The adverse effects on both male and female reproductive capacity and on the fetus are also discussed.

Section 3 outlines the recommended medical evaluation of the worker exposed to inorganic lead, including details of the medical history, physical examination, and recommended laboratory tests, which are based on the toxic effects of lead as discussed in Section 2.

Section 4 provides detailed information concerning the laboratory tests available for the monitoring of exposed workers. Included also is a discussion of the relative value of each test and the limitations and precautions which are necessary in the interpretation of the laboratory results.

I. Medical Surveillance and Monitoring Requirements for Workers Exposed to Inorganic Lead

Under the interim final standard for inorganic lead in the construction industry, initial medical surveillance consisting of biological monitoring to include blood lead and ZPP level determination shall be provided to employees exposed to lead at or above the action level on any one day. In addition, a program of biological monitoring is to be made available to all employees exposed above the action level at any time and additional medical surveillance is to be made available to all employees exposed to lead above 30 μg/m³ TWA for more than 30 days each year and whose BLL exceeds 40 μg/dl. This program consists of periodic blood sampling and medical evaluation to be performed on a schedule which is defined by previous laboratory results, worker complaints or concerns, and the clinical assessment of the examining physician.

Under this program, the blood lead level (BLL) of all employees who are exposed to lead above 30 μg/m³ for more than 30 days per year or whose blood lead is above 40 μg/dl but exposed for no more than 30 days per year is to be determined at least every two months for the first six months of exposure and every six months thereafter. The frequency is increased to every two months for employees whose last blood lead level was 40 μg/dl or above. For employees who are removed from exposure to lead due to an elevated blood lead, a new blood lead level must be measured monthly. A zinc protoporphyrin (ZPP) measurement is strongly recommended on each occasion that a blood lead level measurement is made.

An annual medical examination and consultation performed under the guidelines discussed in Section 3 is to be made available to each employee exposed above 30 μg/m³ for more than 30 days per year for whom a blood test conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 μg/dl. Also, an examination is to be given to all employees prior to their assignment to an area in which airborne lead concentrations reach or exceed the 30 μg/m³ for more than 30 days per year. In addition, a medical examination must be provided as soon as possible after notification by an employee that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice regarding lead exposure and the ability to procreate a healthy child, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during respirator use. An examination is also to be made available to each employee removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited or specially protected pursuant to medical recommendations.

Results of biological monitoring or the recommendations of an examining physician may necessitate removal of an employee from further lead exposure pursuant to the standard's medical removal protection (MRP) program. The object of the MRP program is to provide temporary medical removal to workers either with substantially elevated blood lead levels or otherwise at risk of sustaining material health impairment from continued substantial exposure to lead.

Under the standard's ultimate worker removal criteria, a worker is to be removed from any work having an eight hour TWA exposure to lead of 30 μg/m³ when his or her blood lead level reaches 50 μg/dl and is confirmed by a second follow-up blood lead level performed within two weeks after the employer receives the results of the first blood sampling test. Return of the employee to his or her job status depends on a worker's blood lead level declining to 40 μg/dl.

As part of the interim standard, the employer is required to notify in writing each employee whose blood lead level exceeds 40 μg/dl. In addition each such employee is to be informed that the standard requires medical removal with MRP benefits, discussed below, when an employee's blood lead level exceeds the above defined limit.

In addition to the above blood lead level criterion, temporary worker removal may also take place as a result of medical determinations and recommendations. Written medical opinions must be prepared after each examination pursuant to the standard. If the examining physician includes a medical finding, determination or opinion that the employee has a medical condition which places the employee at increased risk of material health impairment from exposure to lead, then the employee must be removed from exposure to lead at or above 30 μg/m³. Alternatively, if the examining physician recommends special protective measures for an employee (e.g., use of a powered air purifying respirator) or recommends limitations on an employee's exposure to lead, then the employer must implement these recommendations.

Recommendations may be more stringent than the specific provisions of the standard. The examining physician, therefore, is given broad flexibility to tailor special protective procedures to the needs of individual employees. This flexibility extends to the evaluation and management of pregnant workers and male and female workers who are planning to raise children. Based on the history, physical examination, and laboratory studies, the physician might recommend special protective measures or medical removal for an employee who is pregnant or who is planning to conceive a child when, in the physician's judgment, continued exposure to lead at the current job would pose a significant risk. The return of the

employee to his or her former job status, or the removal of special protections or limitations, depends upon the examining physician determining that the employee is no longer at increased risk of material impairment or that special measures are no longer needed.

During the period of any form of special protection or removal, the employer must maintain the worker's earnings, seniority, and other employment rights and benefits (as though the worker had not been removed) for a period of up to 18 months or for as long as the job the employee was removed from lasts if less than 18 months. This economic protection will maximize meaningful worker participation in the medical surveillance program, and is appropriate as part of the employer's overall obligation to provide a safe and healthful workplace. The provisions of MRP benefits during the employee's removal period may, however, be conditioned upon participation in medical surveillance.

The lead standard provides for a multiple physician review in cases where the employee wishes a second opinion concerning potential lead poisoning or toxicity. If an employee wishes a second opinion, he or she can make an appointment with a physician of his or her choice. This second physician will review the findings, recommendations or determinations of the first physician and conduct any examinations, consultations or tests deemed necessary in an attempt to make a final medical determination. If the first and second physicians do not agree in their assessment they must try to resolve their differences. If they cannot reach an agreement then they must designate a third physician to resolve the dispute.

The employer must provide examining and consulting physicians with the following specific information: A copy of the lead regulations and all appendices, a description of the employee's duties as related to exposure, the exposure level or anticipated level to lead and any other toxic substances (if applicable), a description of personal protective equipment used, blood lead levels, and all prior written medical opinions regarding the employee in the employer's possession or control. The employer must also obtain from the physician and provide the employee with a written medical opinion containing blood lead levels, the physicians's opinion as to whether the employee is at risk of material impairment to health, any recommended protective measures for the employee if further exposure is permitted, as well as any recommended limitations upon an employee's use of respirators.

Employers must instruct each physician not to reveal to the employer in writing or in any other way his or her findings, laboratory results, or diagnoses which are felt to be unrelated to occupational lead exposure. They must also instruct each physician to advise the employee of any occupationally or non-occupationally related medical condition requiring further treatment or evaluation.

The standard provides for the use of respirators where engineering and other primary controls are not effective. However, the use of respirator protection shall not be used in lieu of temporary medical removal due to elevated blood lead levels or findings that an employee is at risk of material health impairment. This is based on the numerous inadequacies of respirators including skin rash where the facepiece makes contact with the skin, unacceptable stress to breathing in some workers with underlying cardiopulmonary impairment, difficulty in providing adequate fit, the tendency for respirators to create additional hazards by interfering with vision, hearing, and mobility, and the difficulties of assuring the maximum effectiveness of a complicated work practice program involving respirators. Respirators do, however, serve a useful function where engineering and work practice controls are inadequate by providing supplementary, interim, or short-term protection, provided they are properly selected for the environment in which the employee will be working, properly fitted to the employee, maintained and cleaned periodically, and worn by the employee when required.

In its interim final standard on occupational exposure to inorganic lead in the construction industry, OSHA has prohibited prophylactic chelation. Diagnostic and therapeutic chelation are permitted only under the supervision of a licensed physician with appropriate medical monitoring in an acceptable clinical setting. The decision to initiate chelation therapy must be made on an individual basis and take into account the severity of symptoms felt to be a result of lead toxicity along with blood lead levels, ZPP levels, and other laboratory tests as appropriate. EDTA and penicillamine which are the primary chelating agents used in the therapy of occupational lead poisoning have significant potential side effects and their use must be justified on the basis of expected benefits to the worker. Unless frank and severe symptoms are present, therapeutic chelation is not recommended, given the opportunity to remove a worker from exposure and allow the body to naturally excrete accumulated lead. As a diagnostic aid, the chelation mobilization test using CA-EDTA has limited applicability. According to some investigators, the test can differentiate between lead-induced and other nephropathies. The test may also provide an estimation of the mobile fraction of the total body lead burden.

Employers are required to assure that accurate records are maintained on exposure assessment, including environmental monitoring, medical surveillance, and medical removal for each employee. Exposure assessment records must be kept for at least 30 years. Medical surveillance records must be kept for the duration of employment plus 30 years except in cases where the employment was less than one year. If duration of employment is less than one year, the employer need not retain this record beyond the term of employment if the record is provided to the employee upon termination of employment. Medical removal records also must be maintained for the duration of employment. All records required under the standard must be made available upon request to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health. Employers must also make environmental and biological monitoring and medical removal records available to affected employees and to former employees or their authorized employee representatives. Employees or their specifically designated representatives have access to their entire medical surveillance records.

In addition, the standard requires that the employer inform all workers exposed to lead at or above 30 μg/m³ of the provisions of the standard and all its appendices, the purpose and description of medical surveillance and provisions for medical removal protection if temporary removal is required. An understanding of the potential health effects of lead exposure by all exposed employees along with full understanding of their rights under the lead standard is essential for an effective monitoring program.

II. Adverse Health Effects of Inorganic Lead

Although the toxicity of lead has been known for 2,000 years, the knowledge of the complex relationship between lead exposure and human response is still being refined. Significant research into the toxic properties of lead continues throughout the world, and it should be anticipated that our understanding of thresholds of effects and margins of safety will be improved in future years. The provisions of the lead standard are founded on two prime medical judgments: First, the prevention of adverse health effects from exposure to lead throughout a working lifetime requires that worker blood lead levels be maintained at or below 40 μg/dl and second, the blood lead levels of workers, male or female, who intend to parent in the near future should be maintained below 30 μg/dl to minimize adverse reproductive health effects to the parents and developing fetus. The adverse effects of lead on reproduction are being actively researched and OSHA encourages the physician to remain abreast of recent developments in the area to best advise pregnant workers or workers planning to conceive children.

The spectrum of health effects caused by lead exposure can be subdivided into five developmental stages: Normal, physiological changes of uncertain significance, pathophysiological changes, overt symptoms (morbidity), and mortality. Within this process there are no sharp distinctions, but rather a continuum of effects. Boundaries between categories overlap due to the wide variation of individual responses and exposures in the working population. OSHA's development of the lead standard focused on pathophysiological changes as well as later stages of disease.

1. Heme Synthesis Inhibition. The earliest demonstrated effect of lead involves its ability to inhibit at least two enzymes of the heme synthesis pathway at very low blood levels. Inhibition of delta aminolevulinic acid dehydrase (ALA-D) which catalyzes the conversion of delta-aminolevulinic acid (ALA) to protoporphyrin is observed at a blood lead level below 20 μg/dl. At a blood lead level of 40 μg/dl, more than 20% of the population would have 70% inhibition of

ALA–D. There is an exponential increase in ALA excretion at blood lead levels greater than 40 µg/dl.

Another enzyme, ferrochelatase, is also inhibited at low blood lead levels. Inhibition of ferrochelatase leads to increased free erythrocyte protoporphyrin (FEP) in the blood which can then bind to zinc to yield zinc protoporphyrin. At a blood lead level of 50 µg/dl or greater, nearly 100% of the population will have an increase in FEP. There is also an exponential relationship between blood lead levels greater than 40 µg/dl and the associated ZPP level, which has led to the development of the ZPP screening test for lead exposure.

While the significance of these effects is subject to debate, it is OSHA's position that these enzyme disturbances are early stages of a disease process which may eventually result in the clinical symptoms of lead poisoning. Whether or not the effects do progress to the later stages of clinical disease, disruption of these enzyme processes over a working lifetime is considered to be a material impairment of health.

One of the eventual results of lead-induced inhibition of enzymes in the heme synthesis pathway is anemia which can be asymptomatic if mild but associated with a wide array of symptoms including dizziness, fatigue, and tachycardia when more severe. Studies have indicated that lead levels as low as 50 µg/dl can be associated with a definite decreased hemoglobin, although most cases of lead-induced anemia, as well as shortened red-cell survival times, occur at lead levels exceeding 80 µg/dl. Inhibited hemoglobin synthesis is more common in chronic cases whereas shortened erythrocyte life span is more common in acute cases.

In lead-induced anemias, there is usually a reticulocytosis along with the presence of basophilic stippling, and ringed sideroblasts, although none of the above are pathognomonic for lead-induced anemia.

2. Neurological Effects. Inorganic lead has been found to have toxic effects on both the central and peripheral nervous systems. The earliest stages of lead-induced central nervous system effects first manifest themselves in the form of behavioral disturbances and central nervous system symptoms including irritability, restlessness, insomnia and other sleep disturbances, fatigue, vertigo, headache, poor memory, tremor, depression, and apathy. With more severe exposure, symptoms can progress to drowsiness, stupor, hallucinations, delirium, convulsions and coma.

The most severe and acute form of lead poisoning which usually follows ingestion or inhalation of large amounts of lead is acute encephalopathy which may arise precipitously with the onset of intractable seizures, coma, cardiorespiratory arrest, and death within 48 hours.

While there is disagreement about what exposure levels are needed to produce the earliest symptoms, most experts agree that symptoms definitely can occur at blood lead levels of 60 µg/dl whole blood and therefore recommend a 40 µg/dl maximum. The central nervous system effects frequently are not reversible following discontinued exposure or chelation therapy and when improvement does occur, it is almost always only partial.

The peripheral neuropathy resulting from lead exposure characteristically involves only motor function with minimal sensory damage and has a marked predilection for the extensor muscles of the most active extremity. The peripheral neuropathy can occur with varying degrees of severity. The earliest and mildest form which can be detected in workers with blood lead levels as low as 50 µg/dl is manifested by slowing of motor nerve conduction velocity often without clinical symptoms. With progression of the neuropathy there is development of painless extensor muscle weakness usually involving the extensor muscles of the fingers and hand in the most active upper extremity, followed in severe cases by wrist drop or, much less commonly, foot drop.

In addition to slowing of nerve conduction, electromyographical studies in patients with blood lead levels greater than 50 µg/dl have demonstrated a decrease in the number of acting motor unit potentials, an increase in the duration of motor unit potentials, and spontaneous pathological activity including fibrillations and fasciculations. Whether these effects occur at levels of 40 µg/dl is undetermined.

While the peripheral neuropathies can occasionally be reversed with therapy, again such recovery is not assured particularly in the more severe neuropathies and often improvement is only partial. The lack of reversibility is felt to be due in part to segmental demyelination.

3. Gastrointestinal. Lead may also affect the gastrointestinal system producing abdominal colic or diffuse abdominal pain, constipation, obstipation, diarrhea, anorexia, nausea and vomiting. Lead colic rarely develops at blood lead levels below 80 µg/dl.

4. Renal. Renal toxicity represents one of the most serious health effects of lead poisoning. In the early stages of disease nuclear inclusion bodies can frequently be identified in proximal renal tubular cells. Renal function remains normal and the changes in this stage are probably reversible. With more advanced disease there is progressive interstitial fibrosis and impaired renal function. Eventually extensive interstitial fibrosis ensues with sclerotic glomeruli and dilated and atrophied proximal tubules; all represent end stage kidney disease. Azotemia can be progressive, eventually resulting in frank uremia necessitating dialysis. There is occasionally associated hypertension and hyperuricemia with or without gout.

Early kidney disease is difficult to detect. The urinalysis is normal in early lead nephropathy and the blood urea nitrogen and serum creatinine increase only when two-thirds of kidney function is lost. Measurement of creatinine clearance can often detect earlier disease as can other methods of measurement of glomerular filtration rate. An abnormal Ca-EDTA mobilization test has been used to differentiate between lead-induced and other nephropathies, but this procedure is not widely accepted. A form of Fanconi syndrome with aminoaciduria, glycosuria, and hyperphosphaturia indicating severe injury to the proximal renal tubules is occasionally seen in children.

5. Reproductive effects. Exposure to lead can have serious effects on reproductive function in both males and females. In male workers exposed to lead there can be a decrease in sexual drive, impotence, decreased ability to produce healthy sperm, and sterility. Malformed sperm (teratospermia), decreased number of sperm (hypospermia), and sperm with decreased motility (asthenospermia) can all occur. Teratospermia has been noted at mean blood lead levels of 53 µg/dl and hypospermia and asthenospermia at 41 µg/dl. Furthermore, there appears to be a dose-response relationship for teratospermia in lead exposed workers.

Women exposed to lead may experience menstrual disturbances including dysmenorrhea, menorrhagia and amenorrhea. Following exposure to lead, women have a higher frequency of sterility, premature births, spontaneous miscarriages, and stillbirths.

Germ cells can be affected by lead and cause genetic damage in the egg or sperm cells before conception and result in failure to implant, miscarriage, stillbirth, or birth defects.

Infants of mothers with lead poisoning have a higher mortality during the first year and suffer from lowered birth weights, slower growth, and nervous system disorders.

Lead can pass through the placental barrier and lead levels in the mother's blood are comparable to concentrations of lead in the umbilical cord at birth. Transplacental passage becomes detectable at 12–14 weeks of gestation and increases until birth.

There is little direct data on damage to the fetus from exposure to lead but it is generally assumed that the fetus and newborn would be at least as susceptible to neurological damage as young children. Blood lead levels of 50–60 µg/dl in children can cause significant neurobehavioral impairments and there is evidence of hyperactivity at blood levels as low as 25 µg/dl. Given the overall body of literature concerning the adverse health effects of lead in children, OSHA feels that the blood lead level in children should be maintained below 30 µg/dl with a population mean of 15 µg/dl. Blood lead levels in the fetus and newborn likewise should not exceed 30 µg/dl.

Because of lead's ability to pass through the placental barrier and also because of the demonstrated adverse effects of lead on reproductive function in both the male and female as well as the risk of genetic damage of lead on both the ovum and sperm, OSHA recommends a 30 µg/dl maximum permissible blood lead level in both males and females who wish to bear children.

6. Other toxic effects. Debate and research continue on the effects of lead on the human body. Hypertension has frequently been noted in occupationally exposed individuals although it is difficult to assess whether this is due to lead's adverse effects on the kidney or if some other mechanism is involved. Vascular and electrocardiographic changes have been detected but have not been well characterized. Lead is thought to impair thyroid function and interfere with the pituitary-adrenal axis, but again these effects have not been well defined.

III. Medical Evaluation

The most important principle in evaluating a worker for any occupational disease including lead poisoning is a high index of suspicion on the part of the examining physician. As discussed in Section 2, lead can affect numerous organ systems and produce a wide array of signs and symptoms, most of which are non-specific and subtle in nature at least in the early stages of disease. Unless serious concern for lead toxicity is present, many of the early clues to diagnosis may easily be overlooked.

The crucial initial step in the medical evaluation is recognizing that a worker's employment can result in exposure to lead. The worker will frequently be able to define exposures to lead and lead containing materials but often will not volunteer this information unless specifically asked. In other situations the worker may not know of any exposures to lead but the suspicion might be raised on the part of the physician because of the industry or occupation of the worker. Potential occupational exposure to lead and its compounds occur in many occupations in the construction industry, including demolition and salvaging operations, removal or encapsulation of materials containing lead, construction, alteration, repair or renovation of structures containing lead, transportation, disposal, storage or containment of lead or lead-containing materials on construction sites, and maintenance operations associated with construction activities.

Once the possibility for lead exposure is raised, the focus can then be directed toward eliciting information from the medical history, physical exam, and finally from laboratory data to evaluate the worker for potential lead toxicity.

A complete and detailed work history is important in the initial evaluation. A listing of all previous employment with information on job description, exposure to fumes or dust, known exposures to lead or other toxic substances, a description of any personal protective equipment used, and previous medical surveillance should all be included in the worker's record. Where exposure to lead is suspected, information concerning on-the-job personal hygiene, smoking or eating habits in work areas, laundry procedures, and use of any protective clothing or respiratory protection equipment should be noted. A complete work history is essential in the medical evaluation of a worker with suspected lead toxicity, especially when long term effects such as neurotoxicity and nephrotoxicity are considered.

The medical history is also of fundamental importance and should include a listing of all past and current medical conditions, current medications including proprietary drug intake, previous surgeries and hospitalizations, allergies, smoking history, alcohol consumption, and also non-occupational lead exposures such as hobbies (hunting, riflery). Also known childhood exposures should be elicited. Any previous history of hematological, neurological, gastrointestinal, renal, psychological, gynecological, genetic, or reproductive problems should be specifically noted.

A careful and complete review of systems must be performed to assess both recognized complaints and subtle or slowly acquired symptoms which the worker might not appreciate as being significant. The review of symptoms should include the following:

1. General—weight loss, fatigue, decreased appetite.
2. Head, Eyes, Ears, Nose, Throat (HEENT)—headaches, visual disturbances or decreased visual acuity, hearing deficits or tinnitus, pigmentation of the oral mucosa, or metallic taste in mouth.
3. Cardio-pulmonary—shortness of breath, cough, chest pains, palpitations, or orthopnea.
4. Gastrointestinal—nausea, vomiting, heartburn, abdominal pain, constipation or diarrhea.
5. Neurologic—irritability, insomnia, weakness (fatigue), dizziness, loss of memory, confusion, hallucinations, incoordination, ataxia, decreased strength in hands or feet, disturbances in gait, difficulty in climbing stairs, or seizures.
6. Hematologic—pallor, easy fatigability, abnormal blood loss, melena.
7. Reproductive (male and female and spouse where relevant)—history of infertility, impotence, loss of libido, abnormal menstrual periods, history of miscarriages, stillbirths, or children with birth defects.
8. Musculo-skeletal—muscle and joint pains.

The physical examination should emphasize the neurological, gastrointestinal, and cardiovascular systems. The worker's weight and blood pressure should be recorded and the oral mucosa checked for pigmentation characteristic of a possible Burtonian or lead line on the gingiva. It should be noted, however, that the lead line may not be present even in severe lead poisoning if good oral hygiene is practiced.

The presence of pallor on skin examination may indicate an anemia which, if severe, might also be associated with a tachycardia. If an anemia is suspected, an active search for blood loss should be undertaken including potential blood loss through the gastrointestinal tract.

A complete neurological examination should include an adequate mental status evaluation including a search for behavioral and psychological disturbances, memory testing, evaluation for irritability, insomnia, hallucinations, and mental clouding. Gait and coordination should be examined along with close observation for tremor. A detailed evaluation of peripheral nerve function including careful sensory and motor function testing is warranted. Strength testing particularly of extensor muscle groups of all extremities is of fundamental importance.

Cranial nerve evaluation should also be included in the routine examination.

The abdominal examination should include auscultation for bowel sounds and abdominal bruits and palpation for organomegaly, masses, and diffuse abdominal tenderness.

Cardiovascular examination should evaluate possible early signs of congestive heart failure. Pulmonary status should be addressed particularly if respirator protection is contemplated.

As part of the medical evaluation, the interim lead standard requires the following laboratory studies:

1. Blood lead level
2. Hemoglobin and hematocrit determinations, red cell indices, and examination of the peripheral blood smear to evaluate red blood cell morphology
3. Blood urea nitrogen
4. Serum creatinine
5. Routine urinalysis with microscopic examination.
6. A zinc protoporphyrin level.

In addition to the above, the physician is authorized to order any further laboratory or other tests which he or she deems necessary in accordance with sound medical practice. The evaluation must also include pregnancy testing or laboratory evaluation of male fertility if requested by the employee. Additional tests which are probably not warranted on a routine basis but may be appropriate when blood lead and ZPP levels are equivocal include delta aminolevulinic acid and coproporphyrin concentrations in the urine, and dark-field illumination for detection of basophilic stippling in red blood cells.

If an anemia is detected further studies including a careful examination of the peripheral smear, reticulocyte count, stool for occult blood, serum iron, total iron binding capacity, bilirubin, and, if appropriate, vitamin B12 and folate may be of value in attempting to identify the cause of the anemia.

If a peripheral neuropathy is suspected, nerve conduction studies are warranted both for diagnosis and as a basis to monitor any therapy.

If renal disease is questioned, a 24 hour urine collection for creatinine clearance, protein, and electrolytes may be indicated. Elevated uric acid levels may result from lead-induced renal disease and a serum uric acid level might be performed.

An electrocardiogram and chest x-ray may be obtained as deemed appropriate.

Sophisticated and highly specialized testing should not be done routinely and where indicated should be under the direction of a specialist.

IV. Laboratory Evaluation

The blood lead level at present remains the single most important test to monitor lead exposure and is the test used in the medical surveillance program under the lead standard to guide employee medical removal. The ZPP has several advantages over the blood lead level. Because of its relatively recent development and the lack of extensive data concerning its interpretation, the ZPP currently remains an ancillary test.

This section will discuss the blood lead level and ZPP in detail and will outline their relative advantages and disadvantages. Other blood tests currently available to evaluate lead exposure will also be reviewed.

The blood lead level is a good index of current or recent lead absorption when there is no anemia present and when the worker has not taken any chelating agents. However, blood lead levels along with urinary lead levels do not necessarily indicate the total body burden of lead and are not adequate measures of past exposure. One reason for this is that lead has a high affinity for bone and up to 90% of the body's total lead is

deposited there. A very important component of the total lead body burden is lead in soft tissue (liver, kidney, and brain). This fraction of the lead body burden, the biologically active lead, is not entirely reflected by blood lead levels since it is a function of the dynamics of lead absorption, distribution, deposition in bone and excretion. Following discontinuation of exposure to lead, the excess body burden is only slowly mobilized from bone and other relatively stable body stores and excreted. Consequently, a high blood lead level may only represent recent heavy exposure to lead without a significant total body excess and likewise a low blood lead level does not exclude an elevated total body burden of lead.

Also due to its correlation with recent exposures, the blood lead level may vary considerably over short time intervals.

To minimize laboratory error and erroneous results due to contamination, blood specimens must be carefully collected after thorough cleaning of the skin with appropriate methods using lead-free blood containers and analyzed by a reliable laboratory. Under the standard, samples must be analyzed in laboratories which are approved by OSHA. Analysis is to be made using atomic absorption spectrophotometry, anodic stripping voltammetry or any method which meets the accuracy requirements set forth by the standard.

The determination of lead in urine is generally considered a less reliable monitoring technique than analysis of whole blood primarily due to individual variability in urinary excretion capacity as well as the technical difficulty of obtaining accurate 24 hour urine collections. In addition, workers with renal insufficiency, whether due to lead or some other cause, may have decreased lead clearance and consequently urine lead levels may underestimate the true lead burden. Therefore, urine lead levels should not be used as a routine test.

The zinc protoporphyrin test, unlike the blood lead determination, measures an adverse metabolic effect of lead and as such is a better indicator of lead toxicity than the level of blood lead itself. The level of ZPP reflects lead absorption over the preceding 3 to 4 months, and therefore is a better indicator of lead body burden. The ZPP requires more time than the blood lead to read significantly elevated levels; the return to normal after discontinuing lead exposure is also slower. Furthermore, the ZPP test is simpler, faster, and less expensive to perform and no contamination is possible. Many investigators believe it is the most reliable means of monitoring chronic lead absorption.

Zinc protoporphyrin results from the inhibition of the enzyme ferrochelatase which catalyzes the insertion of an iron molecule into the protoporphyrin molecule, which then becomes heme. If iron is not inserted into the molecule then zinc, having a greater affinity for protoporphyrin, takes the place of the iron, forming ZPP.

An elevation in the level of circulating ZPP may occur at blood lead levels as low as 20–30 µg/dl in some workers. Once the blood lead level has reached 40 µg/dl there is more marked rise in the ZPP value from its normal range of less than 100 µg/dl100 ml. Increases in blood lead levels beyond 40 µg/100 g are associated with exponential increases in ZPP.

Whereas blood lead levels fluctuate over short time spans, ZPP levels remain relatively stable. ZPP is measured directly in red blood cells and is present for the cell's entire 120 day life-span. Therefore, the ZPP level in blood reflects the average ZPP production over the previous 3–4 months and consequently the average lead exposure during that time interval.

It is recommended that a hematocrit be determined whenever a confirmed ZPP of 50 µg/100 ml whole blood is obtained to rule out a significant underlying anemia. If the ZPP is in excess of 100 µg/100 ml and not associated with abnormal elevations in blood lead levels, the laboratory should be checked to be sure that blood leads were determined using atomic absorption spectrophotometry anodic stripping voltammetry, or any method which meets the accuracy requirements set forth by the standard by an OSHA approved laboratory which is experienced in lead level determinations. Repeat periodic blood lead studies should be obtained in all individuals with elevated ZPP levels to be certain that an associated elevated blood lead level has not been missed due to transient fluctuations in blood leads.

ZPP has a characteristic fluorescence spectrum with a peak at 594 nm which is detectable with a hematofluorimeter. The hematofluorimeter is accurate and portable and can provide on-site, instantaneous results for workers who can be frequently tested via a finger prick.

However, careful attention must be given to calibration and quality control procedures. Limited data on blood lead-ZPP correlations and the ZPP levels which are associated with the adverse health effects discussed in Section 2 are the major limitations of the test. Also it is difficult to correlate ZPP levels with environmental exposure and there is some variation of response with age and sex. Nevertheless, the ZPP promises to be an important diagnostic test for the early detection of lead toxicity and its value will increase as more data is collected regarding its relationship to other manifestations of lead poisoning.

Levels of delta-aminolevulinic acid (ALA) in the urine are also used as a measure of lead exposure. Increasing concentrations of ALA are believed to result from the inhibition of the enzyme delta-aminolevulinic acid dehydrase (ALA-D). Although the test is relatively easy to perform, inexpensive, and rapid, the disadvantages include variability in results, the necessity to collect a complete 24 hour urine sample which has a specific gravity greater than 1.010, and also the fact that ALA decomposes in the presence of light.

The pattern of porphyrin excretion in the urine can also be helpful in identifying lead intoxication. With lead poisoning, the urine concentrations of coproporphyrins I and II, porphobilinogen and uroporphyrin I rise. The most important increase, however, is that of coproporphyrin III; levels may exceed 5,000 µg/l in the urine in lead poisoned individuals, but its correlation with blood lead levels and ZPP are not as good as those of ALA. Increases in urinary porphyrins are not diagnostic of lead toxicity and may be seen in porphyria, some liver diseases, and in patients with high reticulocyte counts.

Summary. The Occupational Safety and Health Administration's interim standard for inorganic lead in the construction industry places significant emphasis on the medical surveillance of all workers exposed to levels of inorganic lead above 30 µg/m^3 TWA. The physician has a fundamental role in this surveillance program, and in the operation of the medical removal protection program.

Even with adequate worker education on the adverse health effects of lead and appropriate training in work practices, personal hygiene and other control measures, the physician has a primary responsibility for evaluating potential lead toxicity in the worker. It is only through a careful and detailed medical and work history, a complete physical examination and appropriate laboratory testing that an accurate assessment can be made. Many of the adverse health effects of lead toxicity are either irreversible or only partially reversible and therefore early detection of disease is very important.

This document outlines the medical monitoring program as defined by the occupational safety and health standard for inorganic lead. It reviews the adverse health effects of lead poisoning and describes the important elements of the history and physical examinations as they relate to these adverse effects. Finally, the appropriate laboratory testing for evaluating lead exposure and toxicity is presented.

It is hoped that this review and discussion will give the physician a better understanding of the OSHA standard with the ultimate goal of protecting the health and well-being of the worker exposed to lead under his or her care.

Appendix D to § 1926.62— Qualitative and Quantitative Fit Test Protocols

I. Fit Test Protocols

A. General: The employer shall include the following provisions in the fit test procedures. These provisions apply to both qualitative fit testing (QLFT) and quantitative fit testing (QNFT) permissible for compliance with paragraph (f)(3)(ii) of § 1926.62. All testing is to be conducted annually.

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask; or three sizes of full facepiece. Respirators of each size must be provided from at least two manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator

which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted, maintained and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) position of the mask on the nose;
(b) room for eye protection;
(c) room to talk; and
(d) position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) chin properly placed;
(b) adequate strap tension, not overly tightened;
(c) fit across nose bridge;
(d) respirator of proper size to span distance from nose to chin;
(e) tendency of respirator to slip; and
(f) self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or in ANSI Z88.2–1980. Before conducting the negative or positive pressure test, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

(a) *Positive pressure check.* Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

(b) *Negative pressure check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician to determine whether the test subject can wear a respirator while performing her or his duties.

11. If at any time within the first two week of use the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall maintain a record of the fit test administered to an employee. The record shall contain at least the following information:

(a) name of employee;
(b) type of respirator;
(c) brand, size of respirator;
(d) date of test;
(e) where QNFT is used: the fit factor, strip chart recording or other recording of the results of the test. The record shall be maintained until the next fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage (see below), count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) Grimace. The test subject shall grimace by smiling or frowning.

(g) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) Normal breathing. Same as exercise 1.

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols. 1. *General* (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. *Isoamyl Acetate Protocol.* (a) Odor threshold screening. The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled, dried off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell

banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl acetate fit test.

(1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test has failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber and again begin the procedure described in (I)(B)(2)(b) (1) through (7) of this appendix. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so there is no significant IAA concentration build-up in the test chamber during subsequent tests.

3. *Saccharin Solution Aerosol Protocol.* The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾ inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see (b)(5) below) in 100 cc of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure

(1) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in I. B. 3. (a) of this appendix.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. B. 3. (a) of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(6) As before, the test subject shall breathe through the wide open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 14 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

(12) Successful completion of the test protocol shall allow the use of the tested respirator in contaminated atmospheres up to 10 times the PEL. In other words, this protocol may be used for assigned protection factors no higher than 10.

4. *Irritant Fume Protocol.* (a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristic odor.

(c) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(d) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 14 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocol. 1. General. (a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. Definitions. (a) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(b) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(c) Test subject means the person wearing the respirator for quantitative fit testing.

(d) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(e) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(f) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(g) "Fit Factor" means the ration of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. Apparatus. (a) Instrumentation. Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(d) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(g) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(i) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. Procedural Requirements. (a) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(b) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(h) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g. half mask respirator, full facepiece respirator).

(i) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration inside the respirator.

(2) The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak concentration

(ii) Maximum peak concentration

(iii) Integration by calculation of the area under the individual peak for each exercise. This includes computerized integration.

(j) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(k) The test subject shall not be permitted to wear a half mask, or full facepiece

respirator unless a minimum fit factor equivalent to at least 10 times the hazardous exposure level is obtained.

(l) Filters used for quantitative fit testing shall be replaced at least weekly, or whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

[FR Doc. 93-10102 Filed 4-27-93; 4:12 pm]

BILLING CODE 4510-26-P

federal register

Tuesday
May 4, 1993

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 430, 436, et al.
Antibiotic Drugs; Clarithromycin, Clarithromycin Tablets, et al.; Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 430, 436, and 452

[Docket No. 91N-0458]

Antibiotic Drugs; Clarithromycin, Clarithromycin Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new antibiotic drug, clarithromycin, and the use of the antibiotic drug in a dosage form, clarithromycin tablets. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and request for hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, clarithromycin, and its use in a dosage form, clarithromycin tablets. The agency has concluded that the data supplied by the manufacturer concerning these antibiotic drugs are adequate to establish their safety and efficacy when used as directed in the labeling and that the regulations should be amended in 21 CFR parts 430, 436, and 452 to provide for the inclusion of accepted standards for these products.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for a hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this document and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Part 436

Antibiotics.

21 CFR Part 452

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 430, 436, and 452 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

2. Section 430.4 is amended by adding new paragraph (a)(64) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(64) *Clarithromycin.* Clarithromycin is 6-O-methylerythromycin A.

* * * * *

3. Section 430.5 is amended by adding new paragraphs (a)(99) and (b)(101) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(99) *Clarithromycin.* The term "clarithromycin master standard" means a specific lot of clarithromycin that is designated by the Commissioner as the standard of comparison in determining the potency of the clarithromycin working standard.

(b) * * *

(101) *Clarithromycin.* The term "clarithromycin working standard" means a specific lot of a homogeneous preparation of clarithromycin.

4. Section 430.6 is amended by adding new paragraph (b)(101) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(101) *Clarithromycin.* The term "microgram" applied to clarithromycin means the clarithromycin (potency) contained in 1.010 micrograms of the clarithromycin master standard.

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

5. The authority citation for 21 CFR part 436 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

6. Section 436.215 is amended by alphabetically adding a new entry to the table in paragraph (b) and by adding new paragraph (c)(13) to read as follows:

§ 436.215 Dissolution test.

* * * * *

(b) * * *

Dosage form	Dissolution medium	Rotation rate[1]	Sampling time(s)	Apparatus
*	*	*	*	*
Clarithromycin tablets	900 mL 0.10 *M* sodium acetate buffer, pH 5.0.	50	30 min	2
*	*	*	*	*

[1] Rotation rate of basket or paddle stirring element (revolutions per minute).

(c) * * *

(13) *Clarithromycin.* Proceed as directed in § 452.50(b)(1) of this chapter except:

(i) *Dissolution medium.* Instead of the mobile phase described in § 452.50(b)(1)(i) of this chapter, use 0.10 *M* sodium acetate buffer prepared as follows: Weigh 13.6 grams of sodium acetate trihyrate into a container sufficient to hold 1 liter of solution. Dissolve the salt in 750 milliliters of distilled water. Adjust the pH of the solution to 5.0±0.05 with glacial acetic acid. Dilute to 1,000 milliliters with distilled water.

(ii) *Preparation of the standard and sample solutions*—(a) *Standard solution.* Dissolve (with shaking or sonication) an accurately weighed portion of the clarithromycin working standard, in sufficient methanol to obtain a solution having a known concentration of approximately 625 micrograms per milliliter of clarithromycin. Quantitatively transfer and dilute an aliquot of this solution with mobile phase (described in § 452.50(b)(1)(i) of this chapter) and mix to obtain a solution of known concentration of approximately 125 micrograms per milliliter of clarithromycin.

(b) *Sample solution.* Use the sample solution as it is removed from the dissolution vessel after diluting and mixing with mobile phase (described in § 452.50(b)(1)(i) of this chapter) 1:2 for the 250-milligram tablet and 1:4 for the 500-milligram tablet.

(c) *Calculations.* Determine the total amount of clarithromycin activity dissolved as follows:

$$T = \frac{A_U \times c \times d \times 900}{A_S}$$

where:

T = Total milligrams of clarithromycin activity dissolved;

A_U = Area of the clarithromycin peak (at a retention time equal to that observed for the standard) in the chromatogram of the sample;

A_S = Area of the clarithromycin peak in the chromatogram of the clarithromycin standard;

c = Clarithromycin activity in the clarithromycin working standard solution in milligrams per milliliter; and

d = Dilution factor of sample filtrate.

* * * * *

PART 452—MACROLIDE ANTIBIOTIC DRUGS

7. The authority citation for 21 CFR part 452 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

8. New § 452.50 is added to subpart A to read as follows:

§ 452.50 Clarithromycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clarithromycin is 6-O-methylerythromycin A. It is so purified and dried that:

(i) Its potency is not less than 960 micrograms of clarithromycin activity per milligram, on an anhydrous basis.

(ii) Its moisture content is not more than 2.0 percent.

(iii) The pH of a 0.2 percent (weight per volume) slurry in aqueous methanol (95:5) is not less than 7.5 and not more than 10.0.

(iv) Its residue on ignition is not more than 0.3 percent.

(v) Its heavy metals content is not more than 20 parts per million.

(vi) Its specific rotation in chloroform containing 10 milligrams of clarithromycin per milliliter at 20 °C is between -89° and -95°, calculated on an anhydrous basis.

(vii) It gives a positive identity test.

(viii) 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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for clarithromycin potency, moisture, pH, residue on ignition, heavy metals, specific rotation, identity, and crystallinity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.216 of this chapter, using a constant column temperature of 50 °C, a suitable ultraviolet detection system operating at 210 nanometers, an analytical column 3 to 30 centimeters long packed with a reversed phase packing material such as octadecyl hydrocarbon bonded silicas (3 to 10 micrometers in diameter), the inlet of this column is connected to a guard column 1 to 5 centimeters in length packed with the same material of 5- to 30-micrometer particle size, a constant flow rate of 0.7 to 1.0 milliliters per minute, and a known injection volume of between 10 and 20 microliters. The retention time for clarithromycin is between 5 and 6 minutes and the retention time for 6,11-Di-O-

methylerythromycin A (resolution compound) is between 7 and 8 minutes. Mobile phase, system suitability solution, working standard and sample solutions, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Add 650 milliliters of methanol and 350 milliliters of 0.067 *M* potassium phosphate (monobasic) to a suitable container, mix well, and adjust the pH to 4.0 with phosphoric acid. Filter through a suitable filter capable of removing particulate matter to 0.5 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph.

(ii) *Preparation of system suitability solution.* Prepare a methanol solution containing approximately 625 micrograms per milliliter each of clarithromycin and 6,11-Di-O-methylerythromycin A. Quantitatively transfer an aliquot of this solution to a suitable volumetric flask and dilute it to volume with mobile phase to obtain a solution containing approximately 125 micrograms each of clarithromycin and 6,11-Di-O-methylerythromycin A.

(iii) *Preparation of working standard solution.* Dissolve (by shaking or sonication) an accurately weighed portion of the clarithromycin working standard in sufficient methanol to obtain a known solution containing about 625 micrograms of clarithromycin activity per milliliter. Quantitatively transfer an aliquot of this solution to a suitable volumetric flask and dilute to volume with mobile phase and mix to obtain a known solution containing approximately 125 micrograms of clarithromycin activity per milliliter. Filter through a suitable filter capable of removing particulate matter to 0.5 micron in diameter.

(iv) *Sample solution.* Dissolve (by shaking or sonication) an accurately weighed portion of the sample in sufficient methanol to obtain a solution containing 625 micrograms of clarithromycin activity per milliliter (estimated). Quantitatively transfer an aliquot of this solution to a suitable volumetric flask and dilute to volume with mobile phase and mix to obtain a known solution containing approximately 125 micrograms of clarithromycin activity per milliliter (estimated). Filter through a suitable filter capable of removing particulate matter to 0.5 micron in diameter.

(v) *System suitability requirements*—(A) *Asymmetry factor.* The asymmetry factor (A_S) is satisfactory if it is not less than 0.9 and not more than 1.5 for the clarithromycin peak.

(B) *Efficiency of the column.* The absolute efficiency (h_r) is satisfactory if it is not more than 40.0 for the clarithromycin peak.

(C) *Resolution factor.* The resolution factor (R) between the peak for clarithromycin and the peak for 6,11-Di-O-methylerythromycin A is satisfactory if it is not less than 2.0.

(D) *Coefficient of variation (relative standard deviation).* The coefficient of variation (S_R in percent of 5 replicate injections) is satisfactory if it is not more than 2.0 percent.

(E) *Capacity factor.* Calculate the clarithromycin capacity factor (k') as follows:

$$k' = (t_r/t_0)-1$$

where:

t_r = Retention time of the clarithromycin peak; and

t_0 = Void volume time.

The capacity factor is satisfactory if it is not less than 1.3 and not more than 4.0. If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(vi) *Calculations.* Calculate the micrograms of clarithromycin per milligram of sample on an anhydrous basis as follows:

$$\text{Micrograms of clarithromycin per milligram} = \frac{A_U \times P_S \times 100}{A_S \times C_U \times (100-m)}$$

where:

A_U = Area of the clarithromycin peak (at a retention time equal to that observed for the clarithromycin standard) in the chromatogram of the sample;

A_S = Area of the clarithromycin peak in the chromatogram of the clarithromycin working standard;

P_S = Clarithromycin activity in the clarithromycin working standard solution in micrograms per milliliter;

C_U = Milligrams of sample per milliliter of sample solution; and

m = Percent moisture content of the sample.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter, using the sample preparation described in paragraph (d)(1) of that section and the titration procedure described in paragraph (e)(3) of that section, except that instead of adding 20 milliliters of solvent A before starting the titration, add a sufficient volume of solvent C to cover the electrodes in the dry titrating vessel.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, except standardize the pH meter with pH 7.0 and pH 10.0 buffers and prepare the sample as follows: Transfer 200 milligrams of the sample to a 150-milliliter beaker. Add 5 milliliters of methanol and then 95 milliliters of distilled water. Place the pH electrodes in the slurry and stir at the slowest speed possible to ensure mixing but no vortex. After 10 minutes, while still stirring, determine the pH.

(4) *Residue on ignition.* Proceed as directed in § 436.207(a) of this chapter.

(5) *Heavy metals.* Proceed as directed in § 436.208 of this chapter.

(6) *Specific rotation.* Dilute an accurately weighed sample with sufficient chloroform to give a concentration of approximately 10 milligrams of clarithromycin per milliliter. Proceed as directed in § 436.210 of this chapter, using a 1.0-decimeter polarimeter tube, maintaining the solution at 20 °C, and calculate the specific rotation on an anhydrous basis.

(7) *Identity.* Proceed as directed in § 436.211 of this chapter, preparing the sample as follows: Prepare a 5-percent solution of the sample in chloroform and use 0.1 millimeter matched absorption cells.

(8) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

9. New § 452.150 is added to subpart B to read as follows:

§ 452.150 Clarithromycin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clarithromycin tablets are composed of clarithromycin and one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. Each tablet contains 250 milligrams or 500 milligrams of clarithromycin activity. Its clarithromycin content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of clarithromycin that it is represented to contain. The loss on drying is not more than 6.0 percent. It passes the dissolution test. It passes the identity test. The clarithromycin used conforms to the standards prescribed by § 452.50(a)(1).

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The clarithromycin used in making the batch for potency, moisture, pH, residue on ignition, heavy metals, specific rotation, identity, and crystallinity.

(B) The batch for content, loss on drying, dissolution, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The clarithromycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 tablets.

(b) *Tests and methods of assay*—(1) *Clarithromycin content.* Proceed as directed in § 452.50(b)(1), preparing the sample solution and calculating the clarithromycin content as follows:

(i) *Preparation of sample solution.* Grind and composite five whole tablets in a glass mortar and pestle and quantitatively transfer the powder to a 500-milliliter volumetric flask with 50 milliliters of distilled water and shake mechanically until the tablets are well dispersed (approximately 5 to 10 minutes). Add 300 milliliters of methanol and shake mechanically for 30 minutes. Dilute with methanol to volume and mix. Allow the excipients to settle. Quantitatively transfer and dilute a convenient aliquot of the supernatant with mobile phase (described in § 452.50(b)(1)(i)) to obtain a solution containing 125 micrograms of clarithromycin per milliliter (estimated). Filter through a suitable filter capable of removing particulate matter 0.5 micron in diameter.

(ii) *Calculations.* Calculate the clarithromycin content as follows:

$$\text{Milligrams of clarithromycin per tablet} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000 \times n}$$

where:

A_U = Area of the clarithromycin peak (at a retention time equal to that observed for the clarithromycin standard) in the chromatogram of the sample;

A_S = Area of the clarithromycin peak in the chromatogram of the clarithromycin working standard;

P_S = Clarithromycin activity in the clarithromycin working standard solution in micrograms per milliliter;

d = Dilution factor of the sample; and

n = Number of tablets in the sample.

(2) *Loss on drying.* Proceed as directed in § 436.200(c) of this chapter, using a sample weight of 1 to 2 grams.

(3) *Dissolution.* Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of clarithromycin dissolved) is 80 percent at 30 minutes.

(4) *Identity.* Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention time for the peak of the active ingredient must be within 2 percent of the retention time for the peak of the corresponding reference standard.

Dated: March 26, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 93-10311 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

Food and Drug Administration

21 CFR Parts 430, 436, and 452

[Docket No. 92N-0112]

Antibiotic Drugs; Azithromycin, Azithromycin Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new antibiotic drug, azithromycin, and the use of the antibiotic drug in a dosage form, azithromycin capsules. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and request for hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, azithromycin, and its use in a dosage form, azithromycin capsules. The agency has concluded that the data supplied by the manufacturer concerning these antibiotic drugs are adequate to establish their safety and efficacy when used as directed in the labeling and that the regulations should be amended in 21 CFR parts 430, 436, and 452 to provide for the inclusion of accepted standards for these products.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this document and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information

prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Parts 436 and 452

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 430, 436, and 452 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

2. Section 430.4 is amended by adding new paragraph (a)(65) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(65) *Azithromycin.* Azithromycin is an antibiotic substance having the chemical structure described by the following name: (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-*L-ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-*D-xylo*-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

* * * * *

3. Section 430.5 is amended by adding new paragraphs (a)(100) and (b)(102) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(100) *Azithromycin.* The term "azithromycin master standard" means a specific lot of azithromycin that is designated by the Commissioner as the standard of comparison in determining the potency of the azithromycin working standard.

(b) * * *

(102) *Azithromycin.* The term "azithromycin working standard" means a specific lot of a homogeneous preparation of azithromycin.

4. Section 430.6 is amended by adding new paragraph (b)(102) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(102) *Azithromycin.* The term "microgram" applied to azithromycin means the azithromycin (potency) contained in 1.063 micrograms of the azithromycin master standard.

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

5. The authority citation for 21 CFR part 436 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

6. Section 436.215 is amended by alphabetically adding a new entry to the table in paragraph (b) and by adding new paragraph (c)(14) to read as follows:

§ 436.215 Dissolution test.

* * * * *

(b) * * *

Dosage form	Dissolution medium	Rotation rate[1]	Sampling time(s)	Apparatus
*	*	*	*	*
Azithromycin capsules	900 mL 0.10 *M* sodium phosphate buffer, pH 6.0, 0.1 mg/mL trypsin	100	45 min	2
*	*	*	*	*

[1] Rotation rate of basket or paddle stirring element (revolutions per minute).

(c) * * *

(14) *Azithromycin.* Proceed as directed in § 452.60(b)(1) of this chapter, except:

(i) *Dissolution medium.* Dissolve 85.2 grams of sodium phosphate dibasic and dilute to volume with ultrapure deionized or high-performance liquid chromatographic-grade water in a stoppered 2-liter graduated cylinder. Dilute this entire solution in an appropriate, suitably sized container with 4 liters of ultrapure deionized or high-performance liquid chromatographic-grade water. Adjust the pH to 6.0±0.05 with concentrated hydrochloric acid (about 40.5 milliliters). Add 600 milligrams of trypsin and mix well.

(ii) *Preparation of the standard and sample solutions*—(a) *Standard solution.* Accurately weigh approximately 15 milligrams of the azithromycin working standard into a 50-milliliter volumetric flask. Add 25 milliliters of the dissolution medium and sonicate briefly. Dilute to volume with dissolution medium and mix well. Pipet 2.0 milliliters of this solution into a 25-milliliter volumetric flask and dilute to volume with the mobile phase described in § 452.60(b)(1)(i) of this chapter. Pipet 4.0 milliliters of this solution into a 25-milliliter volumetric flask and bring to volume with the mobile phase.

(*b*) *Sample solution.* Filter the sample solutions through a 0.45-micron filter before use. Pipet 2.0 milliliters of the filtered aliquot into a 25-milliliter volumetric flask and dilute to volume with the mobile phase described in § 452.60(b)(1)(i) of this chapter. Pipet 4.0 milliliters of this solution into another 25-milliliter volumetric flask and bring to volume with the mobile phase. The solution is stable at room temperature for 24 hours.

(c) *Calculations.* Determine the percent of azithromycin dissolved as follows:

$$\text{Percent azithromycin dissolved} = \frac{A_U \times P_S \times D_F \times 100}{A_S \times W_U}$$

where:

A_U = Area of the azithromycin peak (at a retention time equal to that observed for the standard) in the chromatogram of the sample;

A_S = Area of the azithromycin peak in the chromatogram of the azithromycin standard;

P_S = Azithromycin activity in the azithromycin working standard solution in micrograms per milliliter;

$$DF = \text{Dilution factor} = \frac{900^{1} \times 25 \times 25}{2 \times 4}$$

[1] If more than 15 milliliters of dissolution medium are removed, correct for the volume removed; and

W_U = Theoretical azithromycin content (mg) of capsule.

* * * * *

PART 452—MACROLIDE ANTIBIOTIC DRUGS

7. The authority citation for 21 CFR part 452 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

8. New § 452.60 is added to subpart A to read as follows:

§ 452.60 Azithromycin.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Azithromycin is the dihydrate form of (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-*L*-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-*D*-*xylo*-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one. It is so purified and dried that:

(i) Its potency is not less than 945 micrograms and not more than 1,030 micrograms of azithromycin activity per milligram, on the anhydrous basis.

(ii) Its moisture content is not less than 4.0 percent and not more than 5.0 percent.

(iii) The pH of an aqueous methanol (1:1) solution containing 2 milligrams per milliliter is not less than 9 and not more than 11.

(iv) Its residue on ignition is not more than 0.3 percent.

(v) Its heavy metals content is not more than 25 parts per million.

(vi) The specific rotation in absolute ethanol containing 20 milligrams of azithromycin per milliliter at 20 °C is between -45° to -49°, calculated on an anhydrous basis.

(vii) It is crystalline.

(viii) It gives a positive identity test.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for azithromycin potency, moisture, pH, residue on ignition, heavy metals, specific rotation, crystallinity, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an amperometric electrochemical detection system with dual glassy carbon electrodes operated in the oxidative screen mode with electrode 1 set at +0.70 volt±0.05 volt and electrode 2 at +0.82 volt±0.05 volt. (The ±0.05-volt variance allows for optimization of the background current to 70 to 100 nanoamperes.) Detection of azithromycin occurs at electrode 2 where the voltage is sufficiently high to oxidize the amine functional groups on the molecules. Use a 15-centimeters by 4.6-millimeters (inside diameter) column packed with alumina-based polybutadiene 5 micrometer spherical particles with 80-angstrom pore size (e.g., ES Industries γRP1/p). The inlet of this column is connected to a guard column 5 centimeters by 4.6 millimeters (inside diameter) packed with the same material. The flow rate is 1.5 milliliters per minute. Use a fixed volume loop injector or equivalent device to inject a volume of 50 microliters into the system. The retention time for azithromycin is between 10 and 13 minutes. Mobile phase, working standard, sample, and resolution solutions, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Dissolve 5.8 grams of potassium phosphate monobasic in 2,130 milliliters of ultrapure deionized or high-performance liquid chromatographic-grade water. Add 870 milliliters of acetonitrile and mix. The mobile phase is 0.02 *M* potassium phosphate monobasic: acetonitrile (71:29). Adjust the pH of the mobile phase to pH 11.0±0.1 with 10 *M* potassium hydroxide (about 6 milliliters). Filter the mobile phase through a suitable filter capable of removing particulate matter 0.5 micron in diameter and degas it just prior to its introduction into the chromatograph.

(ii) *Preparation of working standard solution.* Accurately weigh approximately 16.5 milligrams of the azithromycin working standard into a 100-milliliter volumetric flask. Dissolve the material, aided by brief sonication, in 10 milliliters of acetonitrile and dilute to volume with acetonitrile. Pipet 2.0 milliliters of this solution into a 100-milliliter volumetric flask and dilute to volume with mobile phase. This solution contains approximately 0.003 milligram per milliliter of azithromycin.

(iii) *Sample solution.* Accurately weigh approximately 16.5 milligrams of sample into a 100-milliliter volumetric flask. Dissolve the sample, aided by brief sonication, in 10 milliliters of acetonitrile and dilute to volume with acetonitrile. Pipet 2.0 milliliters of this solution into a 100-milliliter volumetric flask and dilute to volume with mobile phase.

(iv) *Resolution test solution.* Weigh approximately 16.5 milligrams each of azithromycin working standard and azaerythromycin A reference standard into a 100-milliliter volumetric flask. Dissolve the materials aided by brief sonication in 10 milliliters of acetonitrile and dilute to volume with acetonitrile. Pipet 2.0 milliliters of this solution into a 100-milliliter volumetric flask and dilute to volume with mobile phase.

(v) *System suitability requirements.* Using the resolution test solution, determine the:

(A) *Asymmetry factor.* The asymmetry factor (A_S) is satisfactory if it is not less than 0.9 and not more than 1.5 for the azithromycin peak.

(B) *Efficiency of the column.* The absolute efficiency (h_t) is satisfactory if it is not more than 40.0 for the azithromycin peak.

(C) *Resolution factor.* The resolution factor (R) between the peak from azithromycin and the peak for azaerythromycin A is satisfactory if it is not less than 2.5.

(D) *Coefficient of variation (relative standard deviation).* The coefficient of variation (S_R in percent of 5 replicate injections) is satisfactory if it is not more than 2.0 percent. If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(vi) *Calculations.* Calculate the micrograms of azithromycin per milligram of sample on an anhydrous basis as follows:

$$\text{Micrograms of azithromycin per milligram} = \frac{A_U \times P_S \times 100}{A_S \times C_U \times (100-m)}$$

where:

A_U = Area of the azithromcin peak (at a retention time equal to that observed for the azithromycin standard) in the chromatogram of the sample;

A_S = Area of the azithromcin peak in the chromatogram of the azithromycin working standard;

P_S = Azithromycin activity in the azithromycin working standard solution in micrograms per milliliter;

C_U = Milligrams of sample per milliliter of sample solution; and

m = Percent moisture content of the sample.

(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 methanol (1:1) solution containing 2 milligrams per milliliter, prepared by diluting a methanol solution containing 4 milligrams of azithromycin dihydrate 1:1 with distilled water.

(4) *Residue on ignition.* Proceed as directed in § 436.207(b) of this chapter, except use a temperature of 800 °C instead of a temperature range of 500 to 600 °C.

(5) *Heavy metals.* Proceed as directed in § 436.208 of this chapter.

(6) *Specific rotation.* Dissolve an accurately weighed sample with sufficient absolute ethanol to give a concentration of approximately 20 milligrams per milliliter. Proceed as directed in § 436.210 of this chapter, except dilute and maintain the test solution at 20 °C instead of 25 °C. Use a 1.0-decimeter polarimeter tube and calculate the specific rotation on an anhydrous basis.

(7) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(8) *Identity.* Proceed as directed in § 436.211 of this chapter, using a 0.5 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

9. New § 452.160 is added to subpart B to read as follows:

§ 452.160 Azithromycin capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Azithromycin capsules are composed of azithromycin and one or more suitable and harmless diluents, disintegrants, lubricants, and wetting agents enclosed in a gelatin capsule. Each capsule contains azithromycin equivalent to 250 milligrams of azithromycin. The azithromycin content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of azithromycin that it is represented to contain. The moisture content of the capsules is not more than 5.0 percent. The capsules pass the dissolution test. The capsules pass the identity test. The azithromycin used conforms to the standards prescribed by § 452.60(a)(1) of this part.

(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 § 431.1 of this chapter, each such request shall contain;

(i) Results of tests and assays on:

(A) The azithromycin used in making the batch for potency, moisture, pH, residue on ignition, heavy metals, specific rotation, crystallinity, and identity.

(B) The batch for content, moisture, dissolution, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The azithromycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 capsules.

(b) *Tests and methods of assay*—(1) *Azithromycin content.* Proceed as directed in § 452.60(b)(1), preparing the sample solution and calculating the azithromycin content as follows:

(i) *Preparation of sample solution.* Quantitatively transfer the contents of one capsule into a 250-milliliter volumetric flask. Add about 175 milliliters of acetonitrile and shake on a reciprocating shaker for 30 minutes. Dilute to volume with acetonitrile, stopper the flask and mix well. Place 40 milliliters of the resulting suspension into a suitably sized centrifuge tube. Stopper the tube and centrifuge the suspension (about 10 minutes at 1,000 rpm). Pipet 2.0 milliliters of the supernatant into a 50-milliliter volumetric flask and dilute to volume with the mobile phase. Pipet 2.0 milliliters of this solution into a 25-milliliter volumetric flask and dilute to volume with mobile phase. The final dilution of the sample and standard must be identical. The final concentration of azithromycin in the sample solution is 0.003 milligram per milliliter (estimated).

(ii) *Calculations.* Calculate the azithromycin content as follows:

$$\text{Milligrams of azithromycin per capsule} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000}$$

where:

A_U = Area of the azithromycin peak (at a retention time equal to that observed for the azithromycin standard) in the chromatogram of the sample;

A_S = Area of the azithromycin peak of the azithromycin working standard;

P_S = Azithromycin activity in the azithromycin working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample = 250×50×25/2×2.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Dissolution test.* Proceed as directed in § 436.215 of this chapter. The quantity Q (the percentage of azithromycin activity dissolved) is 75 percent within 45 minutes.

(4) *Identity.* Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section the retention time for the peak of the active ingredient must be with 2 percent of the retention time for the peak of the corresponding reference standard.

Dated: March 26, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Reasearch.

[FR Doc. 93–10312 Filed 5–3–93; 8:45 am]

BILLING CODE 4160-01-F

---

21 CFR Parts 430, 436, and 442

[Docket No. 92N–0041]

Antibiotics Drugs; Cefprozil, Cefprozil Tablets, and Cefprozil for Oral Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new antibiotic drug, cefprozil, and the use of the antibiotic drug in two dosage forms, cefprozil tablets and cefprozil for oral suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and request for hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, cefprozil, and its use in two dosage forms, cefprozil tablets and cefprozil for oral suspension. The agency has concluded that the data supplied by the manufacturer concerning these antibiotic drugs are adequate to establish their safety and efficacy when

used as directed in the labeling and that the regulations should be amended in 21 CFR parts 430, 436, and 442 to provide for the inclusion of accepted standards for these products.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Part 436

Antibiotics.

21 CFR Part 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 430, 436, and 442 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

2. Section 430.4 is amended by adding new paragraph (a)(66) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(66) *Cefprozil.* Cefprozil is an antibiotic substance having the chemical structure described by the following name: (6*R*,7*R*)-7-[(*R*)-2-amino-2-(*p*-hydroxyphenyl)acetamido]8-oxo-3-propenyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is a mixture of the Z (cis) and E (trans) isomers in an approximate ratio of 9:1, respectively.

* * * * *

3. Section 430.5 is amended by adding new paragraphs (a)(101) and (b)(103) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(101) *Cefprozil.* The term "cefprozil master standard" means a specific lot of the (Z) isomer of cefprozil and a specific lot of the (E) isomer of cefprozil that are designated by the Commissioner as the standard of comparison in determining the potency of the cefprozil working standard.

(b) * * *

(103) *Cefprozil.* The term "cefprozil (Z) working standard" means a specific lot of a homogeneous preparation of cefprozil (Z). The term "cefprozil (E) working standard" means a specific lot of a homogeneous preparation of cefprozil (E).

4. Section 430.6 is amended by adding new paragraph (b)(103) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(103) *Cefprozil.* The term "microgram" applied to cefprozil (Z) means the cefprozil (Z) potency contained in 1.060 micrograms of the cefprozil (Z) master standard. The term "microgram" applied to cefprozil (E) means the cefprozil (E) potency contained in 1.106 micrograms of the cefprozil (E) master standard.

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

5. The authority citation for 21 CFR part 436 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

6. Section 436.215 is amended by alphabetically adding a new entry to the table in paragraph (b) and by adding a new paragraph (c)(15) to read as follows:

§ 436.215 Dissolution test.

* * * * *

(b) * * *

Dosage form	Dissolution medium	Rotation rate [1]	Sampling time(s)	Apparatus
*	*	*	*	*
Cefprozil tablets	900 mL purified water	100	45 min	1
*	*	*	*	*

[1] Rotation rate of basket or paddle stirring element (revolutions per minute)

(c) * * *

(15) *Cefprozil.* Proceed as directed in § 442.80(b)(1) of this chapter except:

(i) *Sample solutions.* Filter the sample solutions through a 0.45-micron filter before use. Use the sample solution as it is removed from the dissolution vessel without further dilution for the 250-milligram tablet; prepare the sample solution for the 500-milligram tablet by diluting a 5-milliliter aliquot of the filtered solution to volume in a 10-milliliter volumetric flask with distilled water.

(ii) *Calculations.* Determine the total percent of cefprozil dissolved as follows:

$$\text{Total percentage dissolved} = (\text{mg cefprozil (Z) dissolved} + \text{mg cefprozil (E) dissolved})/\text{label claim}$$

$$\text{Milligrams of cefprozil (Z) or cefprozil (E) dissolved} = \frac{A_U \times c \times d \times 900}{A_S}$$

where:

A_U = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the cefprozil (Z) or cefprozil (E) standard;

c = Concentration of the cefprozil (Z) or cefprozil (E) working standard solution in milligrams per milliliter; and

d = Dilution factor of the sample filtrate.

* * * * *

7. New § 436.368 is added to subpart F to read as follows:

§ 436.368 Thin layer chromatographic identity test for cefprozil.

(a) *Equipment*—(1) *Chromatography tank.* Use a glass rectangular tank approximately 23 x 23 x 9 centimeters lined with filter paper and equipped with a tight-fitting cover.

(2) *Plates.* Use 20 x 20 centimeter thin layer chromatography plates coated with silica gel GF to a thickness of 250 microns.

(b) *Reagents*—(1) *Diluent.* Mix 0.1N HCl and acetone in volumetric proportions of 1:4.

(2) *Developing solvent.* Mix n-butanol, glacial acetic acid and water in volumetric proportions of 60:20:20.

(3) *Detection reagent.* Iodine vapor.

(c) *Assay solutions*—(1) *Reference standard solution.* Dissolve 50 milligrams of cefprozil (Z) reference standard in 10 milliliters of diluent.

(2) *Sample solution.* Place an amount of sample containing approximately 50 milligrams of cefprozil in a 20-milliliter glass stoppered vial. Add 10 milliliters of diluent. Shake for 5 minutes and allow the solids to settle.

(d) *Procedure.* Pour a suitable quantity of the developing solvent into a glass, chromatographic tank lined with filter paper and allow to equilibrate for 1 hour. On a line 2 centimeters from the bottom edge of the plate, spot 10 microliters each of the reference solution and sample solution. Draw a line indicating the distance to which the developing solvent must travel at a point 12 centimeters from the bottom edge of the plate. Place the plate in the tank and allow the solvent to migrate to the finishing line. Remove the plate and air dry in a fume hood. Place the dried plate in a chamber containing iodine vapors.

(e) *Evaluation.* Measure the distance the solvent front traveled from the starting line, and the distance the spots are from the starting line. Divide the latter by the former to calculate the R_f value. The identity test is positive if the sample solution produces a yellow spot at the same R_f value and has the same appearance as the spot obtained for the reference solution. The R_f value for cefprozil (Z) is approximately 0.45. Cefprozil (E), has an R_f value of approximately 0.47.Cefprozil (Z) is "absent" if the above test is performed and no spots, which correspond to those from the reference solution, are obtained for the sample.

PART 442—CEPHA ANTIBIOTIC DRUGS

8. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

9. New § 442.80 is added to subpart A to read as follows:

§ 442.80 Cefprozil.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefprozil is an approximate 9:1 mixture of the Z (cis) and the E (trans) isomers, respectively, of (6*R*,7*R*)-7-[(*R*)-2-amino-2-(*p*-hydroxyphenyl)acetamido]8-oxo-3-propenyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms nor more than 1,050 micrograms of cefprozil activity per milligram, on an anhydrous basis.

(ii) The ratio of its (E) isomer to total cefprozil is not less than 0.06 nor more than 0.11.

(iii) Its moisture content is not less than 3.5 percent nor more than 6.5 percent.

(iv) The pH of an aqueous solution containing 5 milligrams per milliliter is not less than 3.5 nor more than 6.5.

(v) It is crystalline.

(vi) It gives positive identity tests.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for cefprozil potency, E isomer to total cefprozil ratio, moisture, pH, crystallinity, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 280 nanometers, a 25 centimeter x 3.9 to 4.6 millimeter (id) column packed with microparticulate (5 to 10 micrometers in diameter) reversed phase packing material such as octadecyl silane bonded to silicas, a flow rate of 1.0 milliliter per minute, and a known injection volume of 10 microliters. The retention time for cefprozil (Z) is between 4 and 6 minutes and the

retention time for cefprozil (E) is between 6 and 8 minutes. Mobile phase, working standard and sample solutions, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Dissolve 20.7 grams of ammonium phosphate, monobasic in 1,800 milliliters of water and adjust the pH to 4.4 with phosphoric acid, if necessary. Add 200 milliliters of acetonitrile and mix. Filter the mobile phase through a suitable filter capable of removing particulate matter 0.5 micron in diameter and degas it just prior to its introduction into the chromatograph. The proportion of acetonitrile may be modified in the range of 6 to 14 percent to obtain the desired retention times. Increasing the amount of acetonitrile will decrease both the retention times and the separation between the isomers, whereas, decreasing the amount of acetonitrile will increase retention times and the separation between the isomers.

(ii) *Preparation of working standard solutions*—(A) *Cefprozil (Z) working standard solution.* Accurately weigh approximately 12.5 milligrams of the cefprozil (Z) working standard into a 50-milliliter volumetric flask. Dilute to volume with water and shake the flask vigorously until the solute dissolves completely. Use this solution within 6 hours.

(B) *Cefprozil (E) working standard solution.* Accurately weigh approximately 12.5 milligrams of the cefprozil (E) working standard into a 50-milliliter volumetric flask. Dilute to volume with water and shake the flask vigorously until the solute dissolves completely. Pipet 5 milliliters into a 50-milliliter volumetric flask, dilute to volume with water and mix thoroughly. Use this solution within 6 hours.

(iii) *Sample solution.* Accurately weigh approximately 15 milligrams of sample into a 50-milliliter volumetric flask. Dilute to volume with water and shake the flask vigorously until the solute dissolves completely. Use this solution within 6 hours.

(iv) *System suitability requirements*—(A) *Asymmetry factor.* The asymmetry factor (A_S) is satisfactory if it is not less than 0.9 and not more than 1.1 for the cefprozil (Z) response.

(B) *Efficiency of the column.* The absolute efficiency (h_r) is satisfactory if it is not more than 10 for the cefprozil (Z) response.

(C) *Resolution factor.* The resolution factor (R) between the response for cefprozil (Z) and the response for cefprozil (E) is satisfactory if it is not less than 2.5.

(D) *Coefficient of variation (Relative standard deviation).* The coefficient of variation (S_R of 5 replicate injections of the cefprozil (Z) reference solution response) is satisfactory if it is not more than 2.0 percent.

(E) *Capacity factor (k').* The capacity factor (k') for cefprozil (Z) is satisfactory if it is not less than 0.7 and not more than 1.1. If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(v) *Calculations.* Calculate the micrograms of cefprozil per milligram of sample on an anhydrous basis as follows:

$$\text{Micrograms of cefprozil (Z) or cefprozil (E) per milligram (as is)} = \frac{A_U \times P_S}{A_S \times C_U}$$

$$\text{Micrograms of cefprozil per milligram (as is)} = \text{cefprozil (Z)} + \text{cefprozil (E)}$$

$$\text{Micrograms of cefprozil per milligram (Anhydrous)} = \frac{\text{cefprozil potency (as is)} \times 100}{(100-m)}$$

where:

A_U = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the cefprozil (Z) or the cefprozil (E) working standard;

P_S = Cefprozil (Z) or cefprozil (E) activity in the cefprozil (Z) or the cefprozil (E) working standard solution in micrograms per milliliter;

C_U = Milligrams of sample per milliliter of sample solution; and

m = Percent moisture content of the sample.

(2) *Cefprozil (E)/cefprozil ratio.* Using the procedure described in paragraph (b)(1) of this section calculate the cefprozil (E)/cefprozil ratio as follows:

$$\text{Trans ratio} = \frac{\text{cefprozil (E) (mcg/mg, as is)}}{\text{cefprozil (mcg/mg, as is) Total}}$$

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using a carbon dioxide free aqueous solution containing 5 milligrams of cefprozil per milliliter.

(5) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(6) *Identity*—(i) *Infrared.* Proceed as directed in § 436.211 of this chapter, using a 1.0 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

(ii) *High performance liquid chromatography (HPLC).* The HPLC retention times for the responses of the cefprozil isomers in the assay preparation of the sample must be within 2 percent of the HPLC retention times of the responses of the corresponding cefprozil working standards.

10. New §§ 442.180, 442.180a, and 442.180b are added to subpart B to read as follows:

§ 442.180 Cefprozil oral dosage forms.

§ 442.180a Cefprozil tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefprozil tablets are composed of cefprozil and one or more suitable and harmless diluents, binders, lubricants, colorings, and coating substances. Each tablet contains cefprozil equivalent to either 250 milligrams or 500 milligrams of anhydrous cefprozil. The cefprozil content of the tablets is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of anhydrous cefprozil that it is represented to contain. The moisture content of the tablets is not more than 7 percent. The tablets pass the dissolution test. The tablets pass the identity tests. The cefprozil used conforms to the standards prescribed by § 442.80(a)(1) of this part.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefprozil used in making the batch for potency, E-isomer ratio, moisture, pH, crystallinity, and identity.

(B) The batch for content, moisture, dissolution, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefprozil used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 tablets.

(b) *Tests and methods of assay*—(1) *Cefprozil content.* Proceed as directed in § 442.80(b)(1) of this part, preparing the sample solution and calculating the cefprozil content as follows:

(i) *Preparation of sample solution.* Place one or a known number of intact tablets into a 250-milliliter volumetric flask containing about 180 milliliters of

distilled water. Allow the tablet(s) to disintegrate as aided by swirling and brief ultrasonication. Dilute the contents to volume with distilled water and mix thoroughly. Transfer an aliquot of this solution to a volumetric flask of suitable size to obtain a solution containing 0.3 milligram per milliliter of cefprozil (estimated) when diluted to volume with water. Filter through a 0.45 micron filter prior to injection into the chromatographic system.

(ii) *Calculations.* Calculate the cefprozil content as follows:

$$\text{Milligrams of cefprozil (Z) or cefprozil (E) per tablet} = \frac{A_U \times P_S \times d}{A_S \times 1000 \times n}$$

$$\text{Milligrams of cefprozil per tablet} = \text{Milligrams of cefprozil (Z) per tablet} + \text{Milligrams of cefprozil (E) per tablet}$$

where:

A_U = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the cefprozil (Z) or the cefprozil (E) working standard;

P_S = Cefprozil (Z) or cefprozil (E) activity in the cefprozil (Z) or the cefprozil (E) working standard solution in micrograms per milliliter;

d = Dilution factor of the sample; and

n = Number of tablets taken in the sample.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Dissolution test.* Proceed as directed in § 436.215 of this chapter. The quantity Q (the amount of cefprozil activity dissolved) is 75 percent at 45 minutes.

(4) *Identity*—(i) *High performance liquid chromatography.* Using the high performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention times for the responses of the active ingredients must be within 2 percent of the retention times for the responses of the corresponding reference standards.

(ii) *Thin layer chromatography.* Proceed as directed in § 436.368 of this chapter.

§ 442.180b Cefprozil for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefprozil for oral suspension is cefprozil with one or more suitable and harmless preservatives, sweeteners, suspending agents, buffers, and flavorings. The cefprozil content of the oral suspension is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of anhydrous cefprozil that it is represented to contain. When constituted as directed in the labeling, each milliliter contains the equivalent of either 25 or 50 milligrams anhydrous cefprozil activity. Its moisture content is not more than 3 percent. When constituted as described in the labeling, the pH of the suspension is not less than 4.0 nor more than 6.0. It passes the identity tests. The cefprozil used conforms to the standards prescribed by § 442.80(a)(1) of this part.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefprozil used in making the batch for potency, E-isomer ratio, moisture, pH, crystallinity, and identity.

(B) The batch for content, moisture, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefprozil used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 10 intermediate containers.

(b) *Tests and methods of assay*—(1) *Cefprozil content.* Proceed as directed in § 442.80(b)(1), preparing the sample solution and calculating the cefprozil content as follows:

(i) *Preparation of sample solution.* Constitute as directed in the labeling. Transfer a portion of the suspension containing 250 milligrams (estimated) of cefprozil into a 250-milliliter volumetric flask using a glass syringe and a 13-gauge needle. Dilute to volume with water, ultrasonicate briefly to dissolve and mix well. Transfer a 15-milliliter aliquot of this solution to a 50-milliliter volumetric flask and dilute to volume with water to obtain a solution containing 0.3 milligram per milliliter of cefprozil (estimated). Filter through a 0.45 micron filter prior to injection into the chromatographic system.

(ii) *Calculations.* Calculate the cefprozil content as follows:

$$\text{Milligrams of cefprozil (Z) or cefprozil (E) per 5 milliliters of sample} = \frac{A_U \times P_S \times d \times 5}{A_S \times 1000 \times V}$$

$$\text{Milligrams of cefprozil per 5 mL of sample} = \text{Milligrams of cefprozil (Z)/5 mL sample} + \text{Milligrams of cefprozil (E)/5 mL sample}$$

where:

A_U = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefprozil (Z) or cefprozil (E) response in the chromatogram of the cefprozil (Z) or the cefprozil (E) working standard;

P_S = Cefprozil (Z) or cefprozil (E) activity in the cefprozil (Z) or the cefprozil (E) working standard solution in micrograms per milliliter;

d = Dilution factor of the sample; and

V = Volume of sample taken in milliliters.

(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 constituted as directed in the labeling.

(4) *Identity*—(i) *High Performance liquid chromatography.* Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention times for the responses of the active ingredients must be within 2 percent of the retention times for the responses of the corresponding reference standards.

(ii) *Thin layer chromatography.* Proceed as directed in § 436.368 of this chapter.

Dated: March 26, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 93-10313 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

---

21 CFR Parts 430 and 450

[Docket No. 92N-0042]

Antibiotic Drugs; Idarubicin Hydrochloride for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for inclusion of accepted standards for a new antibiotic drug idarubicin hydrochloride, and use of the antibiotic drug in a dosage form, idarubicin hydrochloride for injection. The manufacturer has supplied sufficient

data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and request for a hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, idarubicin hydrochloride and its use in a dosage form, idarubicin hydrochloride for injection. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in parts 430 and 450 (21 CFR parts 430 and 450) to provide for the inclusion of accepted standards for this product.

I. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

II. Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number found in brackets in the heading of this document and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Part 450

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 430 and 450 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

2. Section 430.4 is amended by adding new paragraph (a)(67) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(67) *Idarubicin.* Idarubicin is an anthracycline antibiotic substance having the chemical structure described by the following name: 5,12-Naphthacenedione, 9-acetyl-7-[(3-amino-2,3,6-trideoxy-α-*L-lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,9,11-trihydroxy-(7*S-cis*).

* * * * *

3. Section 430.5 is amended by adding new paragraphs (a)(102) and (b)(104) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(102) *Idarubicin.* The term "idarubicin master standard" means a specific lot of idarubicin that is designated by the Commissioner as the standard of comparison in determining the potency of the idarubicin working standard.

(b) * * *

(104) *Idarubicin.* The term "idarubicin working standard" means a specific lot of a homogeneous preparation of idarubicin.

4. Section 430.6 is amended by adding new paragraph (b)(104) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(104) *Idarubicin.* The term "microgram" applied to idarubicin means the idarubicin activity (potency) calculated as idarubicin hydrochloride contained in 1.036 micrograms of the idarubicin master standard.

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

3. The authority citation for 21 CFR part 450 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

4. Section 450.30 is added to subpart A to read as follows:

§ 450.30 Idarubicin hydrochloride.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Idarubicin hydrochloride is the monohydrochloride salt of 5,12-Naphthacenedione,9-acetyl-7-[(3-amino-2,3,6-trideoxy-α-*L-lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,9,11-trihydroxy-(7*S-cis*). It is an orange-red powder. It is so purified and dried that:

(i) Its idarubicin hydrochloride content is not less than 960 micrograms and not more than 1,030 micrograms of idarubicin hydrochloride per milligram on the anhydrous basis.

(ii) Its moisture content is not more than 5.0 percent.

(iii) The pH of an aqueous solution containing 5 milligrams per milliliter is not less than 5.0 and not more than 6.5.

(iv) It is crystalline.

(v) The level of any individual impurity detected by high-performance liquid chromatography (HPLC) assay is not more than 1.0 percent.

(vi) The total of all detected impurities is not more than 3.0 percent.

(vii) It passes the identity test for idarubicin.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for idarubicin hydrochloride content, solvent residues, moisture, pH, crystallinity, related individual thin-layer chromatography and HPLC impurities, total impurities, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 14 packages, each containing approximately 40 milligrams.

(b) *Tests and methods of assay.* Idarubicin hydrochloride is toxic. It must be handled with care in the laboratory. Transfer all dry powders into a suitable hood while wearing rubber gloves. Avoid inhaling fine particles of powder. Solutions should not be pipetted by mouth. If the substance contacts the skin, wash with soap and water. Dispose of all waste material by dilution with large volumes of dilute sodium hypochlorite (bleach) solution.

(1) *Potency (HPLC).* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 254 nanometers, a 4.6-millimeter by 25-centimeter column packed with microparticulate (5 to 10 micrometers in diameter) packing material such as trimethylsilane chemically bonded to porous silica, a flow rate of not more than 2.0 milliliters per minute, and a known injection volume of between 10 and 20 microliters. The retention time for idarubicin hydrochloride is between 14 and 16 minutes. The retention time for the resolution compound 4-demethoxydaunorubicinone (generated in situ) is between 6 and 9 minutes. Mobile phase, diluent, working standard and sample solutions, resolution test solution, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Prepare a suitably sized quantity of a mixture of water, acetonitrile, and methanol (540:290:170). Dissolve 1 gram of sodium lauryl sulfate and 2 milliliters of 85 percent phosphoric acid per liter of this solution. Adjust with 2 *N* sodium hydroxide to a pH of 3.6±0.1. Filter through a suitable filter capable of removing particulate matter to 0.5 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph.

(ii) *Diluent.* Prepare as mobile phase, excluding the sodium lauryl sulfate.

(iii) *Preparation of working standard solution.* Dissolve an accurately weighed quantity of idarubicin hydrochloride working standard in diluent to obtain a solution having a known concentration of 0.5 milligram of idarubicin hydrochloride per milliliter.

(iv) *Sample solution.* Transfer approximately 50 milligrams of sample, accurately weighed, to a 100-milliliter volumetric flask, add diluent to volume, and mix. This yields a solution containing 0.5 milligram of idarubicin hydrochloride per milliliter (estimated).

(v) *Resolution test solution.* To 2 milliliters of a 1.0 milligram per milliliter aqueous solution of idarubicin hydrochloride, add 20 microliters of 1 *N* hydrochloric acid. Hold for 30 minutes at 95 C in an oil bath. This procedure generates the aglycone of idarubicin, 4-demethoxydaunorubicinone. Transfer 1.0 milliliter of this solution to a 10-milliliter volumetric flask, add diluent to volume, and mix. Use this solution to determine the resolution requirement for the chromatographic system.

(vi) *System suitability requirements*—(A) *Asymmetry factor.* The asymmetry factor (A_S), measured at a point 5 percent of the peak height from the baseline, is satisfactory if it is not less than 0.85 and not more than 1.1.

(B) *Efficiency of the column.* The absolute efficiency (h_r) is satisfactory if it is not more than 10.0 for the idarubicin hydrochloride peak, equivalent to 4,500 theoretical plates for a 25-centimeter column of 6-micrometer particles.

(C) *Resolution factor.* The resolution factor (R_S) between the peak for idarubicin and 4-demethoxydaunorubicinone (generated in situ) is satisfactory if it is not less than 9.5.

(D) *Coefficient of variation (relative standard deviation).* The coefficient of variation (S_R in percent of 5 replicate injections) is satisfactory if it is not more than 2.0 percent.

(E) *Capacity factor.* The capacity factor (K') for idarubicin hydrochloride is satisfactory if it is not less than 5 and not more than 15. If the system suitability parameters have been met, proceed as described in § 436.216(b) of this chapter.

(vii) *Calculations.* Calculate the micrograms of idarubicin hydrochloride per milligram of sample as follows:

$$\text{Micrograms of idarubicin hydrochloride per milligram} = \frac{A_U \times P_S \times 100}{A_S \times C_U \times (100 - m)}$$

where.

A_U=Area of the idarubicin hydrochloride peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S=Area of the idarubicin hydrochloride peak in the chromatogram of the idarubicin hydrochloride working standard;

P_S=Idarubicin hydrochloride activity in the idarubicin hydrochloride working standard solution in micrograms per milliliter;

C_U=Milligrams of idarubicin hydrochloride sample per milliliter of sample solution;

m=Percent moisture content of the

sample.

(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 5 milligrams per milliliter.

(4) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(5) *HPLC impurities.* Proceed as directed in paragraph (b)(1) of this section. Calculate the percentage of impurities as follows:

$$\text{Percent individual impurity} = \frac{A_i \times 100}{A_t}$$

$$\text{Percent total HPLC impurities} = \frac{A \times 100}{A_t}$$

where:

A_i=Area of the individual impurity peak;

A=The sum of areas of all peaks minus the area due to the idarubicin hydrochloride peak and solvent peak; and

A_t=The sum of areas of all peaks in the chromatogram excluding the solvent peak.

(6) *Identity.* Proceed as directed in § 436.211 of this chapter, using a 1.0 percent potassium bromide disc prepared as directed in § 436.211(b)(1).

5. Section 450.230 is added to subpart C to read as follows:

§ 450.230 Idarubicin hydrochloride for injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Idarubicin hydrochloride for injection is a lyophilized mixture of idarubicin hydrochloride and lactose. Its idarubicin hydrochloride content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of idarubicin hydrochloride that it is represented to contain. It is sterile. It contains not more than 8.93 U.S.P. endotoxin units per milligram of idarubicin hydrochloride. Its moisture content is not more than 4.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.0. It passes the identity test. The idarubicin hydrochloride used conforms to the standards prescribed by § 450.30(a)(1).

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The idarubicin hydrochloride used in making the batch for idarubicin hydrochloride content, solvent residues, moisture, pH, crystallinity, related individual thin layer chromatography and high-performance liquid chromatography (HPLC) impurities, total impurities, and identity.

(B) The batch for idarubicin hydrochloride content, sterility, bacterial endotoxins, moisture, pH, and identity.

(ii) Samples required if requested by the Director, Center for Drug Evaluation and Research:

(A) The idarubicin hydrochloride used in making the batch: 14 packages, each containing approximately 40 milligrams.

(B) The batch:

(*1*) For all tests except sterility: A minimum of 34 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay.* Idarubicin hydrochloride is toxic. It must be handled with care in the laboratory. Transfer all dry powders into a suitable hood while wearing rubber gloves. Avoid inhaling fine particles of powder. Solutions should not be pipetted by mouth. If the substance contacts the skin, wash with soap and water. Dispose of all waste material by dilution with large volumes of dilute sodium hypochlorite (bleach) solution.

(1) *Idarubicin hydrochloride content (HPLC).* Proceed as directed in § 450.30(b)(1), preparing the sample solution and calculating the idarubicin hydrochloride as follows:

(i) *Sample solution.* Prepare the sample solution by rinsing the contents of the vial into an appropriate-sized volumetric flask with sufficient diluent to obtain a concentration of 0.5 milligram of idarubicin hydrochloride per milliliter (estimated).

(ii) *Calculations.* Calculate the idarubicin hydrochloride content per vial as follows:

$$\text{Micrograms of idarubicin hydrochloride per vial} = \frac{A_U \times P_S \times d}{A_s \times 1{,}000}$$

where:

A_U=Area of the idarubicin hydrochloride peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S=Area of the idarubicin hydrochloride peak in the chromatogram of the idarubicin hydrochloride working standard;

P_S=Idarubicin hydrochloride activity in the idarubicin hydrochloride working standard solution in micrograms per milliliter; and

d=Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in § 436.20(e)(1).

(3) *Bacterial endotoxins.* Proceed as directed in the U.S.P. Bacteria endotoxin test. The specimen under test contains not more than 8.93 U.S.P. endotoxin units per milligram of idarubicin hydrochloride.

(4) *Moisture.* Proceed as directed in § 436.201 of this chapter, using the sample preparation method described in § 436.201(d)(4).

(5) *pH.* Proceed as directed in § 436.202 of this chapter, using the sample obtained after reconstituting the drug as directed in the labeling, except use distilled water instead of saline.

(6) *Identity.* The high-performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the idarubicin hydrochloride working standard.

Dated: March 23, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 93-10314 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-P

---

21 CFR Parts 430, 436, and 443

[Docket No. 92N-0113]

Antibiotic Drugs; Loracarbef, Loracarbef Capsules, and Loracarbef for Oral Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for inclusion of accepted standards for a new antibiotic drug, loracarbef, and use of the antibiotic drug in two dosage forms, loracarbef capsules and loracarbef for oral suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and request for hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug

Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, loracarbef, and its use in two dosage forms, loracarbef capsules and loracarbef for oral suspension. The agency has concluded that the data supplied by the manufacturer concerning these antibiotic drugs are adequate to establish their safety and efficacy when used as directed in the labeling and that the regulations should be amended in 21 CFR parts 430, 436, and 443 to provide for the inclusion of accepted standards for these products.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in § 314.300 (21 CFR 314.300). A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this document and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in § 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 430

Administrative practice and procedure, Antibiotics.

21 CFR Parts 436 and 443

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 430 and 436 are amended and new part 443 is added as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. The authority citation for 21 CFR part 430 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 357, 371); secs. 215, 301, 351 of the Public Health Service Act (42 U.S.C. 216, 241, 262).

2. Section 430.4 is amended by adding new paragraph (a)(68) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(68) *Loracarbef.* Loracarbef is an antibiotic substance having the chemical structure described by the following name: (6*R*,7*S*)-7-[(*R*)-2-amino-2-phenylacetamido]-3-chloro-8-oxo-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

* * * * *

3. Section 430.5 is amended by adding new paragraphs (a)(103) and (b)(105) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(103) *Loracarbef.* The term "loracarbef master standard" means a specific lot of loracarbef that is designated by the Commissioner as the standard of comparison in determining the potency of the loracarbef working standard.

(b) * * *

(105) *Loracarbef.* The term "loracarbef working standard" means a specific lot of a homogeneous preparation of loracarbef.

4. Section 430.6 is amended by adding new paragraph (b)(105) to reads as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(105) *Loracarbef.* The term "microgram" applied to loracarbef means the loracarbef (potency) contained in 1.059 micrograms of the loracarbef master standard.

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

5. The authority citation for 21 CFR part 436 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

6. Section 436.215 is amended by alphabetically adding a new entry to the table in paragraph (b) and by adding a new paragraph (c)(16) to read as follows:

§ 436.215 Dissolution test.

* * * * *

(b) * * *

Dosage form	Dissolution medium	Rotation rate[1]	Sampling time(s)	Apparatus
*	*	*	*	*
Loracarbef capsules	900 mL distilled water	50	30 min	2
*	*	*	*	*

[1] Rotation rate of basket or paddle stirring element (revolutions per minute).

(c) * * *

(16) *Loracarbef*—(i) *Preparation of the working standard solution.* Accurately weigh approximately 110 milligrams of the loracarbef working standard into a suitable-sized volumetric flask. Dissolve and dilute to volume with water. Further dilute an accurately measured portion with distilled water to obtain a known concentration of 0.02 milligram of loracarbef activity per milliliter.

(ii) *Preparation of sample solutions.* Dilute an accurately measured portion of the sample with sufficient distilled water to obtain a concentration of 0.02 milligram of loracarbef activity per milliliter (estimated).

(iii) *Procedure.* Using a suitable spectrophotometer and water as the blank, determine the absorbance of each standard and sample solution at the absorbance maximum at approximately 260 nanometers. Determine the exact position of the absorbance maximum for the particular instrument used.

(iv) *Calculations.* Determine the total amount of loracarbef dissolved as follows:

$$T = \frac{A_U \times c \times d \times 900}{A_S}$$

where:

T = Total milligrams of loracarbef activity dissolved;
A_U = Absorbance of sample;
A_S = Absorbance of the standard;
c = Concentration of the working standard solution in milligrams per milliliter; and
d = Dilution factor of the sample filtrate.

* * * * *

7. Part 443 is added to read as follows:

PART 443—CARBACEPHEM ANTIBIOTIC DRUGS

Subpart A—Bulk Drugs

Sec.
443.20 Loracarbef.

Subpart B—Oral Dosage Forms

443.120 Loracarbef oral dosage forms.
443.120a Loracarbef capsules.
443.120b Loracarbef for oral suspension.

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

Subpart A—Bulk Drugs

§ 443.20 Loracarbef.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Loracarbef is the monohydrate form of (6*R*,7*S*)-7-[(*R*)-2-amino-2-phenylacetamido]-3-chloro-8-oxo-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 960 micrograms and not more than 1,020 micrograms of loracarbef activity per milligram, on an anhydrous basis.

(ii) Its moisture content is not less than 3.5 percent and not more than 6.0 percent.

(iii) The pH of an aqueous slurry containing 100 milligrams per milliliter is not less than 3.5 and not more than 5.5.

(iv) Its specific rotation in an 0.1 *N* HCl solution containing 10 milligrams of loracarbef per milliliter at 25 °C is +27° to +33° on an anhydrous basis.

(v) It is crystalline.

(vi) It gives a positive identity test.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for loracarbef potency, moisture, pH, specific rotation, crystallinity, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 265 nanometers, a 25-centimeter by 4.6-millimeter (inside diameter) column packed with microparticulate (5 micrometers in diameter) reversed phase packing material such as octadecyl silane bonded to silicas, a flow rate of 1.5 milliliters per minute, and a known injection volume between 10 and 20 microliters. The retention time for loracarbef is between 10 and 13 minutes. Mobile phase, working standard, sample and resolution test solutions, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Dissolve 2.0 grams of pentanesulfonic acid sodium salt monohydrate in 1,560 milliliters of water. Add 20 milliliters of triethylamine. Adjust the pH to 2.5 with phosphoric acid. Add 440 milliliters of methanol and mix. Filter the mobile phase through a suitable filter capable of removing particulate matter 0.5 micron in diameter and degas it just prior to its introduction into the chromatograph.

(ii) *Preparation of working standard, sample, and resolution test solutions*—(A) *Working standard solution.* Accurately weigh approximately 10 milligrams of the loracarbef working reference standard into a 50-milliliter volumetric flask. Dissolve and dilute to volume with mobile phase. Brief sonication may be required to obtain complete dissolution of the material.

(B) *Sample solution.* Accurately weigh approximately 10 milligrams of sample into a 50-milliliter volumetric flask. Dissolve and dilute to volume with mobile phase. Brief sonication may be required to obtain complete dissolution of the material.

(C) *Resolution test solution.* Prepare a resolution test solution containing approximately 0.2 milligram per milliliter each of loracarbef and loracarbef *L*-isomer in the mobile phase.

(iii) *System suitability requirements*—(A) *Asymmetry factor.* The asymmetry factor (A_S) at 5 percent peak height is satisfactory if it is not less than 0.8 and not more than 1.3 for the loracarbef peak.

(B) *Efficiency of the column.* The absolute efficiency (h_r) is satisfactory if it is not more than 20 for the loracarbef peak.

(C) *Resolution factor.* The resolution factor (R) between the peak for loracarbef and the peak for the resolution standard loracarbef *L*-isomer in the resolution test solution is satisfactory if it is not less than 6.0.

(D) *Coefficient of variation (relative standard deviation).* The coefficient of variation (S_R in percent of 5 replicate injections) is satisfactory if it is not more than 2.0 percent.

(E) *Capacity factor (k')*. The capacity factor (k') for loracarbef is satisfactory if it is not less than 5 and not more than 8.

If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(iv) *Calculations*. Calculate the micrograms of loracarbef per milligram of sample on an anhydrous basis as follows:

$$\text{Micrograms of loracarbef per milligram} = \frac{A_U \times P_S \times 100}{A_S \times C_U \times (100-m)}$$

where:

A_U = Area of the loracarbef peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the loracarbef peak in the chromatogram of the loracarbef working standard;

P_S = Loracarbef activity in the loracarbef working standard solution in micrograms per milliliter;

C_U = Milligrams of sample per milliliter of sample solution; and

m = Percent moisture content of the sample.

(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 suspension containing 100 milligrams per milliliter.

(4) *Specific rotation*. Dissolve and dilute an accurately weighed sample with sufficient 0.1 *N* HCl to obtain a concentration of approximately 10 milligrams of loracarbef activity per milliliter. Proceed as directed in § 436.210 of this chapter, using a 1.0-decimeter polarimeter tube. Calculate the specific rotation on the anhydrous basis.

(5) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

(6) *Identity*. Proceed as directed in § 436.211 of this chapter, using the 1.0 percent potassium bromide disc prepared as described in § 436.211(b)(1).

Subpart B—Oral Dosage Forms

§ 443.120 Loracarbef oral dosage forms.

§ 443.120a Loracarbef capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Loracarbef capsules are composed of loracarbef and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains loracarbef equivalent to either 200 milligrams or 400 milligrams of loracarbef. Its loracarbef content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of loracarbef that it is represented to contain. Its moisture content is not more than 8.5 percent. It passes the dissolution test. It passes the identity test. The loracarbef used conforms to the standards prescribed by § 443.20(a)(1).

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The loracarbef used in making the batch for potency, moisture, pH, specific rotation, crystallinity, and identity.

(B) The batch for content, moisture, dissolution, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The loracarbef used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 100 capsules.

(b) *Tests and methods of assay*—(1) *Loracarbef content*. Proceed as directed in § 443.20(b)(1), preparing the sample solution and calculating the loracarbef content as follows:

(i) *Preparation of sample solution*. Place one intact capsule in a 200-milliliter volumetric flask containing 150 milliliters of distilled water. Shake the mixture vigorously to aid disruption of the capsule. Sonicate the mixture briefly (5 minutes). Dilute the contents to volume with distilled water. Mix well and immediately transfer a suitable aliquot to a volumetric flask of appropriate size to obtain a solution containing 0.2 milligram per milliliter (estimated) of loracarbef when diluted to volume with mobile phase (described in § 443.20(b)(1)(i)). Filter this solution through a 0.45-micron membrane filter before injecting it into the chromatograph.

(ii) *Calculations*. Calculate the loracarbef content as follows:

$$\text{Milligrams of loracarbef per capsule} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000}$$

where:

A_U = Area of the loracarbef peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the loracarbef peak in the chromatogram of the loracarbef working standard;

P_S = Loracarbef activity in the loracarbef working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(3) *Dissolution test*. Proceed as directed in § 436.215 of this chapter. The quantity Q, the amount of loracarbef activity dissolved, is 75 percent within 30 minutes.

(4) *Identity*. The retention time of the loracarbef response in the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section as applied to the sample solution compares qualitatively to that of the loracarbef reference standard.

§ 443.120b Loracarbef for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Loracarbef for oral suspension is loracarbef with one or more suitable and harmless preservatives, sweeteners, suspending agents, colorings, antifoaming agents, and flavorings. When constituted as directed in the labeling, each milliliter contains the equivalent of either 20 or 40 milligrams loracarbef activity. Its loracarbef content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of loracarbef that it is represented to contain. Its moisture content is not more than 2.0 percent. When constituted as described in the labeling, the pH of the suspension is not less than 3.5 and not more than 6.0. It passes the identity test. The loracarbef used conforms to the standards prescribed by § 443.20(a)(1).

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The loracarbef used in making the batch for potency, moisture, pH, specific rotation, crystallinity, and identity.

(B) The batch for content, moisture, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The loracarbef used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 10 immediate containers.

(b) *Tests and methods of assay*—(1) *Loracarbef content*. Proceed as directed in § 443.20(b)(1), preparing the sample solution and calculating the loracarbef content as follows:

(i) *Preparation of sample solution*. Constitute as directed in the labeling. Transfer a 5.0-milliliter portion of the suspension into an appropriately sized

volumetric flask and quantitatively dilute stepwise with mobile phase (described in § 443.20(b)(1)(i)) to obtain a concentration of 0.2 milligram of loracarbef activity per milliliter (estimated).

(ii) *Calculations.* Calculate the loracarbef content as follows:

$$\text{Milligrams of loracarbef per 5 milliliters of sample} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000}$$

where:

A_U = Area of the loracarbef peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the loracarbef peak in the chromatogram of the loracarbef working standard;

P_S = Loracarbef activity in the loracarbef working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(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 constituted as directed in the labeling.

(4) *Identity.* The retention time of the loracarbef response in the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section as applied to the sample solution compares qualitatively to that of the loracarbef reference standard.

Dated: April 14, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 93-10315 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

---

21 CFR Part 441

[Docket No. 91N-0147]

Antibiotic Drugs; Sterile Imipenem Monohydrate-Cilastatin Sodium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of imipenem monohydrate-cilastatin sodium, sterile imipenem monohydrate-cilastatin sodium. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and requests for a hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of imipenem monohydrate-cilastatin sodium, sterile imipenem monohydrate-cilastatin sodium. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 441 (21 CFR part 441) to provide for the inclusion of accepted standards for this product.

I. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

II. Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this final rule, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions, and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this final rule and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 441

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 441 is amended as follows:

PART 441—PENEM ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 441 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

§ 441.220b [Redesignated from § 441.220]

2. Section 441.220 is redesignated as § 441.220b and new §§ 441.220 and 441.220a are added to subpart C to read as follows:

§ 441.220 Imipenem monohydrate-cilastatin sodium injectable dosage forms.

§ 441.220a Sterile imipenem monohydrate-cilastatin sodium.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Imipenem monohydrate-cilastatin sodium is a dry mixture of imipenem monohydrate and cilastatin sodium packaged for dispensing. Its potency is satisfactory if it contains not less than 400 micrograms of imipenem and not less than 400 micrograms of cilastatin per milligram. Its imipenem content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of imipenem that it is represented to contain. Its cilastatin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of cilastatin that it is represented to contain. It is sterile. It is nonpyrogenic. Its loss on drying is not more than 3.5 percent. When reconstituted as directed in the labeling, its pH is not less than 6.0 and not more than 7.5. The imipenem monohydrate used conforms to the standards prescribed by § 441.20a(a)(1).

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The imipenem monohydrate used in making the batch for potency, sterility, pyrogens, loss on drying, specific rotation, identity, and crystallinity.

(B) The batch for imipenem potency, cilastatin potency, imipenem content, cilastatin content, sterility, pyrogens, loss on drying, and pH.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The imipenem monohydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch:

(*1*) For all tests except sterility: A minimum of 20 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Imipenem and cilastatin potency and content.* Determine the potency of the sample in micrograms per milligram of both imipenem and cilastatin and the milligrams of both imipenem and cilastatin per container. Proceed as directed in § 441.20a(b)(1), preparing the cilastatin reference standard solution, the sample solution and calculating the imipenem and cilastatin potency and content as follows:

(i) *Cilastatin reference standard.* Accurately weigh approximately 25 milligrams of the cilastatin reference standard into a 50-milliliter volumetric flask. Immediately prior to analysis, add 10 milliliters of a 0.9 percent saline solution and 1.0 milliliter of a 0.1 percent bicarbonate solution. Add phosphate buffer, 0.001*M*, and shake until dissolved. Sonicate, if necessary, but no longer than 1 minute. Dilute to volume with phosphate buffer, 0.001*M*, to obtain a solution containing approximately 500 micrograms of cilastatin per milliliter. Mix well and inject immediately.

(ii) *Preparation of sample solutions*—(A) *Imipenem and cilastatin potency (micrograms of imipenem and cilastatin per milligram).* Remove the metal seal from each of 10 containers and determine the gross weight in grams. Dissolve and wash out the entire contents of each container with a 0.9 percent saline solution into an appropriate size volumetric flask to give a concentration of 5 milligrams per milliliter each of imipenem and cilastatin. Further dilute with phosphate buffer, 0.001*M*, to obtain a solution containing 500 micrograms each of imipenem and cilastatin per milliliter (estimated). Wash each stopper and container with small quantities of acetone or methanol three times being careful not to wet the container labeling. Allow the containers to air dry about 3 hours or to constant weight. Weigh each container and stopper to determine tare weight in grams.

(B) *Imipenem and cilastatin content (milligrams of imipenem and cilastatin per container).* Reconstitute the sample as directed in the labeling, except use a 0.9 percent saline solution as the reconstituting fluid. Then, 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. Accurately dilute the solution thus obtained in a suitable volumetric flask with sufficient 0.9 percent saline solution to obtain a stock solution containing about 2,500 micrograms of imipenem and 2,500 micrograms of cilastatin per milliliter. Transfer a 10-milliliter aliquot of this solution to a 50-milliliter volumetric flask and dilute to volume with phosphate buffer, 0.001*M*, to obtain a solution containing 500 micrograms of imipenem and 500 micrograms of cilastatin per milliliter (estimated).

(iii) *Calculations*—(A) *Imipenem and cilastatin potency.* Calculate the micrograms of imipenem and cilastatin per milligram as follows:

$$\text{Milligrams of imipenem or cilastatin per milligram} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000 \times W_S}$$

where:

A_U = Area of the imipenem or cilastatin peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the imipenem or cilastatin peak in the chromatogram of the imipenem or cilastatin working standard;

P_S = Anhydrous imipenem or cilastatin activity in the respective working standard solution in micrograms per milliliter;

d = Dilution factor of the 10 samples; and

W_S = Net contents of 10 containers in grams (gross weight of 10 containers in grams--tare weight of 10 containers in grams).

(B) *Imipenem and cilastatin content.* Calculate the imipenem or cilastatin content of the container as follows:

$$\text{Milligrams of imipenem or cilastatin per milligram} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000}$$

where:

A_U = Area of the imipenem or cilastatin peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the imipenem or cilastatin peak in the chromatogram of the imipenem or cilastatin working standard;

P_S = Anhydrous imipenem or cilastatin activity in the imipenem or cilastatin working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in § 436.20(e)(1).

(3) *Pyrogens.* Proceed as directed in § 436.32(a) of this chapter, using a solution containing 5.0 milligrams of imipenem per milliliter except inject 10 milliliters per kilogram of rabbit weight.

(4) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(5) *pH.* Proceed as directed in § 436.202 of this chapter.

Dated: March 26, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 93-10316 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 444

[Docket No. 91N-0265]

Antibiotic Drugs; Tobramycin-Fluorometholone Acetate Ophthalmic Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new ophthalmic dosage form of tobramycin, tobramycin-fluorometholone acetate ophthalmic suspension. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective June 3, 1993; written comments, notice of participation, and requests for a hearing by June 3, 1993; data, information, and analyses to justify a hearing by July 6, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0335.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) as amended, with respect to a request for approval of a new ophthalmic dosage form of tobramycin, tobramycin-fluorometholone acetate ophthalmic suspension. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 444 (21 CFR part 444) by adding new § 444.380e to subpart D to provide for the inclusion of accepted standards for this product.

I. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

II. Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective June 3, 1993. However, interested persons may, on or before June 3, 1993, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before June 3, 1993, a written notice of participation and request for hearing, and (2) on or before July 6, 1993, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order, and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 444

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 444 is amended as follows:

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 444 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. New § 444.380e is added to subpart D to read as follows:

§ 444.380e Tobramycin-fluorometholone acetate ophthalmic suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Tobramycin-fluorometholone acetate ophthalmic suspension is an aqueous suspension containing, in each milliliter, 3.0 milligrams of tobramycin and 1.0 milligram of fluorometholone acetate in a suitable and harmless aqueous vehicle. It contains one or more suitable and harmless dispersants, preservatives, buffers, and tonicity agents. Its tobramycin potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of tobramycin that it is represented to contain. Its fluorometholone acetate content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of fluorometholone acetate than it is represented to contain. It is sterile. Its pH is not less than 6.0 and not more than 7.0. It passes the identity tests for tobramycin and fluorometholone acetate. The tobramycin used conforms to the standards prescribed by § 440.80(a)(1) of this chapter, except heavy metals. The fluorometholone acetate used conforms to the standards prescribed in the U.S. Pharmacopeia XXII.

(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 § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The tobramycin used in making the batch for potency, moisture, pH, identity, and residue on ignition.

(B) The fluorometholone acetate used in making the batch for all requirements in U.S. Pharmacopeia XXII.

(C) The batch for tobramycin potency, fluorometholone acetate content, sterility, pH, tobramycin identity, and fluorometholone acetate identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The tobramycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch:

(*1*) For all tests except sterility: A minimum of 10 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Tobramycin potency.* 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 with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with distilled water to the reference concentration of 2.5 micrograms of tobramycin per milliliter (estimated).

(2) *Fluorometholone acetate content.* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 254 nanometers, a column or cartridge packed with microparticulate (3 to 10 micrometers in diameter) reversed phase packing material such as octadecyl hydrocarbon bonded silicas, a flow rate not to exceed 2.0 milliliters per minute, and an injection volume of 10 or 20 microliters. Mobile phase, working standard and sample solutions, resolution test solution, system suitability requirements, and calculations are as follows:

(i) *Mobile phase.* Mix acetonitrile:water (50:50) and adjust if necessary by reducing the amount of acetonitrile to increase retention, or by increasing the amount of acetonitrile to decrease the retention of the solute. Filter the mobile phase through a suitable glass fiber filter or equivalent that is capable of removing particulate contamination to 1 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph pumping system.

(ii) *Preparation of working standard and sample solutions, and resolution test solution*—(A) *Working standard solution.* Accurately weigh approximately 25 milligrams of the fluorometholone acetate working standard into a 10-milliliter volumetric flask and add about 5 milliliters of acetonitrile. Shake until dissolved. Dilute to volume with acetonitrile. Further dilute 1.0 milliliter of this solution in a volumetric flask to 10 milliliters with acetonitrile to obtain a solution of known concentration containing approximately 250 micrograms of fluorometholone acetate per milliliter. Mix well.

(B) *Sample solution.* Shake vial thoroughly, to homogenize its contents, and immediately remove an accurately measured representative portion from it. Quantitatively dilute the suspension thus obtained with sufficient acetonitrile to obtain a solution containing 250 micrograms of fluorometholone acetate per milliliter (estimated). For instance, dilute a 1.0 milliliter aliquot of suspension with 3.0 milliliters of acetonitrile and filter.

(C) *Resolution test solution.* Prepare as directed in paragraph (b)(2)(ii)(A) of this section, except use 10 milligrams of fluorometholone in addition to the 25 milligrams of fluorometholone acetate working standard.

(iii) *System suitability requirements*—(A) *Asymmetry.* The asymmetry (A_S) is satisfactory if it is not more than 1.35 at 10 percent of peak height.

(B) *Efficiency of the column.* The efficiency of the column (h_r) is satisfactory if it is not greater than 20, equivalent to 1,000 plates for a 10-centimeter column of 5 microns or 2,500 plates for a 25-centimeter column of 5 micron size particles.

(C) *Resolution.* The resolution (R_S) between the peaks of fluorometholone acetate and fluorometholone is satisfactory if it is not less than 2.0.

(D) *Capacity factor.* The capacity factor (k) for fluorometholone acetate is satisfactory if it is in the range between 1.0 and 5.0.

(E) *Coefficient of variation.* The coefficient of variation (*RSD* in percent) of 5 replicate injections is satisfactory if it is not more than 2.0 percent. If the system suitability requirements have been met, then proceed as described in § 436.216(b) of this chapter.

(iv) *Calculations.* Calculate the fluorometholone acetate content of the container as follows:

$$\text{Milligrams of fluorometholone acetate per container} = \frac{A_U \times P_S \times d}{A_S \times 1{,}000}$$

where:

A_U = Area of the fluorometholone acetate peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the fluorometholone acetate peak in the chromatogram of the fluorometholone acetate working standard;

P_S = Fluorometholone acetate content in the fluorometholone acetate working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(3) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in § 436.20(e)(1).

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted suspension.

(5) *Tobramycin identity.* Proceed as directed in § 436.318 of this chapter, except prepare the sample for assay as follows: Decant 1.0 milliliter of the unshaken sample into a test tube. Add 100 milligrams of sodium sulfate to the test tube and shake until the sodium sulfate has been dispersed. Centrifuge to obtain a clear supernatant. Use the supernatant as the sample solution.

(6) *Fluorometholone acetate identity.* The high performance liquid chromatogram of the sample determined as directed in paragraph (b)(2) of this section, compares qualitatively to that of the fluorometholone acetate working standard.

Dated: March 26, 1993.

Paul F. Vogel,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 93-10317 Filed 5-3-93; 8:45 am]

BILLING CODE 4160-01-F

federal register

Tuesday
May 4, 1993

Part IV

Department of Education

34 CFR Part 668

Student Assistance General Provisions; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 668

RIN 1840-AB30

Student Assistance General Provisions

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations for the Student Assistance General Provisions to add the Office of Management and Budget (OMB) control numbers to certain sections of the regulations. Those sections contain information collection requirements approved by OMB. The Secretary takes this action to inform the public that these requirements have been approved.

EFFECTIVE DATE: These regulations are effective on May 4, 1993.

FOR FURTHER INFORMATION CONTACT: Claude Denton, General Provisions Branch, Division of Policy Development, U.S. Department of Education, 400 Maryland Avenue, SW., (Regional Office Building 3, room 4318), Washington, DC 20202-5444. Telephone (202) 708-7888. Individuals who are hearing impaired may call the Federal Dual Party Relay Service at 1-800-877-8339 (in the Washington, DC 202 area code, telephone 708-9300) between 8 a.m. and 7 p.m. Eastern time.

SUPPLEMENTARY INFORMATION: On January 7, 1993, final regulations for the Student Assistance General Provisions were published in the **Federal Register** at 58 FR 3180. The effective date of certain sections of these regulations was delayed until information collection requirements contained in those sections were approved by OMB under the Paperwork Reduction Act of 1980, as amended. OMB has approved the information collection requirements, and those sections of the regulations are now effective.

Waiver of Proposed Rulemaking

In accordance with section 431(b)(2)(A) of the General Education Provisions Act (20 U.S.C. 1232(b)(2)(A)) and the Administrative Procedure Act (5 U.S.C. 553), it is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations. However, the publication of OMB control numbers is purely technical and does not establish substantive policy. Therefore, the Secretary has determined under 5 U.S.C. 553(b)(B), that proposed rulemaking is unnecessary and contrary to the public interest and that a delayed effective date is not required under 5 U.S.C. 553(d)(3).

List of Subjects in 34 CFR Part 668

Administrative practice and procedure, Colleges and universities, Consumer protection, Education, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Student aid.

Dated: April 28, 1993.

Richard W. Riley,

Secretary of Education.

The Secretary amends part 668 of title 34 of the Code of Federal Regulations as follows:

PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

1. The authority citation for part 668 continues to read as follows:

Authority: 20 U.S.C. 1091, 1092, and 1094, unless otherwise noted.

§§ 668.133, 668.134, 668.135 [Amended]

2. Sections 668.133, 668.134, and 668.135 are amended by adding the OMB control number at the end of these sections to read as follows:

(Approved by the Office of Management and Budget under control number 1840-0650)

[FR Doc. 93-10438 Filed 5-3-93; 8:45 am]

BILLING CODE 4000-01-M

federal register

Tuesday
May 4, 1993

Part V

Department of Health and Human Services

National Institutes of Health

Recombinant DNA Advisory Committee Meeting; Recombinant DNA Research; Proposed Actions Under the Guidelines; Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on June 7–8, 1993. The meeting will be held at the National Institutes of Health, Building 31C, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20892, starting at approximately 9 a.m. on June 7, 1993, to adjournment at approximately 5 p.m. on June 8, 1993. The meeting will be open to the public to discuss the following proposed actions under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (51 FR 16958):

Proposed Major Actions to the NIH Guidelines

Additions to Appendix D of the *NIH Guidelines* regarding thirteen (13) Human Gene Therapy/Gene Transfer Protocols;

Additions to Appendix D of the *NIH Guidelines* Regarding Semliki Forest Virus; Poxvirus Vectors-NYVAC, ALVAC, TROVAC, and Reickettsia prowazeki;

Amendment to Section IV–C–3–c of the *NIH Guidelines* Regarding the *Recombinant DNA Technical Bulletin* and the Data Management of the NIH-Approved Human Gene Transfer Protocols;

Amendments to the *Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into the Genome of Human Subjects* Regarding Reporting Requirements for Human Gene Transfer/Gene Therapy Protocols; the term "Subject(s);" Satellite Institutions; Categorization of Protocols; and Protocol Format.

Other Matters To Be Considered by the Committee

Attendance by the public will be limited to space available. Members of the public wishing to speak at this meeting may be given such opportunity at the discretion of the Chair.

Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, Phone (301) 496–9838, FAX (301) 496–9839, will provide materials to be discussed at this meeting, roster of committee members, and substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Wivel in advance of the meeting. A summary of the meeting will be available at a later date.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the *Catalog of Federal Domestic Assistance*. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the *NIH Guidelines*. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the *Catalog of Federal Domestic Assistance* are affected.

Dated: April 28, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–10487 Filed 5–3–93; 8:45 am]

BILLING CODE 4140–01–M

Recombinant DNA Research: Proposed Actions Under the Guidelines

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (51 FR 16958).

SUMMARY: This notice sets forth proposed actions to be taken under the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (51 FR 16958). Interested parties are invited to submit comments concerning these proposals. These proposals will be considered by the Recombinant DNA Advisory Committee (RAC) at its meeting on June 7–8, 1993. After consideration of these proposals and comments by the RAC, the Director of the National Institutes of Health will issue decisions in accordance with the NIH Guidelines.

DATES: Comments received by May 25, 1993, will be reproduced and distributed to the RAC for consideration at its June 7–8, 1993, meeting.

ADDRESSES: Written comments and recommendations should be submitted to Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities (ORDA), Building 31, room 4B11, National Institutes of Health, Bethesda, Maryland 20892, or sent by FAX to 301–496–9839.

All comments received in timely response to this notice will be considered and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Recombinant DNA Activities, Building 31, room 4B11, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–9838.

SUPPLEMENTARY INFORMATION: The NIH will consider the following actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules:

I. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Drs. Deisseroth, Kavanagh, Champlin

In a letter dated March 4, 1993, Drs. Albert B. Deisseroth, John Kavanagh, and Richard Champlin of the University of Texas MD Anderson Cancer Center, Houston, Texas, indicated their intention to resubmit a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: Use of Safety-Modified Retroviruses to Introduce Chemotherapy Resistance Sequences into Normal Hematopoietic Stem Cells for Chemoprotection During the Therapy of Ovarian Cancer: A Pilot Trial.

II. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Drs. Das Gupta, Cohen, Richards

In a letter dated February 26, 1993, Drs. Tapas K. Das Gupta and Edward P. Cohen of the University of Illinois College of Medicine, Chicago, Illinois, and Dr. Jon M. Richards of the University of Chicago, Chicago, Illinois, submitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: Immunization of Malignant Melanoma Patients with Interleukin-2-

Secreting Melanoma Cells Expressing Defined Allogeneic Histocompatibility Antigens.

III. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Drs. Galpin, Casciato

On April 9, 1993, a human gene therapy protocol was submitted for Drs. Jeffrey E. Galpin of the University of Southern California, Los Angeles, California, and Dr. Dennis A. Casciato of the University of California, Los Angeles, California, by Dr. Bruce Merchant, Viagene, Inc., San Diego, California (sponsor of the protocol), to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *A Preliminary Study to Evaluate the Safety and Biologic Effects of Murine Retroviral Vector Encoding HIV-1 Genes [HIV-IT(V)] in Asymptomatic Subjects Infected with HIV-1.*

IV. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Drs. Karlsson, Dunbar, Kohn

In a letter dated April 10, 1993, Drs. Stefan Karlsson and Cynthia Dunbar of the National Institutes of Health, Bethesda, Maryland, and Dr. Donald B. Kohn of Childrens Hospital Los Angeles, Los Angeles, California, submitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Retroviral Mediated Transfer of the cDNA for Human Glucocerebrosidase into Hematopoietic Stem Cells of Patients with Gaucher Disease.*

V. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Dr. Barranger

In a letter dated March 26, 1993, Dr. John A. Barranger of the University of Pittsburgh, Pittsburgh, Pennsylvania, indicated his intention to submit a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Gene Therapy for Gaucher Disease: Ex Vivo Gene Transfer and Autologous Transplantation of CD34(+) Cells.*

VI. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Drs. Raffel, Culver

In a letter dated April 5, 1993, Dr. Corey Raffel of the Childrens Hospital Los Angeles, Los Angeles, California, and Dr. Kenneth Culver of Iowa Methodist Medical Center, Des Moines, Iowa, submitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Gene Therapy for the Treatment of Recurrent Pediatric Malignant Astrocytomas with In Vivo Tumor Transduction with the Herpes Simplex Thymidine Kinase Gene.*

VII. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Drs. Hesdorffer, Antman

In a letter dated March 8, 1993, Dr. Arthur Bank of Columbia University, New York, New York, indicated the intention of Drs. Charles Hesdorffer and Karen Antman of the Columbia University, College of Physicians and Surgeons, New York, New York, to submit a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Human MDR Gene Transfer in Patients with Advanced Cancer.*

VIII. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Freedman

In a letter dated March 22, 1993, Dr. Ralph S. Freedman of the University of Texas MD Anderson Cancer Center, Houston, Texas, indicated the intention to submit a human gene transfer protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Use of a Retroviral Vector to Study the Trafficking Patterns of Purified Ovarian TIL Populations Used in Intraperitoneal Adoptive Immunotherapy of Ovarian Cancer Patients—A Pilot Study.*

IX. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Dr. Ilan

In a letter dated April 10, 1993, Dr. Joseph Ilan of the Case Western Reserve University School of Medicine and University Hospitals of Cleveland, Cleveland, Ohio, submitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Gene Therapy for Human Brain Tumors Using Episome-Based Antisense cDNA Transcription of Insulin-Like Growth Factor I.*

X. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Dr. Nabel

In a letter dated April 9, 1993, Dr. Gary J. Nabel of the University of Michigan Medical Center, Ann Arbor, Michigan, submitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *Immunutherapy for Cancer by Direct Gene Transfer into Tumors.*

XI. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Dr. Nabel

In a letter dated April 9, 1993, Dr. Gary J. Nabel of the University of Michigan Medical Center, Ann Arbor, Michigan, submitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: *A Molecular Genetic Intervention for AIDS—Effects of a Transdominant Negative Form of Rev.*

XII. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Dr. Seigler

In a letter dated April 9, 1993, Dr. Hilliard F. Seigler of the Duke University Medical Center, Durham, North Carolina, resubmitted a human gene therapy protocol to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: A Phase I Trial of Human Gamma Interferon-Transduced Autologous Tumor Cells in Patients With Disseminated Malignant Melanoma.

XIII. Amendment to Appendix D-XV of the NIH Guidelines Regarding a Human Gene Therapy Protocol/Dr. Blaese

On April 8, 1993, an amendment to the human gene therapy protocol was submitted for Dr. R. Michael Blaese of the National Institutes of Health, Bethesda, Maryland, by Dr. Craig A. Mullen of the National Institutes of Health, Bethesda, Maryland, to the Recombinant DNA Advisory Committee for formal review and approval. The title of this protocol is: Treatment of Severe Combined Immune Deficiency (SCID) due to Adenosine Deaminase (ADA) Deficiency with CD34(+) Selected Autologous Hematopoietic Stem Cells.

XIV. Addition to Appendix D of the NIH Guidelines Regarding Semliki Forest Virus/Dr. Temple

In a letter dated February 8, 1993, Dr. Gary F. Temple of Life Technologies, Inc., Gaithersburg, Maryland, submitted a request for a reduction in physical containment from Biosafety Level 3 to Biosafety Level 2 for a Semliki Forest Virus vector expression system.

XV. Addition to Appendix D of the NIH Guidelines Regarding Poxvirus Vectors-NYVAC, ALVAC, TROVAC/Dr. Trag

In a letter dated January 8, 1993, Dr. Arvilla L. Trag of Virogenetics Corporation, Troy, New York, submitted a request for reduction in physical containment from Biosafety Level 2 to Biosafety Level 1 for three poxvirus vectors: NYVAC, ALVAC, TROVAC.

XVI. Addition to Appendix D of the NIH Guidelines Regarding Rickettsia prowazeki/Dr. Policastro

In a letter dated March 23, 1993, Dr. Paul Policastro of the National Institutes of Health, Bethesda, Maryland, submitted a request to transfer a chloramphenicol resistance marker to an avirulent strain of Rickettsia prowazeki.

XVII. Amendment to Section IV-C-3-c of the NIH Guidelines Regarding the Recombinant DNA Technical Bulletin and the Data Management of the NIH-Approved Human Gene Transfer Protocols/Ms. Wilson

In a letter dated April 5, 1993, Debra Wilson of the National Institutes of Health submitted a request that Section IV-C-3-c be amended to delete the requirement that the Office of Recombinant DNA Activities (ORDA) publish the *Recombinant DNA Technical Bulletin*, and to add the requirement that ORDA will serve as the focal point for data management of the NIH-approved human gene transfer protocols.

XVIII. Amendment to the Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects Regarding Reporting Requirements for Human Gene Transfer/Gene Therapy Protocols

The *Points to Consider* (March 1, 1990, 55 FR 7447) under *Part IV—Reporting Requirements* states that:

"B. Reports regarding the general progress of patients should be filed with both your local IRB and ORDA within six-months of the commencement of the experiments and at six-month intervals thereafter. These twice-yearly reports should continue for a sufficient period of time to allow observation of all major effects. In the event of a patient's death, a summary of the special port-mortem studies and statements of the cause of death should be submitted to the IRB and ORDA, if available."

Dr. Brigid Leventhal, Chair of Working Group on Data Management, will provide a summary of the reports submitted to ORDA by the principal investigators of NIH-approved protocols, and make recommendations regarding actions to be taken in the event of non-reporting.

XIX. Amendment to Section III-A-4 of the NIH Guidelines and the Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects Regarding the Term Subject(s)

During the March 1-2, 1993, Recombinant DNA Advisory Committee meeting, Dr. Robertson Parkman requested that the terms *subject* and *subjects* be amended to read *subject(s)*. Section III-A-4 currently reads:

"III-A-4. Deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into human subjects [21] * * *

Throughout the *Points to Consider* document the terms *subject* and *subjects* are used.

This amendment will clarify Section III-A-4 and the *Points to Consider*.

XX. Amendment to the Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects Regarding Satellite Institutions

On April 19, 1993, Dr. Nelson A. Wivel made a request that NIH-approved human gene therapy/gene transfer protocols may be conducted at satellite institutions with approval from the Chair of the Recombinant DNA Advisory Committee. The amendment would read:

"Protocols can be conducted at satellite institutions with approval from the Chair of the Recombinant DNA Advisory Committee. The Chair may consult others as necessary. The principal investigators must submit to the Office of the Recombinant DNA Activities the following: (1) Curricula vitae of new principal investigators, (2) Institutional Biosafety Committee approval, (3) Institutional Review Board approval, and (4) new Informed Consent document."

XXI. Amendment to the Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects Regarding Categorization of Protocols

The Working Group on Categorization of Protocols will make a report on decentralizing review for gene marking protocols utilizing vectors that have been previously approved by the Recombinant DNA Advisory Committee.

XXII. Amendment to the Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects Regarding Protocol Format

The Working Group on Protocol Format will present its report on condensing materials required for the submission of human gene therapy/gene transfer protocols for review and approval by the Recombinant DNA Advisory Committee.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the *Catalog of Federal Domestic Assistance*. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the *NIH Guidelines*. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the *Catalog of Federal Domestic Assistance* are affected.

Dated: April 26, 1993.

Jay Moskowitz,

Deputy Director for Science Policy and Technology Transfer, NIH.

[FR Doc. 93-10486 Filed 5-3-93; 8:45 am]

BILLING CODE 4140-01-M

Reader Aids

Federal Register

Vol. 58, No. 84

Tuesday, May 4, 1993

INFORMATION AND ASSISTANCE

Federal Register

Index, finding aids & general information	202–523–5227
Public inspection desk	523–5215
Corrections to published documents	523–5237
Document drafting information	523–3187
Machine readable documents	523–3447

Code of Federal Regulations

Index, finding aids & general information	523–5227
Printing schedules	523–3419

Laws

Public Laws Update Service (numbers, dates, etc.)	523–6641
Additional information	523–5230

Presidential Documents

Executive orders and proclamations	523–5230
Public Papers of the Presidents	523–5230
Weekly Compilation of Presidential Documents	523–5230

The United States Government Manual

General information	523–5230

Other Services

Data base and machine readable specifications	523–3447
Guide to Record Retention Requirements	523–3187
Legal staff	523–4534
Privacy Act Compilation	523–3187
Public Laws Update Service (PLUS)	523–6641
TDD for the hearing impaired	523–5229

ELECTRONIC BULLETIN BOARD

Free **Electronic Bulletin Board** service for Public Law numbers, Federal Register finding aids, and a list of Clinton Administration officials. **202–275–1538, or 275–0920**

FEDERAL REGISTER PAGES AND DATES, MAY

26225–26498.....3
26499–26678.....4

CFR PARTS AFFECTED DURING MAY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6553.....26499
6554.....26501
6555.....26503
6556.....26505

10 CFR

Proposed Rules:
20.....26257

12 CFR

215.....26507
265.....26508
Proposed Rules:
303.....26259

14 CFR

73.....26225
97.....26225, 26227
Proposed Rules:
33.....26262
39.....26264
71.....26265, 26266, 26267, 26268, 26269

17 CFR

1.....26229
200.....26383
201.....26383
228.....26383, 26509
230.....26509
232.....26383
239.....26509
240.....26383, 26509
249.....26509
Proposed Rules:
1.....26270
229.....26442
230.....26442
239.....26442
249.....26442

18 CFR

381.....26522

20 CFR

Proposed Rules:
416.....26383

21 CFR

430.....26652, 26655, 26658, 26662, 26665
436.....26652, 26655, 26658, 26665
441.....26669
442.....26658
443.....26665
444.....26671
450.....26662
452.....26652, 26655
510.....26523
520.....26523
1020.....26386
Proposed Rules:
1020.....26407

26 CFR

1.....26524
5c.....26524

29 CFR

1926.....26590

33 CFR

100.....26428
Proposed Rules:
117.....26280

34 CFR

222.....26524
668.....26674
Proposed Rules:
361.....26281
363.....26281
365.....26281
366.....26281
367.....26281
369.....26281
370.....26281
371.....26281
373.....26281
374.....26281
375.....26281
376.....26281
377.....26281
378.....26281
379.....26281
380.....26281
385.....26281
386.....26281
387.....26281
388.....26281
389.....26281
390.....26281
396.....26281

38 CFR

21.....26239
Proposed Rules:
36.....26282
44.....26282

40 CFR

261.....26420
264.....26420
265.....26420
271.....26242, 26420
279.....26420

43 CFR

Public Land Orders:
6968.....26251

6971.....26251
6972.....26252

47 CFR

73.....26252, 26524, 26525

Proposed Rules:

73.....26528

48 CFR

2012.....26253
2015.....26253
2030.....26253
2052.....26253

49 CFR

571.....26526

50 CFR

683.....26255

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

Last List April 29, 1993