highlights

SUNSHINE ACT MEETINGS........................................... 35271

MIGRANT AND SEASONAL FARMWORKER PROGRAMS
Labor/ETA announces FY 1978 state planning allocations (Part V of this issue) .................................................. 35329

VITAMIN AND MINERAL PRODUCTS
HEW/FDA revises effective date for regulations governing labeling and composition .................................................. 35152

PESTICIDE PROGRAMS
EPA proposes tolerances for residues of the herbicide Dalapon in or on a variety of crops and crop groupings; comments by 8-8-77 .......................................................................................... 35173
EPA establishes exemptions from the requirement of a tolerance for certain inert ingredients used in pesticide formulations ......................................................................................................................... 35158
EPA proposes tolerance for pesticide chemical Naled .................................................................................................. 35172

OCCUPATIONAL SAFETY
HEW/PHS solicits information concerning coal gasification and vinyls (2 documents); comments by 10-6-77 .............................................................. 35226, 35227

FISHERY CONSERVATION AND MANAGEMENT
State notice on applications for permits to fish off the coasts of the United States (Part II of this issue) .................. 35309

CONSUMER SERVICES
FEA establishes guidelines for grant program for state offices to assist representation of consumer interests before electric utility regulatory commissions; effective 7-3-77 ......................................................................................................................... 35163

VOLATILE ORGANIC COMPOUNDS
EPA recommends policy control (Part III of this issue) .................................................................................................. 35313

PESTICIDES
HEW/FDA proposes food additive tolerance for Dalapon; comments by 8-8-77 ......................................................................................................................... 35171

SMALL BUSINESS POLICY
SBA establishes new requirements and procedures for participation in loan programs; effective 7-8-77 ...................................................................................... 35150

COMPREHENSIVE EMPLOYMENT AND TRAINING ACT
Labor/Secy proposes to clarify existing policies and provide new approaches to the grant process; comments by 8-8-77 (Part IV of this issue) .................................................................................. 35317

CONTINUED INSIDE
AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The six-month trial period ended August 6. The program is being continued on a voluntary basis (see OFR notice, 41 FR 32914, August 6, 1976). The following agencies have agreed to remain in the program:

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
</tr>
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<tr>
<td>NRC</td>
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Documents normally scheduled on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

ATTENTION: For questions, corrections, or requests for information please see the list of telephone numbers appearing on opposite page.
FEDERAL REGISTER, Daily Issue:
Subscription orders (GPO) 202-783-3238
Subscription problems (GPO) 202-275-3050
"Dial-a-Regulation" (recorded summary of highlighted documents appearing in next day's issue).
Scheduling of documents for publication.
Copies of documents appearing in the Federal Register.
Corrections 523-5286
Public Inspection Desk 523-5215
Finding Aids 523-5227
Public Briefings: "How To Use the Federal Register."
Code of Federal Regulations (CFR) 523-5266
Finding Aids 523-5227

PRESIDENTIAL PAPERS:
Executive Orders and Proclamations 523-5233
Weekly Compilation of Presidential Documents 523-5235
Public Papers of the Presidents 523-5235
Index 523-5235

PUBLIC LAWS:
Public Law dates and numbers 523-5237
Slip Laws 523-5237
U.S. Statutes at Large 523-5237
Index 523-5237
U.S. Government Manual 523-5230
Automation 523-5240

OVER THE COUNTER DRUGS
HEW/FDA proposes establishment of a monograph for OTC internal analgesic, antipyretic and antirheumatic products; comments by 10-6-77; reply comments by 11-7-77 (Part VII of this issue) 35435

FOREIGN SERVICE INFORMATION OFFICERS
USIA revises eligibility requirements regarding minimum age, and the elimination of reference to citizenship of spouse in the examination and appointment of applicants 35156

MEDICARE PROGRAM
HEW/HFSA issues schedule of limits on Hospital Inpatient General Routine Service Costs on or after 7-1 and before 10-1-77 (Part VIII of this issue) 35495

MANDATORY PETROLEUM PRICE REGULATIONS
FEA issues ruling on treatment of separate reservoirs as stripper well properties 35161

PRIVACY ACT
DOD/DMA notice of new system of records 35181.
DOD/Secy corrects system of records exemption; effective 9-27-75 35187

MEETINGS—
USDA/FSQS: Expert Panel on Nitrates and Nitrosamines, 7-25-77 35177
DOD/Army: Winter Navigation Board, 7-26 and 7-27-77 35181
Secy: Wage Committee, 9-6, 9-13, 9-20, and 9-27-77 35183
FEA: Petroleum Company Financial Reporting System, 7-29-77 35187
HEW/HRA: Health Services Developmental Grants Study Section, 7-31 thru 8-1 and 9-25 thru 9-26-77 (2 documents) 35223, 35224
National Advisory Council on Health Professions

EXECUTIVE ORGANIZATIONS
AMENDED MEETINGS—
HEW/NIH: Allergy and Immunology Research Committee, 7-29-77 35224
Minority Access to Research Careers Review Committee, 7-20-77 35226
National Commission on Digestive Diseases, 7-21 and 7-22-77 35226
CANCELL ED MEETINGS—
HEW/NIH: Carcinogenesis Scientific Advisory Committee, 7-18 and 7-19-77. .................................................. 35225
HRA: Long-Term Care Advisory Committee, 7-14 and 7-15-77 .......................................................... 35224

HEARINGS—
Commerce/NOAA: Foreign Fishing Ventures Within U.S. Fishery Conservation Zone (2 documents), 8-3, 8-5, 8-6, 8-8, 8-9, 8-16 thru 8-19, 8-22, 8-22, 8-23 and 8-24-77. ........................................................................... 35175

SEPARATE PARTS OF THIS ISSUE
Part II, State ........................................................................ 35309
Part III, EPA ........................................................................ 35313
Part IV, Labor/Secy .............................................................. 35317
Part V, Labor/ETA ............................................................... 35329
Part VI, Interior/BLM ............................................................ 35333
Part VII, HEW/FOA .............................................................. 35345
Part VIII, HEW/HCFA .......................................................... 35495
Part IX, Labor/ESA ............................................................... 35507

AGENCY FOR INTERNATIONAL DEVELOPMENT
Notices
Authority delegations: Bangladesh, Mission Director, et al.; contracting functions. ............................................. 35228
Indonesia, Mission Director, et al.; loan agreements. ....................................................................................... 35227
Pakistan, Mission Director, et al.; loan agreements. ....................................................................................... 35237
Philippines, Mission Director, et al.: loan agreements. .................................................................................... 35239

AGRICULTURAL MARKETING SERVICE
Rules
Apricots grown in Wash .................................................. 35144
Avocados grown in So. Fla. .................................................. 35142
Lemons grown in Ariz. and Calif. ......................................... 35142
Nectarines grown in Calif. ................................................... 35143
Potatoes (Irish) grown in Idaho and Ore. ............................. 35144
Walnuts; imported. ............................................................ 35146

AGRICULTURE DEPARTMENT
See Agricultural Marketing Service; Food Safety and Quality Service; Rural Electrification Administration.

ARMY DEPARTMENT
Notices
Meetings: Winter Navigation Board on Great Lakes-St. Lawrence Seaway ......................................................... 35181

CIVIL SERVICE COMMISSION
Rules
Exempted service: Arts and Humanities, National Foundation ................................................................. 35141
Environmental Protection Agency .............................................. 35141
Interior Department ............................................................ 35141
Labor Department ............................................................... 35142
National Aeronautics and Space Transportation Department .................................................................. 35141

Notices
Noncareer executive assignments: Labor Department ............................................................................. 35178

COMMERCE DEPARTMENT
See Economic Development Administration; National Oceanic and Atmospheric Administration.

CONSUMER AFFAIRS AND REGULATORY FUNCTIONS, OFFICE OF ASSISTANT SECRETARY
Rules
Mobile home procedural and enforcement regulations: Certification label, elimination of deadline. ................ 35156
DEFENSE DEPARTMENT
See also Army Department; Defense Mapping Agency.

Drug Enforcement Administration
Notices
Pesticide Act; implementation, correction .................................................. 35157

Drug Enforcement Administration
Rules
Privacy Act; systems of records ........................................ 35181

EMERGENCY NATURAL GAS ACT OF 1977, ADMINISTRATOR
Notices
Emergency orders, etc. ..................................................... 35177

EMERGENCY REGULATORY AGENCY
Notices
Water pollution: effluent guidelines for certain point source categories: Petroleum refining: extension of time .................................................................................................................. 35150

ENVIRONMENTAL PROTECTION AGENCY
Rules
Pesticide chemicals in or on raw agricultural commodities; tolerances and exemptions, etc.: Inert ingredients in pesticide formulations .................................................. 35150

Proposed Rules
Air programs; energy-related authority: Georgia ................................................................. 35172
Pesticide chemicals in or on raw agricultural commodities; tolerances and exemptions, etc.: Dalapon ........................................................................ 35173
Naled .......................................................... 35172

Notices
Air quality standards; photochemical oxidants; volatile organic compounds, control policy ........................................ 35184
Pesticide applicator certification and interim certification: State plans: Alaska ........................................... 35183
California ........................................................................ 35184
Pesticide chemicals; tolerances, exemptions, etc.: Petitions: Elanco Products Co. .................................................. 35186
Mobay Chemical Corp ......................................................... 35184
Pesticide registration: Applications ........................................ 35184
Toxic substances control: Chemicals, candidate list; availability on magnetic tape ........................................ 35183
The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published in today's issue. A cumulative list of parts affected, covering the current month to date, follows beginning with the second issue of the month. A Cumulative List of CFR Sections Affected is published separately at the end of each month. The guide lists the parts and sections affected by documents published since the revision date of each title.

<table>
<thead>
<tr>
<th>Title</th>
<th>CFR Part(s)</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 CFR</td>
<td>213 (6 documents)</td>
<td>35141</td>
</tr>
<tr>
<td>7 CFR</td>
<td>910 - 916</td>
<td>35142</td>
</tr>
<tr>
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<td>999</td>
<td>35146</td>
</tr>
<tr>
<td>9 CFR</td>
<td>Proposed Rules:</td>
<td></td>
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<tr>
<td></td>
<td>381</td>
<td>35170</td>
</tr>
<tr>
<td>10 CFR</td>
<td>70 - 212</td>
<td>35160</td>
</tr>
<tr>
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<td>409</td>
<td>35163</td>
</tr>
<tr>
<td></td>
<td>Proposed Rules:</td>
<td></td>
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<tr>
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<td>211 - 212</td>
<td>35170</td>
</tr>
<tr>
<td></td>
<td>430</td>
<td>35170</td>
</tr>
<tr>
<td>12 CFR</td>
<td>228</td>
<td>35146</td>
</tr>
<tr>
<td>13 CFR</td>
<td>120</td>
<td>35150</td>
</tr>
<tr>
<td>21 CFR</td>
<td>5 - 105</td>
<td>35151</td>
</tr>
<tr>
<td></td>
<td>135 - 310</td>
<td>35152</td>
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<td></td>
<td>310 - 555</td>
<td>35153</td>
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<tr>
<td></td>
<td>555 - 801</td>
<td>35155</td>
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<td>Proposed Rules:</td>
<td></td>
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<td></td>
<td>193</td>
<td>35171</td>
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<td>343</td>
<td>35346</td>
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<tr>
<td>22 CFR</td>
<td>501</td>
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<td>24 CFR</td>
<td>3282</td>
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<td>29 CFR</td>
<td>3290a</td>
<td>35157</td>
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<tr>
<td>32 CFR</td>
<td>601 (2 documents)</td>
<td>35158</td>
</tr>
<tr>
<td>39 CFR</td>
<td>410 - 419</td>
<td>35158</td>
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<td>Proposed Rules:</td>
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<td>55 (2 documents)</td>
<td>35172</td>
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<td>160 (2 documents)</td>
<td>35172, 35173</td>
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<tr>
<td>43 CFR</td>
<td>Proposed Rules:</td>
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<tr>
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<td>4100 - 4700</td>
<td>35334</td>
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<td>9230</td>
<td>35334</td>
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<tr>
<td>49 CFR</td>
<td>258 - 1033</td>
<td>35159</td>
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<td>1063</td>
<td>35159</td>
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<td>1331</td>
<td>35175</td>
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<tr>
<td>50 CFR</td>
<td>661</td>
<td>35160</td>
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<td>Proposed Rules:</td>
<td></td>
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<tr>
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<td>611 (2 documents)</td>
<td>35175</td>
</tr>
</tbody>
</table>
CUMULATIVE LIST OF PARTS AFFECTED DURING JULY

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during July.

<table>
<thead>
<tr>
<th>CFR</th>
<th>Ch. I</th>
<th>3 CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>33711</td>
</tr>
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</tr>
</tbody>
</table>

MEMORANDUMS:

June 29, 1977

PROPOSED

3 CFR

EXECUTIVE ORDERS:
November 6, 1912 (Revised in part by PLO 5621) 36159
1140 (Revised by EO 12001) 36170
12001 35709
12003 35709

MEMORANDUMS:

June 29, 1977 33909, 33911, 33913, 33915

5 CFR

213 33711-33713, 34275, 34308, 35141
735 34009

7 CFR

68 34375
908 33713, 34655
1010 33714, 35143
1948 35143
918 34499, 35143
922 35144
946 35144
990 35146
1434 33714, 34585
1464 34275

PROPOSED RULES:

68 33753
923 34687
930 34687
946 34687
948 34687
958 33765
960 34309, 34887, 34889
1446 33765
1701 33767
3976 33767

9 CFR

97 34276

PROPOSED RULES:

381 35170

10 CFR

2 34686
21 34686
31 34686
34 34686
35 34686
40 34686
51 34276
70 34886, 35160
211 35161
212 35161
460 35163

PROPOSED RULES:

70 34310, 34689
73 34310, 34321, 34890
211 35170
212 34680, 35170
490 34891, 35170

12 CFR

220 35146
309 33715
310 33719

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 6, 1977
PROPOSED RULES:

Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

PROPOSED RULES:

(The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)
PART 213—EXCEPTED SERVICE

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment extends the exception from the competitive service under Schedule C one position of Assistant to the Chairman, National Endowment for the Arts because it is confidential in nature. This section is amended to show that one position of Assistant to the Chairman, National Endowment for the Arts is revoked under Schedule A because it is confidential in nature and therefore has been excepted under Schedule C.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3182(a) (17) is revoked and 213.3382(b) is amended to read as follows:

§213.3182 National Foundation on the Arts and the Humanities.

(17) (Revised).

§213.3382 National Foundation on the Arts and the Humanities.

(b) Two Assistants to the Chairman, National Endowment for the Arts.


United States Civil Service Commission, James C. Spiry, Executive Assistant to the Commissioners.

[FR Doc.77-19525 Filed 7-7-77; 8:15 am]

PART 213—EXCEPTED SERVICE

Department of Transportation

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This section is amended to show that one position of Special Assistant to the Associate Administrator for Planning, Federal Highway Administration, is excepted under Schedule C because it is confidential in nature.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3394(d) (4) is added as set out below:

§213.3394 Special Assistant to the Associate Administrator for Planning, Federal Highway Administration.

(4) (Revised).

§213.3394 National Endowment for the Arts and the Humanities.

(b) Two Assistants to the Chairman, National Endowment for the Arts.


United States Civil Service Commission, James C. Spiry, Executive Assistant to the Commissioners.

[FR Doc.77-19526 Filed 7-7-77; 8:45 am]

PART 213—EXCEPTED SERVICE

National Foundation on the Arts and the Humanities

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This addition excepts from the competitive service under Schedule C one position of Assistant to the Chairman, National Endowment for the Arts because it is confidential in nature.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3182(a) (17) is revoked and 213.3382(b) is amended to read as follows:

§213.3182 National Foundation on the Arts and the Humanities.

(17) (Revised).

§213.3382 National Foundation on the Arts and the Humanities.

(b) Two Assistants to the Chairman, National Endowment for the Arts.


United States Civil Service Commission, James C. Spiry, Executive Assistant to the Commissioners.

[FR Doc.77-19524 Filed 7-7-77; 8:45 am]

PART 213—EXCEPTED SERVICE

Department of Environmental Protection

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This section is amended to show that one position of Assistant to the Director, Office of Regional and Intergovernmental Liaison Operations is excepted under Schedule C because it is confidential in nature.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3382(b) is amended to read as follows:

§213.3382 National Foundation on the Arts and the Humanities.

(b) Two Assistants to the Chairman, National Endowment for the Arts.


United States Civil Service Commission, James C. Spiry, Executive Assistant to the Commissioners.

[FR Doc.77-19523 Filed 7-7-77; 8:45 am]
SUMMARY: This regulation establishes the quantity of California-Arizona lemons that may be marketed fresh during the weekly regulation period July 10–16, 1977. This regulation is needed to provide for orderly marketing of fresh lemons for the regulation period because of the production and marketing situation confronting the lemon industry.

EFFECTIVE DATE: July 10, 1977.

FOR FURTHER INFORMATION CONTACT:


[FR Doc.77-19522 Filed 7-7-77; 8:45 am]

PART 213—EXCEPTED SERVICE

Department of Labor

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts the quantity of California-Arizona lemons grown in California and Arizona, effective under the amended provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–614), and upon the basis of the recommendations and information submitted to the Lemon Administrative Committee established under the amended marketing agreement and order, and, upon other available information, it is found that the limitation of handling of such lemons, as provided in this section, will tend to effectuate the declared policy of the act.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION ON POSITION AUTHORITY CONTACT:

Dean Bollman, Civil Service Commission, 202–632–7676.

FOR FURTHER INFORMATION ON POSITION CONTENT CONTACT:

Margaret Giovanni, Assistant Director for Executive Staffing, Department of Labor, 202–523–6555.

Accordingly, 5 CFR 213.3315(a) (57) is added as set out below:

§ 213.3315 Department of Labor.

(a) Office of the Secretary. * * *

(57) Counselor and Executive Assistant to the Secretary. * * *


United States Civil Service Commission,

James C. Spy, Executive Assistant to the Commissioners.

[FR Doc.77–19561 Filed 7–7–77; 8:45 am]

Title 7—Agriculture

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, AND NUTS), DEPARTMENT OF AGRICULTURE

[Leom Reg. 100]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of California-Arizona lemons that may be marketed fresh during the weekly regulation period July 10–16, 1977. This regulation is needed to provide for orderly marketing of fresh lemons for the regulation period because of the production and marketing situation confronting the lemon industry.

EFFECTIVE DATE: July 10, 1977.

FOR FURTHER INFORMATION CONTACT:


[FR Doc.77–19522 Filed 7–7–77; 8:45 am]

PART 915—AVOCADOS GROWN IN SOUTH FLORIDA

Expenses for 1977–78 Fiscal Year and Carryover of Unexpended Funds

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This document authorizes expenses of $58,760 and the carryover as a reserve of unexpended funds for the functioning of the Avocado Administrative Committee for the 1977–78 fiscal year. The committee administers locally a Federal marketing order program regulating the handling of avocados grown in South Florida. The regulation enables the committee to use available reserve funds for its operational expenses to support its activities under the program.

DATES: Effective for fiscal year April 1, 1977, through March 31, 1978.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On June 15, 1977, notice of rulemaking was published in the Federal Register (42 FR 30513) inviting written comments...
not later than June 29, 1977, regarding proposed expenses for the period begin-
ning April 1, 1977, through March 31, 1978, and carryover of unexpended funds, un-
der the marketing agreement and Or-
der No. 915, both as amended (7 C.F.R. part 915), regulating the handling of
avocados grown in South Florida. None were received. This regulatory program is
effective under the Agricultural Mar-

After consideration of all relevant
matters presented, including the pro-
posals set forth in such notice which were
submitted by the Avocado Administrative
Committee (established pursuant to
said marketing agreement and order), it
is hereby found and determined that:
§ 915.216 Expenses and carryover of
unexpended funds.

(a) Expenses. Expenses which are rea-
sonable and likely to be incurred by the
Avocado Administrative Committee under
the period April 1, 1977, through
March 31, 1978, will amount to $85,760.

(b) Reserve. Unexpended assessment
funds in the amount of approximately
$63,910, which are in excess of expenses
incurred during the fiscal year ending
March 31, 1977, shall be carried over
as a reserve in accordance with §§ 915.42
and 915.303 of the amended marketing agree-
ment and order.

It is hereby further found that good
cause exists for not postponing the effec-
tive date hereof until 30 days after pub-
lication in the Federal Register (5 U.S.C.
553) in that (1) shipments of avocados
began on or about May 30, 1977, (2) the
recommendations upon which this regu-
lation is based were developed by the
committee at open meetings on April
13 and May 11, 1977, after due notice
thereof, and all interested persons
present were given an opportunity to
express their views; (3) a notice of pro-
posed expenses and carryover of unex-
pended funds for the functioning of the
Avocado Administrative Committee for
the 1977-78 fiscal year was published in
the Federal Register (42 FR 30513); and
(4) the expenses and carryover of funds
herein authorized are the same as
those in the proposal.

(Secs. 1-19, 48 Stat. 31, as amended (7 U.S.C.
601-674).)

Dated: July 1, 1977.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural
Marketing Service.

[FR Doc. 77-1947 Filed 7-1-77; 8:45 am]

Nectarine Reg. 9, Amdt. 1

PART 916—NECTARINES GROWN
IN CALIFORNIA

Minimum Grade and Size Requirements

AGENCY: Agricultural Marketing Service,
USDA.

ACTION: Final rule.

SUMMARY: This amended regulation con-

in California nectarines. The amendment is
necessary to ensure the continued shipment of nec-
tarines which satisfy the demands of the
fresh fruit market. The amendment is con-
sistent with the objective of the act of
promoting order and protecting the
interest of consumers.

After consideration of all relevant
matter presented, including the proposal
set forth in the notice and the in-
available information, it is found that the
regulation of shipments of California
nectarines, as set forth, is in accordance
with the amended marketing agreement and
order and will tend to effectuate the
declared policy of the act.

It is further found that good cause
exists for making this amendment effec-
tive at the time set forth and for not
postponing the effective date until 30
days after publication in the Federal
Register (5 U.S.C. 553) in that (1) ship-
mments of nectarines are currently in
progress and this amendment should be
applicable to all nectarine shipments occur-
curring during the effective period speci-
fied in order to effectuate the declared
policy of the act; (2) the amendment is
the same as specified in the notice; and
(3) compliance with this amended regu-
lation will not require any special prepa-
ration on the part of the persons
subject thereto which cannot be com-
pleted by the effective time.

Order. Section 916.351 (Nectarine
Regulation 9 (42 FR 24229)) is amended
to read as follows:

§ 916.351 Nectarine Regulation 9.

Order. (a) During the period July 16,
1977, through May 31, 1978, no handler
shall handle:

(1) Any package or container of any
variety of nectarines unless such nec-
tarines grade at least U.S. No. 1: Pro-
vided, That nectarines 2 inches in diam-
eter or smaller, shall not have fairly
light-colored, fairly smooth scars which
exceed the aggregate area of a circle 

inch in diameter, and nectarines larger
than 2 inches in diameter shall not have
fairly light-colored, fairly smooth scars
which exceed the aggregate area of a

inches in diameter:

An additional tolerance of 25 percent
shall be permitted for fruit that is not
well formed but not badly
misshapen.

(2) Any package or container of May-
red variety nectarines unless:

(i) Such nectarines, when packed in
molded forms (tray pack) in a No. 22D
standard lug box, are of a size that will
pack, in accordance with the require-
ments of a standard pack, not more than
118 nectarines in the lug box;

(ii) Such nectarines in any container
when packed other than as specified in
subdivision (i) of this subparagraph
are of a size that a 16 pound sample,
representative of the nectarines in the
package or container, contains not more
than 112 nectarines.

(3) Any package or container of May-
red variety nectarines unless:

(i) Such nectarines, when packed in
molded forms (tray pack) in a No. 22D
standard lug box, are of a size that will
pack, in accordance with the require-
ments of a standard pack, not more than
112 nectarines in the lug box;

(ii) Such nectarines in any container
when packed other than as specified in
subdivision (i) of this subparagraph
are of a size that a 16 pound sample,
representative of the nectarines in the
package or container, contains not more
than 105 nectarines.

(4) Any package or container of Crim-
son Gold, June Belle, June Grand, May
Grand, Red June, Spring Grand, Arm-
king, or Zee Gold variety nectarines un-
less:

(i) Such nectarines, when packed in
molded forms (tray pack) in a No. 22D
standard lug box, are of a size that will
pack, in accordance with the require-
ments of a standard pack, not more than
108 nectarines in the lug box:

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
(ii) Such nectarines in any container when packed other than as specified in subdivision (i) of this subparagraph (4) are of a size that a 16 pound sample, representative of the nectarines in the package or container, contains not more than 102 nectarines.

(5) Any package or container of Early Sungrand, Independence, Moon Grand, Star Grand I, Star Grand II, Sun Flame, Summer Grand, Sun Grand, Kent-Grand, Early Star, Firebright, or Red Diamond variety nectarines unless:

(i) Such nectarines, when packed in molded forms (tray pack) in a No. 22D standard lug box, are of a size that will pack, in accordance with the requirements of a standard pack, not more than 96 nectarines in the lug box; or

(ii) Such nectarines in any container when packed other than as specified in subdivision (i) of this subparagraph (5) are of a size that a 16 pound sample, representative of the nectarines in the package or container, contains not more than 90 nectarines,


(i) Such nectarines, when packed in molded forms (tray pack) in a No. 22D standard lug box, are of a size that will pack, in accordance with the requirements of a standard pack, not more than 88 nectarines in the lug box; or

(ii) Such nectarines in any container, when packed other than as specified in subdivision (i) of this subparagraph (6) are of a size that a 16 pound sample, representative of the nectarines in the package or container, contains not more than 76 nectarines.

(7) When used herein, "U.S. No. 1" and "standard pack" shall have the same meaning as set forth in the United States Standards for Grades of Nectarines (7 CFR 51.3145-51.316D); the term "No. 22D standard lug box" shall have the same meaning as set forth in Section 1307.11 of the "Regulations of the California Department of Food and Agriculture" and all other terms shall have the same meaning as when used in the marketing agreement and order.

(See Secs. 1-19, 48 Stat. 31, as amended (7 U.S.C. 601-674).)


CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.77-19416 Filed 7-7-77; 8:45 am]

PART 922—APRICOTS GROWN IN WASHINGTON

Expenses and Rate of Assessment for 1977-78 Fiscal Period and Carryover of Unexpended Funds

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This document authorizes expenses of $2,692 and a rate of assessment of $0.70 per ton of apricots for the functioning of the Washington Apricot Marketing Committee for the 1977-78 fiscal period. The committee administers locally a Federal marketing order program regulating the handling of apricots grown in Washington. The regulations will enable the committee to collect assessments from first handlers on all assessable apricots handled and to use the resulting funds for its expenses.

DATES: Effective for fiscal year April 1, 1977, through March 31, 1978.


SUPPLEMENTARY INFORMATION:

On June 15, 1977, notice of proposed rule making was published in the Federal Register (42 FR 30514), regarding proposed expenses and the proposed rate of assessment, under the amended marketing agreement and Order No. 922, as amended (7 CFR Part 922) regulating the handling of apricots grown in the State of Washington. This notice allowed interested persons until June 30, 1977, during which time they could submit written comments pertaining to these proposals. None were submitted. This regulatory program is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674).

After consideration of all relevant matters presented, including the proposals which were set forth in the notice, which were submitted by the Washington Apricot Marketing Committee (established pursuant to the amended marketing agreement and order), it is hereby found and determined that:

§ 922.217 Expenses, rate of assessment, and carryover of unexpended assessment funds.

(a) Expenses. Expenses that are reasonable and likely to be incurred by the Washington Apricot Marketing Committee during the fiscal year April 1, 1977, through March 31, 1978, will amount to $2,692.

(b) Rate of assessment. The rate of assessment for the fiscal year payable by each handler in accordance with § 922.41, is established at $0.70 per assessable ton of apricots.

(c) Carryover of unexpended funds. Unexpended funds in excess of expenses incurred during the fiscal year ended March 31, 1977, will be carried over as a reserve in accordance with § 922.32 of said amended marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553) in that (1) shipments of the current crop of apricots grown in the designated production area are now being made; (2) provisions of the marketing agreement and this part require that the rate of assessment shall apply to all assessable apricots handled during the fiscal year, and (3) the year began on April 1, 1977, and the rate of assessment will automatically apply to all apricots handled during the year.

Handing Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: During the period July 15 through August 15, 1977, this regulation will require fresh market shipments of potatoes grown in certain counties in Idaho and Malheur County, Oregon, to be inspected and meet minimum grade, size, maturity and pack requirements. The regulation should promote orderly marketing of such potatoes by keeping less desirable quality and sizes from being shipped to consumers.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Findings: (1) Pursuant to Order No. 945, as amended (7 CFR Part 945), regulating the handling of potatoes grown in designated counties of Idaho and Malheur County, Oregon, effective under
the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations of the Idaho-Eastern Oregon Potato Committee established pursuant to the order, and upon other available information, it is hereby found that the handling regulation, hereinafter set forth, will tend to effectuate the declared policy of the act.

(2) The regulation imposes minimum grade, size, maturity and pack requirements on the handling of potatoes. The regulation is based upon an appraisal of the crop and plant disease matters with respect to which conditions as required in § 945.50 of the order. This regulation is necessary to prevent the handling of any potatoes of lower grades or smaller sizes than those specified in the regulation, and to provide the trade and consumers with potatoes of acceptable quality pursuant to the declared policy of the act.

(3) It is hereby further found that it is impractical and contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date of this regulation until 30 days after publication thereof in the Federal Register (5 U.S.C. 553) because shipments of potatoes from the production area are expected to begin on or about the effective date hereof. The recommendations and supporting information for regulations were submitted to the Department after a public meeting of the Idaho-Eastern Oregon Potato Committee; said meeting was held to consider recommendations for regulations, after giving due notice of the meeting, and interested persons were afforded an opportunity to submit their views at the meeting; and handlers have been informed of the regulation, and to provide the trade and consumers with potatoes of acceptable quality pursuant to the declared policy of the act.

§ 945.336 Handling regulation.

During the period July 15, 1977, through August 15, 1977, no person shall handle any lot of potatoes unless such potatoes meet the requirements of paragraphs (a), (b), (c), and (d) of this section, or unless such potatoes are handled in accordance with paragraphs (e), (f), or (g) of this section.

(a) Minimum quality requirements.—

(1) All varieties—U.S. No. 2 or better grade.

(2) Size—(i) Round red varieties—1¾ inches minimum diameter.

(ii) All other varieties. 2 inches minimum diameter, or 4 ounces minimum weight.

(iii) All varieties. Size B if U.S. No. 1 or better grade.

(3) Cleanliness. All varieties—"Fairly clean."

(b) Minimum maturity requirements.—(1) White Rose and red skin varieties: "moderately skinned."

(2) Norgold variety. "Moderately skinned."

(3) All other varieties. "Slightly skinned."

(c) Exceptions. (1) Subject to compliance with subdivision (ii) of this subparagraph, any lot of potatoes not exceeding a total of 50 hundredweight of each variety may be handled for any producer without regard to the foregoing maturity requirements.

(ii) If an officially inspected lot of potatoes meets the foregoing maturity requirements, but fails to meet the grade and size requirements, the lot may be regraded. If, after regrading, such lot then meets the grade and size requirements but fails to meet the maturity requirements, as indicated by the applicable Federal-State inspection certificate, such lot if not exceeding 100 hundredweight shall be exempt from the foregoing maturity requirements: Provided, That the handler complies with subdivision (iii) of this subparagraph.

(iii) Prior to each shipment of potatoes exempt from the foregoing requirements, the handler thereof shall report to the committee the name and address of the producer of such potatoes, and each such shipment shall be handled as an identifiable entity.

(d) Pack. (1) When 50-pound containers (except master containers) of long varieties of potatoes are marked with a count, size or similar designation they must meet the count, average count and weight ranges for the count designation listed below.

<table>
<thead>
<tr>
<th>Range</th>
<th>Average count</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larger than 50 count</td>
<td>10 per count or under</td>
<td>5 per count or under</td>
</tr>
<tr>
<td>50 count</td>
<td>45 to 52</td>
<td>45 to 52</td>
</tr>
<tr>
<td>60 count</td>
<td>57 to 64</td>
<td>57 to 64</td>
</tr>
<tr>
<td>70 count</td>
<td>67 to 74</td>
<td>67 to 74</td>
</tr>
<tr>
<td>80 count</td>
<td>75 to 82</td>
<td>75 to 82</td>
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<tr>
<td>90 count</td>
<td>81 to 88</td>
<td>81 to 88</td>
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<tr>
<td>100 count</td>
<td>90 to 110</td>
<td>90 to 110</td>
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<tr>
<td>110 count</td>
<td>100 to 121</td>
<td>100 to 121</td>
</tr>
<tr>
<td>120 count</td>
<td>110 to 131</td>
<td>110 to 131</td>
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<tr>
<td>130 count</td>
<td>120 to 141</td>
<td>120 to 141</td>
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<tr>
<td>140 count</td>
<td>130 to 159</td>
<td>130 to 159</td>
</tr>
<tr>
<td>Smaller than 100 count</td>
<td>10 per count or under</td>
<td>5 per count or under</td>
</tr>
</tbody>
</table>

1 Applicable to lots.

The following tolerances by weight, are provided for potatoes in any lot which fail to meet the weight range for the designated count:

(i) Not to exceed 5 percent for undersize;

(ii) Not to exceed 10 percent for oversize.

(2) Potatoes packed in 50-pound cartons shall be U.S. No. 1 or better grade.

(c) Inspection. (1) No handler shall handle potatoes unless such potatoes are inspected by either the Idaho and Federal-State Inspection Service or Oregon Federal-State Inspection Service and are covered by a valid inspection certificate except when relieved of such requirement pursuant to paragraphs (a), (b), or (g) of this section.

(2) Each lot moving by truck shall be accompanied by a copy of a valid inspection certificate.

(e) Special purpose shipments. (1) The minimum grade, size, cleanliness, maturity and pack requirements set forth in paragraphs (a), (b) and (c) of this section shall not be applicable to shipments of potatoes for any of the following purposes:

(i) Charity;

(ii) Certified seed;

(iii) Seed pieces cut from stock eligible for certification as certified seed;

(iv) Experimentation; and

(v) Canning, freezing and "other processing" as hereinafter defined: Except shipments for the purpose specified in this subdivision (v) shall be exempt from inspection requirements specified in § 945.65 and paragraph (d) of this section and from any requirement specified in § 945.42.

(2) The minimum grade, size, cleanliness, maturity and pack requirements set forth in paragraphs (a), (b) and (c) of this section shall be applicable to shipments of potatoes for each of the following purposes:

(i) Export. Except potatoes of a size not smaller than 1½ inches in diameter or better grade not less than U.S. No. 2;

(ii) Prepeeling. Except potatoes of a size not smaller than 1½ inches in diameter may be shipped if the potatoes grade not less than Idaho Utility or Oregon Utility grade.

(f) Safeguards. (1) Each handler making shipments of potatoes for charity, seed pieces cut from stock eligible for certification, experimentation, export, or for prepeeling pursuant to paragraph (e) of this section shall:

(i) First, apply to the committee or obtain a Certificate of Privilege to make shipments for each purpose;

(ii) Upon request by the committee, furnish reports of each shipment pursuant to the applicable Certificate of Privilege;

(iii) At the time of applying for the Certificate of Privilege, or promptly thereafter furnish the committee with a certificate of the buyer's certification that the potatoes so handled are to be used only for the purpose stated in the application and that such receiver...
will complete and return to the commit-
ment such periodic receiver's reports that
the committee may require;
(iv) Mail to the office on the com-
mittee a copy of the bill of lading for each
Certificate of Privilege shipment promptly
after the date of shipment;
(v) Bill each shipment directly to the
applicable receiver.
(2) Each handler making shipments of potatoes for canning, freezing, or
marketing, for canning, freezing, or
applicable receiver.
promptly after the date of shipment;
(iii) First apply to the committee for
and obtain a Certificate of Privilege to make
shipments for processing;
(ii) Make shipments only to those
firms whose names appear on the com-
mittee's current list of manufacturers of potato products;
(iii) Upon request by the committee,
firm's reports of each shipment pursuant
to the applicable Certificate of Privilege;
(iv) Mail to the committee's office a
copy of the bill of lading for each Cer-
ificate of Privilege shipment promptly
after the date of shipment;
(v) Bill each shipment directly to the
applicable processor.
(3) Each receiver of potatoes for
processing pursuant to paragraph (e) of
this section shall:
(i) Complete and return an application
form for listing as a manufacturer of potato products;
(ii) Certify to the committee and to
the Secretary that potatoes received from the production area for processing
will be used for such purpose and will
not be placed in fresh market channels;
(iii) Within thirty days after approval by
the committee, the processor may not store,
process, or market such potatoes other than for
processing.
(iv) If the Secretary determines that the
processors are in violation of the provisions of
the applicable regulations, he may
impose a penalty for each day of violation.
(v) In the event of violation of these
provisions, the Secretary shall have the
discretion to withdraw the processor's
approval.

RULES AND REGULATIONS

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the committee may require;
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after the date of shipment;
(v) Bill each shipment directly to the
applicable receiver.
(2) Each handler making shipments of potatoes for canning, freezing, or
applicable receiver.
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and obtain a Certificate of Privilege to make
shipments for processing;
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(iii) Upon request by the committee,
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RULES AND REGULATIONS

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and obtain a Certificate of Privilege to make
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the Secretary that potatoes received from the production area for processing
will be used for such purpose and will
not be placed in fresh market channels;
(iii) Within thirty days after approval by
the committee, the processor may not store,
process, or market such potatoes other than for
processing.
(iv) If the Secretary determines that the
processors are in violation of the provisions of
the applicable regulations, he may
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RULES AND REGULATIONS

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(iv) If the Secretary determines that the
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RULES AND REGULATIONS

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the Secretary that potatoes received from the production area for processing
will be used for such purpose and will
not be placed in fresh market channels;
(iii) Within thirty days after approval by
the committee, the processor may not store,
process, or market such potatoes other than for
processing.
(iv) If the Secretary determines that the
processors are in violation of the provisions of
the applicable regulations, he may
impose a penalty for each day of violation.
(v) In the event of violation of these
provisions, the Secretary shall have the
discretion to withdraw the processor's
approval.
ACTION: Official staff interpretation(s).

SUMMARY: The Board is publishing the following official staff interpretations of Regulation Z, issued by a duly authorized official of the Division of Consumer Affairs.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
(1) Identifying details have been deleted to the extent required to prevent a clearly unwarranted invasion of personal privacy. The Board maintains and makes available for public inspection and copying a current index providing identifying information for the public subject to certain limitations stated in 12 CFR 226.1.

(2) Official staff interpretations may be reconsidered upon request of interested parties and in accordance with 12 CFR 226.1(d)(2). Every request for reconsideration should clearly identify the number of the official staff interpretation in question, and should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.


§ 226.6(a) Consumer leasing disclosures need not be more conspicuous than non-required contract provisions where lease and disclosure statement are combined.

This is in reply to your letter of 4-25-77, requesting an official staff interpretation of the requirements of the consumer leasing disclosure statement contained in the Consumer Leasing Disclosure Statement. The statement is to be prepared in accordance with the disclosure requirements of Regulation Z.

This letter is an official staff interpretation of Regulation Z, issued in accordance with 12 CFR 220.6(a) and the lease contract, the use of which in its application to the facts and issues presented herein is appropriate for an official staff interpretation as staff's position in response thereto do not appear to be such that a lessor would wish to rely upon them in attempting to comply with the regulation.

§ 226.6(a) (2) The disclosures need not be made in the sequence required, disclosures set forth in §226.15(b). We believe that §226.6(a) requires to be presented in an order which will assist the customer in understanding their relationship to each other. Given the wide variety and varying complexity of terms and conditions which can be encountered in consumer leases, the meaning of "clearly," "conspicuously" and "meaningful sequence" must be determined by reference to the particular set of disclosures under consideration. I am enclosing a copy of Official Staff Interpretation FC-0034, which framed in the context of a consumer credit transaction disclosure, it contains a discussion of the "meaningful sequence" requirements which may be helpful to you. In any event, staff cannot accommodate your request for specific review of the disclosure forms enclosed with your letter. Limitations upon our resources and the practical usefulness of such specific review to other lessors have led staff to adopt a general policy not undertaking this type of individual review. Staff, however, directs your attention to the sample consumer leasing disclosure forms contained in the copy of the Regulation Z pamphlets enclosed with this letter. Although use of these sample forms is not required, their use, when properly completed, insures compliance with the consumer leasing disclosure requirements of the regulation.

This letter is an official staff interpretation of Regulation Z, issued in accordance with §226.15(b)(3) of the regulation, and limited in its application to the facts and issues presented herein. I trust it will be of assistance to you.

Sincerely,

JEROMO C. KLEINZIAN, Associate Director.

FEDERAL REGISTER, VOL 42, NO. 131-FRIDAY, JULY 8, 1977

RULING REGULATIONS

Although phrased in various manners, your questions 3 and 4 and the first part of question 8, 7, 8 and 9 request an official staff interpretation regarding the requirement in §226.6(a) that the disclosures be "clearly, conspicuously, and in meaningful sequence."

Section 226.6(a) does not require the use of any particular sequential system or arithmetical progression in making the disclosures required in connection with a consumer credit transaction disclosure. The disclosures need not be made in the sequence required, disclosures set forth in §226.15(b). We believe that §226.6(a) requires to be presented in an order which will assist the customer in understanding their relationship to each other. Given the wide variety and varying complexity of terms and conditions which can be encountered in consumer leases, the meaning of "clearly," "conspicuously" and "meaningful sequence" must be determined by reference to the particular set of disclosures under consideration. I am enclosing a copy of Official Staff Interpretation FC-0034, which framed in the context of a consumer credit transaction disclosure, it contains a discussion of the "meaningful sequence" requirements which may be helpful to you. In any event, staff cannot accommodate your request for specific review of the disclosure forms enclosed with your letter. Limitations upon our resources and the practical usefulness of such specific review to other lessors have led staff to adopt a general policy not undertaking this type of individual review. Staff, however, directs your attention to the sample consumer leasing disclosure forms contained in the copy of the Regulation Z pamphlets enclosed with this letter. Although use of these sample forms is not required, their use, when properly completed, insures compliance with the consumer leasing disclosure requirements of the regulation.

This letter is an official staff interpretation of Regulation Z, issued in accordance with §226.15(b)(3) of the regulation, and limited in its application to the facts and issues presented herein. I trust it will be of assistance to you.

Sincerely,

JEROMO C. KLEINZIAN, Associate Director.

[12 CFR Part 226, FC-0034] § 226.15(a) Two sides of a single page may be used to make consumer leasing disclosures in a combined lease-disclosure statement so long as all disclosures are above the place for the lessor's signature.

This is in response to your letter of 4-25-77, which requested an official staff interpretation of Regulation Z. You inquire whether §226.15(a)(1) permits the use of two sides of a single page when making the consumer leasing disclosures required by §226.15(b) in a combined lease-disclosure statement so long as all disclosures are above the place for the lessor's signature.

This is in response to your letter of 4-25-77, which requested an official staff interpretation of Regulation Z. You inquire whether §226.15(a)(1) permits the use of two sides of a single page when making the consumer leasing disclosures required by §226.15(b) in a combined lease-disclosure statement so long as all disclosures are above the place for the lessor's signature.

Sincerely,

JEROMO C. KLEINZIAN, Associate Director.

[12 CFR Part 226, FC-0035] § 226.15(a) (1) The disclosures need not be made in the sequence required, disclosures set forth in §226.15(b). We believe that §226.6(a) requires to be presented in an order which will assist the customer in understanding their relationship to each other. Given the wide variety and varying complexity of terms and conditions which can be encountered in consumer leases, the meaning of "clearly," "conspicuously" and "meaningful sequence" must be determined by reference to the particular set of disclosures under consideration. I am enclosing a copy of Official Staff Interpretation FC-0034, which framed in the context of a consumer credit transaction disclosure, it contains a discussion of the "meaningful sequence" requirements which may be helpful to you. In any event, staff cannot accommodate your request for specific review of the disclosure forms enclosed with your letter. Limitations upon our resources and the practical usefulness of such specific review to other lessors have led staff to adopt a general policy not undertaking this type of individual review. Staff, however, directs your attention to the sample consumer leasing disclosure forms contained in the copy of the Regulation Z pamphlets enclosed with this letter. Although use of these sample forms is not required, their use, when properly completed, insures compliance with the consumer leasing disclosure requirements of the regulation.

This letter is an official staff interpretation of Regulation Z, issued in accordance with §226.15(b)(3) of the regulation, and limited in its application to the facts and issues presented herein. I trust it will be of assistance to you.

Sincerely,

JEROMO C. KLEINZIAN, Associate Director.
It should be pointed out, however, that multiple copies) would dictate the use of a signature on or other instrument evidencing the lease be made together on the periodic statement for an open end account. Regulation Z, issued in accordance with combined contract and disclosure document. For contract or evidentiary purposes, the all disclosures be above the place for there is no signature requirement in the disclosure contract provisions from the section into the body of the contract in which the staff in Public of Regulation Z (formerly 666, to disclose in its application to the Issue and facts presented herein. It trust is responsive to your inquiry.

Sincerely,
JERALD C. KLUCKMAN, Associate Director.

[12 CFR Part 226, FC-0087]

§ 226.7(b) It is permissible to provide a periodic statement for an open end account that separately discloses the purchase and cash advance portions of finance charge without disclosing a total of the two figures.

June 20, 1977.

This will respond to your letter of * * * in which you request official confirmation of the opinion expressed by staff in Public Information Letter 668 to the effect that § 226.7(b) (1) (iv) of Regulation Z (formerly § 226.7(b) (3)) does not require the elements of the finance charge to be added together and disclosed on the periodic statement for an open end credit account. Section 226.7(b) (1) (iv) requires the itemization and identification of the amounts of the finance charge and interest on the periodic statement to the transactions. The adjustment made in order to charge the customer at a lower annual percentage rate that had already been charged, the situation is somewhat analogous to that addressed in Board Interpretation § 226.15(a) (1) (ii) of 1977 states that a new rate is increased. You indicate that your client is raising the periodic rates on its client is raising the periodic rates on its account to the balance of their term to incrementally computed the annual percentage rate in the following situation. Your client, a creditor, discovered that it may have erroneously computed the annual percentage in the balance of the term to which the customer of the periodic rate or added to. In light of these considerations, staff does not believe new disclosures are required.

This is an official staff interpretation of Regulation Z, issued in accordance with § 226.1(d) (3) of the regulation and limited to the facts presented herein. It trust is responsive to your inquiry.

Sincerely,
JERALD C. KLUCKMAN, Associate Director.

[12 CFR Part 226, FC-0098]

§ § 226.8(j) and 226.8(j). Where a creditor adjusts accounts after discovery of APR computation, staff believes that the adjustment is not an (f) refinancing requiring new disclosures. However, since Connecticut has a statute analogous to § 226.8 APR reduction.


This is to reply to your letter of * * *, in which you request official staff interpretation concerning the proper method of disclosure of the periodic rates in the periodic statement given to a customer during the last billing cycle before the periodic rate is increased. You indicate that your client is raising the periodic rates on its open end accounts and will give its existing customers notice of the change of the periodic rates pursuant to § 226.7(f) of Regulation Z. You question, however, whether § 226.7(b) (1) (i) only requires disclosure of the periodic rates in effect during the last billing cycle or that section requires disclosure of both the periodic rates in effect during the last billing cycle and the periodic rate in effect during the next billing cycle. Therefore, you request official staff interpretation concerning the proper method of disclosure of the periodic rates in the periodic statement.

Section 226.7(b) (1) (i) requires that "the periodic rate, using the term "periodic rate" (or "rates"), which may be used to compute the finance charge (whether or not applied during the billing cycle) * * * *

You indicate that the phrase "may be used" could be interpreted to be prospective in nature and that, consequently, it could be concluded that § 226.7(b) (1) (i) requires disclosure of the periodic rate or rates which would "apply in the next billing cycle (i.e., the one immediately following the last billing cycle to which the particular periodic statement applies.)" You state in your letter that the "transaction date," "posting date," etc. Staff does not believe that the regulation imposes such a requirement. As you suggest, it is sufficient to have a single column headed by the "Date" identifier column in which the required dates are placed.

Staff's conclusion, and advice to you, is based upon the assumption that the date will be disclosed to describe each account entry. Official Staff Interpretation FC-0055, issued on March 29, 1977, explains that where a creditor desires to provide both a transaction date and a crediting date for every transaction on an account, then the dates should be separately and appropriately identified.

This is an official staff interpretation of Regulation Z, issued in accordance with § 226.1(d) (3) of the regulation and limited in its application to the issue and facts presented herein. It trust is responsive to your inquiry.

Sincerely,
JERALD C. KLUCKMAN, Associate Director.

[12 CFR Part 226, FC-0098]

§ 226.7(b) Creditor that has increased periodic rates (and gives notice as required by § 1(f)) must disclose on the periodic statement for an existing extension of credit not pay more than the disclosed rate, this is responsive to your inquiry.

Sincerely,
JERALD C. KLUCKMAN, Associate Director.

[12 CFR Part 226, FC-0098]
would only be applied during future billing cycles.

This is an official staff interpretation of Regulation Z pursuant to § 226.8(b) (3) of the regulation and limited in its application to the facts as outlined above. We note, however, that the creditor you represent may be located in the State of Massachusetts, which has been granted an exemption under the applicable portion of the Federal Act. If your company is such a creditor, we suggest that you contact the office of Ms. Carol S. Greenwald, Commissioner of Consumer Affairs, for her views. I trust that this is responsive to your inquiry.

Sincerely,

JERIALD C. KLUESCHM, Associate Director.

[12 CFR Part 226, FC-0090]

§ 226.8(b) Single composite APR, rather than 2 APR’s or maximum of 2 rates, must be disclosed in transaction where 2 different interest rates are imposed to different portions of loan amount.

§ 226.8(c) Portions of finance charge applicable to imposition of 2 different interest rates are single component of finance charge and need not be separately itemized.


This is in response to your letter of * * * to our office of the interpretation of Regulation Z with regard to the proper disclosure of the finance charge and annual percentage rate when different interest rates are imposed on two portions of an obligation.

You indicate that your client is engaged in making government-subsidized residential rehabilitation loans. Based on certain income limits of the borrower, your client will make a closed end loan, a portion of which will be at a low interest rate and the remainder of which will be at a higher interest rate. The loan is amortized over a fixed term, and your client provides for an earnest payment schedule for the term of the loan.

It is staff's position that, with respect to the annual percentage rate disclosure, § 226.8 (b) (2) requires the disclosure of a single composite annual percentage rate which is computed by relating the total finance charge to the total amount financed in accordance with the applicable portions of § 226.5 of the regulations. In credit transactions, it would not be permissible to show two annual percentage rates, nor would it be proper to state the maximum of the two rates, since this would not accurately reflect the annual percentage rate imposed on the transaction.

Your second question is whether § 226.8 (c) (1)(i) requires the creditor to separately describe the portions of the finance charge applicable to the imposition of each rate.

In staff's opinion, the amount of finance charge computed by the imposition of the applicable interest rate to the two portions of the obligation constitutes a single component of the finance charge. Thus, it need not be further itemized on the disclosure statement to indicate the portions of the finance charge attributable to the imposition of each rate.

This is an official staff interpretation of Regulation Z, issued pursuant to § 226.1(d) (3) of the regulation and limited in its application to the facts as outlined above. We trust that this is responsive to your inquiry.

Sincerely,

JERIALD C. KLUESCHM, Associate Director.

[12 CFR Part 226, FC-0091]

§ 226.6 Use of name of savings and loan association which solicits credit card accounts for bank on the credit card, periodic statement and card brochure does not violate the general guidelines of § 226.6(c).

JUNE 24, 1977.

This is in response to your letter of * * * requesting an official interpretation of Regulation Z. Your concern is that (credit card) accounts for a large number of ( ) banks, and you ask staff's view about the application of § 226.6(c) of the regulation to a proposal which you have outlined.

You intend to have savings and loan associations solicit their customers to apply to your company for a (credit card) account. For the applications so generated and approved by your company to your knowledge, we specifically reference the savings and loan association's involvement in the following ways: (1) The name of the savings and loan will appear on the top front of the credit card; (2) the name of the savings and loan will appear at the top-left portion of the front side of the periodic billing statement; and (3) the name of the savings and loan will appear at the top of the brochure which encloses the actual credit card. The back side of your (credit) cards, which presently state "This card is issued by the Bank which issued it. ** **", will not be changed, but your Cardholder and User Agreement will be altered. "This card is issued by the Bank which issued it. ** **", will be printed on the front of the (credit) card. Your (credit) card will have the word "savings" clearly indicated on it.

You also indicated that your primary reason for requesting an official interpretation was to insure that the modifications proposed in your (credit) card and accompanying documents not be viewed as violating the general guidelines of § 226.6(c) regarding the disclosure of additional information. It is staff's opinion that your proposal, as outlined in your letter, is consistent with those guidelines.

This is an official staff interpretation of Regulation Z, issued in accordance with § 226.1(d) (4) of the regulation and limited to the facts and issues stated herein. I trust that we have been responsive to your inquiry.

Sincerely,

JERIALD C. KLUESCHM, Associate Director.

[12 CFR Part 226, FC-0092]

§ 226.8(b) The fact that habitual late payments on a single interest loan may cause the final payment to be a "balloon payment" does not require disclosure of this fact or labelling of final payment as "balloon payment."

§ 226.8(a) Statement due to customer with simple interest loan showing (1) difference between estimated and actual principal balance caused by late payments and suggesting payment of difference to return to schedule, or (2) amount due for final payment, is not periodic statement.

JUNE 24, 1977.

This is in response to your letter of * * * in which you requested an official staff interpretation of § 226.8(n) of Regulation Z concerning periodic statements for closed end credit.

Your client is in the process of converting the closed end credit loans to a simple interest basis. This means that a customer's regular monthly payment will be credited on the date received, and interest would continue to accrue at a simple interest rate until the actual date of payment. For this reason, if a customer is habitually somewhat late in making payments, the interest which will be charged for the difference between the estimated principal balance and the actual principal balance will be somewhat greater than that originally estimated based on payment on, for example, the first of the month. This increase in the finance charge will reduce the amount of principal reduction made with each payment so that it is possible that the final payment will be larger than the prior payments. Because of this discrepancy between the amount of the final payment and the amount of the payment which would have been made with two types of notices. You have asked whether either of these notices would be considered a periodic statement for purposes of § 226.8(n). The first type of notice which may be sent out is a notice of the need for additional principal payment. For example, a notice that the principal due falls somewhat behind the estimated principal balance based on regular monthly payments, would not send out a notice which tells the customer that he "may wish to submit the difference indicated below along with your next regular payment in order to return to schedule and to avoid a final payment higher than your normal payment."

The current principal payment is shown and added to the difference figure, and the notice indicates "total payment required to return to schedule." You have indicated by telephone that this notice of need for additional principal payment would not be sent out at any regular intervals but, rather, would be sent out when the total amount due exceeds the estimated principal balance by some specified percentage.

Staff is of the opinion that the notice of need for additional principal payment described above would not be considered a periodic statement for purposes of § 226.8(n). The notice is not labeled periodically, and it does not relate to any particular installment payment. Furthermore, it does not pay the amount specified; his final payment will be larger than his regular payments. While it is true that the customer will continue to receive similar notices prior to each final payment, the additional principal payment, staff nevertheless believes that this would not constitute notice of this type into a periodic statement.

The other type of notice which your client will send connections to customers is a notice that a notice is a notice of final payment. The bank issues coupons to its borrowers and does not send out regular periodic notices of payment. The bank does not send out a final notice which is due; on the contrary, it merely tells the customer that he may wish to submit this notice of need for additional principal payment, staff nevertheless believes that this would not constitute notice of this type into a periodic statement.

Staff is of the opinion that the notice of final payment described above is not a periodic statement under § 226.8(n) because the notice is mailed periodically. That notice only mailed notice is mailed with respect to any one loan.

Your final question is whether it is necessary in making the initial disclosures to add a statement that if it is not made on time, it is possible that the final payment will amount to more than twice the regular payment. Staff believes that, in the case of a simple interest installment loan, disclosures required under Regulation Z should
be made on the assumption that the loan payments will be made when due. Therefore, staff believes that Regulation Z does not require that, in the above described fact situation, the creditor disclose that it is possible that the final payment will amount to more than twice the regular payment and, thus, be a "balloon payment." This is in accordance with § 226.1(d) (8) and confined to the facts as stated. I trust that it is responsive to your inquiry.

Sincerely,

JERALD C. KLUCKMAN,
Associate Director.

[12 CFR Part 226, FC-0093] § 226.2(q) Sale of cancelable credit life insurance on existing obligations subsequent to its commencement. Monthly installments are computed on outstanding indebtedness, remitted to creditor as part of increased monthly payment, and, thus, the cash balance would be made separately from the insured, and would not be crediting the reduced insurance proceeds. The final premium would be transferred to the original creditor as part of the account balance.

JUNE 24, 1977.

This is in reply to your letter requesting an interpretation of the applicability of the Truth in Lending Act and Regulation Z to certain sales of credit life insurance. According to your letter, your client proposes to contact persons who have existing debts and offer to sell them credit life insurance on those obligations. Any sales of insurance would, therefore, be made separately from the insured, and would not be credited to the reduced insurance proceeds. The final premium would be transferred to the original creditor as part of the account balance.

You state that, in your opinion, such sales of credit life insurance are not credit transactions subject to the provisions of the Truth in Lending Act and Regulation Z. I agree with your conclusion on the facts as stated. I trust that it is responsive to your inquiry.

Sincerely,

JERALD C. KLUCKMAN,
Associate Director.
Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart C—Organization

HEADQUARTERS

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the organization structure of agency headquarters to revise the listings for the Bureau of Drugs, the Bureau of Medical Devices, and the Bureau of Veterinary Medicine, in accordance with recent reorganization approvals.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

Robert L. Miller, Office of Administration (HFA-540), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: The Bureau of Drugs reorganization (see the Federal Register of April 11, 1977 (42 FR 18904)) established a new Division of Scientific Investigations. The organization listing for the Bureau is amended accordingly. In separate actions subsequent to the reorganization of the Bureau of Medical Devices (see the Federal Register of May 24, 1977 (42 FR 26470)) and the Bureau of Veterinary Medicine (see the Federal Register of May 26, 1976 (41 FR 21827)), Associate Directors reporting to the Bureau Director were established to oversee division operations in major functional areas. The new organization listings for the two bureaus depict this organizational concept.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 5 is amended in § 5.100 by adding new "Division of Scientific Investigations" under the Associate Director for New Drug Evaluation in the Bureau of Drugs; by deleting the Bureau of Medical Devices and Diagnostic Products listing and substituting therefor a Bureau of Medical Devices listing; and by adding two Associate Directors to the Bureau of Veterinary Medicine. As revised, the listings for the Bureau of Drugs, the Bureau of Medical Devices and Diagnostic Products, and the Bureau of Veterinary Medicine read as follows:

§ 5.100 Headquarters.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

RULING ON CLAIMS OF PERSONS WHOSE PROPERTY HAS BEEN CONCEIVED AS PATIENTS WITHIN THE MEANING OF 18 U.S.C. § 2115 FOR OFFENSES COMMITTED FROM 1946 TO 1954


A. VERNON WEAVER,

Administrator.

(F.R. Doc. 1977-19388 Filed 7-7-77; 8:14 am)
Associate Director for Scientific Evaluation
Division of Drugs for Swine and Minor Species
Division of Drugs for Ruminant Species
Division of Drugs for Avian Species
Division of Drugs for Non-Food Animals

Effective date: This regulation becomes effective July 8, 1977.

Dated: June 29, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

PART 105—FOODS FOR SPECIAL DIETARY USE

Vitamin and Mineral Products; Effective Date Revision

AGENCY: Food and Drug Administration.

ACTION: Revision of effective date.

SUMMARY: This document revises the effective date for recently published regulations governing vitamins and minerals. This action is taken because of a petition for stay of the effective date of those regulations. This revision provides that voluntary compliance may begin immediately and that products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply.

EFFECTIVE DATE: This revision is effective immediately.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

In the Federal Register of October 19, 1976 (41 FR 46156) and April 19, 1977 (42 FR 20292), the Commissioner issued final regulations governing the labeling and composition of dietary supplements and other foods that purport or are represented to be for special dietary use because of their vitamin and/or mineral properties. The effective date for the regulations was announced as January 1, 1978 for all products initially introduced into interstate commerce on or after that date. It was provided that voluntary compliance might begin immediately.

The Commissioner has received a petition for stay of the effective date of the regulations from the law firm of Bass, Ulleberg & Lustigman, New York City, on behalf of the National Nutritional Foods Association, the National Association of Pharmaceutical Manufacturers, and the Solgar Co., Inc. The petition for stay states that a petition for review of the regulations has been filed in the United States Court of Appeals for the Second Circuit, and requests that the effective date of the regulations be modified to provide that all products labeled 9 months after judicial review proceedings have been concluded or initially introduced into interstate commerce 15 months after judicial review proceedings have been completed must comply, or, in the alternative, that the regulations be stayed without date pending judicial review.

Among other things, the petition for stay states that although the final revised vitamin and mineral regulations were published April 19, 1977, they did not incorporate the new uniform effective date for food labeling regulations (July 1, 1979) which FDA had announced in the Federal Register of April 12, 1977 (42 FR 19234) would be applicable to final food labeling regulations published after April 1, 1977.

The Commissioner concludes that the vitamin and mineral regulations should incorporate the new uniform effective date of July 1, 1979. The new effective date should provide ample time for judicial review and, assuming the regulations are sustained on review, for companies to come into compliance after completion of judicial review. If judicial review were to be stayed without date pending judicial review, the Commissioner will entertain petitions with respect to further postponement of the effective date at that time.

Accordingly, the effective date paragraph for the regulations published in the Federal Register of October 19, 1976 (41 FR 46156) and as reaffirmed and amended April 19, 1977 (42 FR 20292) is revised to read as follows:

Effective date: Voluntary compliance with these regulations may begin immediately, and all products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply.

Dated: June 24, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

PART 135—FROZEN DESSERTS

Standards of Identity for Frozen Desserts: Confirmation of Effective Date, Partial Confirmation of Effective Date, Stay of Certain Provisions, and Request for Data and Information

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date for the standard of identity for water ices and certain portions of the standards of identity for ice cream, frozen custard, ice milk, and sherbet; stays portions of the standard of identity for water ice; continues the stay of the effective date for the standard of identity for ice cream, frozen custard, ice milk, and sherbet standards pending the receipt and review of the information the Commissioner of Food and Drugs considers essential for him to make a final decision on the merits of granting requests for a hearing; and provides an opportunity for all interested parties to submit more definitive data and information on the issues to which certain objections have been raised. Following a review of this information the Commissioner will make a determination on whether to grant or deny the requested hearing.

DATES: Except as to those portions that are stayed, compliance with the final regulations for frozen desserts published in the Federal Register of April 12, 1977 (42 FR 19127) may have begun on June 13, 1977, and all products initially introduced into interstate commerce on or after July 1, 1979 shall fully comply.

Data and information must be received by September 6, 1977.

ADDRESS: Written data and information to the Hearing Clerk (HFC-30), Food and Drug Administration, Rm. 4-65, 5600 Fisher's Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

The Commissioner of Food and Drugs issued final regulations in the Federal Register of April 12, 1977 (42 FR 19127) revising the standards of identity for ice cream and frozen custard, ice milk, sherbet, and water ices to (1) provide for full ingredient declaration, (2) relax recipe requirements to permit the use of safe and suitable ingredients that do not change the basic identity of the food or adversely affect its physical and nutritional characteristics, and (3) provide for replacing the milk solids nonfat minimum with a milk protein minimum. The final regulations provided that any person who would be adversely affected could, at any time on or before May 12, 1977, file written objections and request a hearing.

Thirty-four responses were filed relative to the subject regulations. Six contained comments that were not in the form of objections or requests for hearing. 18 contained objections and no requests for hearing, and the other 14 contained objections and requests for hearing. One of the 34 responses contained all of the identified objections to the regulations that were submitted, as well as all of the requests for hearing. This single response was supported by 30 interested parties. 7 of which also submitted objections and 3 of which also submitted objections and requests for hearing.

Pursuant to section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)), the Commissioner has considered the objections and requests for hearing. His conclusions follow:

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
Objections and Requests for a Hearing

I. Absence of an Economic Impact Statement in the Final Regulation

The assertion is made that the Commissioner was required to prepare and submit an economic impact statement with the final regulations in accordance with Executive Order 11821, OMB Circular No. A-107, and Executive Order 11949.

The Commissioner points out that the proposal to amend the frozen desserts regulations was published in the Federal Register of July 25, 1974 (39 FR 27144). It is the assertion that the regulations were published on December 31, 1976, dealt only with terminology, e.g., inflation impact vs. economic impact. The Commissioner concludes that this objection does not raise an issue of fact that warrants a hearing.

II. Adverse Economic Impact Due to Potential Supplementation of Imported Casein and Caseinates for Domestic Nonfat Milk Solids

This objection is based on a potential increase in the use of imported casein and caseinates that would decrease the use of domestic nonfat milk solids as ingredients in the fabrication of ice cream, frozen custard, ice milk, and sherbet. The assertion is made that the Commissioner has an economic impact on milk producers, consumers, and the Federal Government.

The Commissioner agrees that if, due to technological advances, certain components or combinations of components derived from the milk of cows are allowed to compete with historical ingredients such as nonfat dry milk or condensed skim milk, there would be an adverse impact on the milk producers, sellers, and buyers of those ingredients. The Commissioner, however, does not believe that this impact is an issue that can legally be considered in deciding upon the merits of a standard of identity. The Commissioner concludes that the objection does not raise an issue of fact that warrants a hearing.

III. The Concept of “Safe and Suitable”

(Defined in 21 CFR 130.3(d)) as Utilized to Provide for the Use of Milk-Derived Ingredients Alone or in Combination with Nonfat Milk Solids in Ice Cream and Frozen Custard

§ 135.110 (b) (1) Ice milk § 135.20 (a), and Sherbet § 135.140 (b) (1) (1) and (2)

The basic for this objection is that (a) the physical characteristics of ice cream, frozen custard, ice milk and sherbet will be adversely affected and (b) the nutritional profile of ice cream, frozen custard, ice milk and sherbet will be adversely affected. The objection states that this would occur by substantially and significantly altering their compositional makeup by the use of “other milk-derived ingredients” not considered by the objector to be “suitable.”

The Commissioner, having reviewed the data and information presented in support of this objection, as well as the data and information available to him which led to the publication of the final regulations, comments as follows:

1. The Commissioner utilizing the “safe and suitable” concept would:
   (a) Remove the current restriction on the use of sweet cheese whey, (b) allow the use of the chemical composition of whey and whey from the manufacture of casein to be blended together as a substitute for nonfat milk solids from milk, nonfat milk or nonfat dry milk, and would allow the use of fat from butterfat or milk fat, including fat from whey cream extracted from cheese whey.

2. The current regulations provide for the use of whey of the following form (a) milk, nonfat milk, cream, butterfat, buttermilk (a byproduct from manufacturing butter from cream), (b) partially deacetylated nonfat milk (an ingredient obtained by altering the chemical composition of nonfat milk), concentrated or dried skim milk that has been modified by treatment with the chemicals sodium hydroxide and disodium phosphate, (c) concentrate of cheese whey, (d) casein (a milk protein substance obtained from nonfat milk much in the same manner as certain cheeses are obtained from nonfat milk, but with most of the lactose and milk fat removed and some of the soluble proteins (coprecipitates of whey) removed with the whey portion), and (e) caseinates made by dissolving with sodium hydroxide and disodium phosphate to manufacture an ingredient mentioned in (2) above.

3. The amended regulations do not set specific limits as to how or when nonfat milk solids and/or other milk-derived ingredients can be used. The option as to which safe and suitable ingredients will be used and in what proportion is left up to the manufacturer of the ice cream, frozen custard, ice milk or sherbet as long as the other minimum requirements of the applicable standards are met and the basic physical and nutritional characteristics of the food defined by the applicable regulation and anticipated by the consumer.

6. The current regulations set a maximum use level for cheese whey at 25 percent of the nonfat milk solids of the food, and only provide for the use of casein and caseinates after the minimum requirements for milk solids have been met. These restrictions were primarily based on previous technological inabilities to (a) utilize more cheese whey, (b) produce modified whey, and (c) formulate blends of milk-derived ingredients utilizing casein or caseinates.

7. Milk varies in composition and nutritional values. The variations in composition depend on the milk used, processes used, capability of manufacturing procedures to produce a uniform product, temperature and duration of storage as factors which affect the milk obtained from milk also vary in composition and nutritional value. These variations in composition and nutritional values apply to those ingredients provided for in both the current and amended regulations.

8. The physical and nutritional characteristics of ice cream, frozen custard, ice milk and sherbet vary depending on the characteristics of the ingredient or blend of ingredients used to fabricate a food meeting the minimum requirements of the applicable regulation. This would be whether the minimum requirements of the current or amended regulations were met.

9. The physical characteristics of ice cream, frozen custard, ice milk and sherbet include, but are not limited to, flavor, color, texture, appearance, melting point, performance in the freezer, whipping ability, melt-down characteristics, resistance to heat shock, and ability to retain physical characteristics during transportation and storage.

The Commissioner concludes that insufficient data and information have been made available to make a final decision on the merits of granting the requested hearing relative to this objection. Therefore, the Commissioner invites the submission of specific data and information about the physical and nutritional characteristics of ice cream, frozen custard, ice milk and sherbet that would result from the amended regulations, (b) parameters of the nutritional value variations of milk-derived ingredients allowable under both the current and amended regulations for ice cream, frozen custard, ice milk and sherbet, (c) parameters of the nutritional value variations of milk-derived ingredients allowable under both the current and amended regulations for ice cream, frozen custard, ice milk and sherbet...
made in accordance with the minimum requirements of the current and amended regulations, (d) that feasible, practical and most commonly acceptable combinations or blends of nonfat milk solids and/or other milk-derived ingredients be used to fabricate ice cream, frozen custard, ice milk and sherbet meeting the applicable regulation, (e) nutritional value data and information specifically calculated or derived, including protein, vitamins B₆, B₁₂, thiamine, riboflavin, and pantothenic acid, and (f) any other pertinent data or information.

Upon receipt and review of the data and information presented, the Commissioner will make a determination on whether to grant or deny the requested hearing. Until such a determination is announced, the applicable portions of the amended regulations for ice cream, frozen custard, ice milk and sherbet are stayed.

IV. UTILIZATION OF MINIMUM MILK PROTEIN REQUIREMENT IN LIEU OF MINIMUM NONFAT MILK SOLIDS REQUIREMENT IN ICE CREAM, FROZEN CUSTARD § 135.120(a), I C E M I L K § 135.120(a), AND S H E R B E T § 135.140

The basis for this objection is that by utilizing the minimum milk protein requirement, recognition and acceptance are given from the milk solids content of the milk ingredient category as well as those from the other milk-derived ingredient category as a means of meeting one of the minimum compositional requirements of the regulations. The minimum required level of protein quantity and quality established by the amended regulations is also part of the basis for these specified objections.

The Commissioner, having reviewed the data and information presented in support of this objection, as well as the data and information available to him which led to publication of the final regulations, comments as follows:

1. This objection is directly related to the objection discussed in III above. The use of the milk protein level in lieu of the minimum nonfat milk solids requirement was intended to provide an analytical means to enforce the nonfat milk solids and/or other milk-derived ingredient requirement of the amended regulations.

2. The minimum milk protein quantity and quality requirements were established so as to be equal to the average minimum milk protein present when all of the other minimum requirements of the applicable regulations were met.

3. For the reasons elaborated in III above, the minimum milk content of individual ingredients used to fabricate ice cream, frozen custard, ice milk and sherbet vary. Based on the blend of such ingredients, the protein content of these fabricated foods will also vary.

4. While there are discussion and controversy over the value of a protein efficiency ratio (PER) as a method of evaluating human nutritional value data and information, the use here is one of a comparative nature. Whatever the value of PER, its use is relative, e.g., PER of whole milk protein (which is 108 percent that of casein) would be available to make a final decision on the merits of granting the requested hearing relative to this objection. Therefore, the Commissioner requests additional data and information about (a) the changes in physical and nutritional characteristics in bulky flavored ice milk as a result of providing for a decrease in milk solids when bulky flavors are used and (b) why ice milk should not have the same provisions for bulky flavors as ice cream.

Upon receipt and review of the data and information presented, the Commissioner will make a determination on whether to grant or deny the requested hearing. Until such a determination is announced, the applicable portion of the amended regulation for ice milk is stayed.

V. THE PROVISION FOR REDUCTION IN MILK FAT AND MILK PROTEIN WHEN BULKY FLAVORS ARE ADDED TO ICE MILK § 135.120 (b) and (c)

The basis for this objection is that the current regulations did not provide for a decrease in the milk solids content of ice milk when various amounts and kinds of bulky flavors are used to characterize ice milk.

The Commissioner, having reviewed the data and information presented in support of this objection, as well as the data and information available to him which led to publication of the subject final regulation, comments as follows:

1. Except for the fact that the current regulations did not provide for a decrease in the milk solids content of ice milk when bulky flavors are added, no additional information was provided in opposition to providing such a decrease.

2. The regulations provide for a decrease in the milk solids content of ice milk when bulky flavors are added to the food in order to eliminate a manufacturer's use of the terms "optional" and states that the term "optional ingredients" would not have to be declared in the ingredient statement. The submission also objects to the use of the word "optional" and states that the term "optional ingredients" has not been specified in the paragraph. It also alleges an error in not including buttermilk in the ingredients allowed to be declared as "milk fat and nonfat milk."

The Commissioner, having reviewed the information submitted in support of this objection, as well as the information which led to the publication of the final regulations, points out:

1. Section 135.110 (d) in the standard for ice cream and frozen custard and the comparable provisions in the standards for ice milk and sherbet state that all of the optional ingredients that are derived ingredients be declared either in descending order of appearance or by the use of the words "other milk-derived ingredients" which must also equal the PT of whole casein, when one or more of the ingredients listed in § 101.4(b) (3) (skimmed milk content or nonfat dry milk, skimmed buttermilk, and anhydrous milkfat) are used they may be declared as required by the applicable sections of 21 CFR Part 101, except that when one or more of the ingredients listed in § 101.4(b) (3) (skimmed milk, concentrated skimmed milk, reconstituted skimmed milk and nonfat dry milk), § 101.4(b) (4) (milk, concentrated milk, reconstituted milk and dry whole milk), § 101.4(b) (5) (cream, reconstituted cream, dried cream and plastic cream) and § 101.4(b) (9) (butterol and anhydrous butterfat) are used they may be declared as required in descending order of appearance or by the use of the words "other milk-derived ingredients".

2. Since all ingredients in these standards are optional, all ingredients must be declared as set forth above. This would require that the names of the caseinates and other similar milk derived ingredients be declared by their common or usual name since they would not be entitled to the alternative labeling set forth above.

2. He does not consider liquid, concentrated or dried buttermilk (byproducts from the manufacture of butter) to be

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
VI. THE USE OF THE TERM "NONFAT MILK-DERIVED SOLIDS" IN LIEU OF THE TERM "NONFAT MILK SOLIDS" AND THE USE OF THE TERM "MILK-DERIVED SOLIDS" AS APPLIED TO § 135.140(A) (2), SHERBERT

This objection is based on the use of nonfat milk solids and/or other milk-derived ingredients to be used to meet the minimum nonfat milk-derived solids content of the amended regulation.

The Commissioner, having reviewed the information presented in support of this objection, as well as the information which led to the publication of the final regulation, concludes that (a) the objection to the publication of the final regulation submitted in III above, and (b) there is insufficient information available to make a final decision on the merits of granting the requested hearing in III above, and (c) the decision on the merits of granting a hearing relative to this objection will also be deferred until the data and information, related to III above have been received and reviewed. Until such determination is announced, the applicable portions of the amended regulation for sherbert are stayed.

SUBMISSION OF DATA AND INFORMATION

Any interested party wishing to submit data or information in response to this notice must do so by September 6, 1977. Such data or information shall be filed with the Hearing Clerk (HEFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and identified with Docket No. 76F-0500.

PROVISIONS STATED

Pursuant to 21 U.S.C. 371(e), the Commissioner hereby announces that the following provisions of the April 12, 1977 final regulations for frozen desserts are stayed by the objections filed, pending receipt and review of data and information the Commissioner deems essential to make a final decision on the merits of granting the requested hearing.

For the convenience of the reader, those provisions of the regulations set forth below as being stayed are accompanied by a listing of the provisions of the former regulations that will remain in effect pending final action on the objections and requests for hearing:

1. Section 135.110(a) (1) is stayed to the extent that it establishes minimum milk protein requirements.

Therefore, former § 135.30 (c) and (e) remains in effect.

2. Section 135.110(a) (2) is stayed to the extent that it establishes minimum milk protein requirements.

Therefore, in former § 135.30, the nonfat milk solids requirements of paragraph (a), the whey limitation requirements of paragraph (c), and the caseinate limitation requirements of paragraph (e) remain in effect. The provisions of former § 135.10 incorporating these requirements also remain in effect.

3. Section 135.130(a) (2) is stayed in its entirety.

Therefore, former § 135.40 (a), (b), (c), and (d) remains in effect.

4. Section 135.140(a) (1) is stayed to the extent that it establishes the use of safe and suitable milk derived ingredients not specifically listed as permitted in former § 135.20 (e) and (f) (7).

Therefore, former § 135.20 (a) and former § 135.65(a) remain in effect with respect to the provisions for "nonfat milk solids" and "milk-derived solids.

Therefore, former § 135.20 (a) and former § 135.65(a) remain in effect with respect to the provisions for "nonfat milk solids.

Effective Date

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 401, 76P-0500. (21 CFR 801.425) (f 801.425), and former § 135.20(a), and under authority delegated to the Commissioner (21 CFR 801-425) and for the purpose of contraception is corrected in paragraph (c) by changing "§ 801.425" to read "§ 801.427"; and amendment 2 and the section heading are corrected to read as follows:

2. In Part 801 by adding new § 801.427 to read as follows:

§ 801.427 Professional and patient labeling for intrauterine contraceptive devices.

Dated: July 1, 1977.

WILLIAM P. RANDOLPH,
Acting Associate Commissioner for Compliance.
[FR Doc. 77-19420 Filed 7-7-77; 8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

Chloramphenicol Tablets

Correction

In FR Doc. 77-16427, appearing at page 29859 in the issue for Friday, June 10, 1977, in § 555.110(a)(c) (1) (ii), in the neck to last line, the number now reading "No. 017039" should have read "No. 017030."

[FR Doc. 77-16427 Filed 7-17-77: 8:45 am]

PART 561—TOLERANCES FOR PESTICIDES IN ANIMAL FEEDS ADMINISTERED BY THE ENVIRONMENTAL PROTECTION AGENCY

ACTION: Final rule.

SUMMARY: This rule renews a feed additive regulation permitting the experience

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

35155
mental use of the fungicide O-ethyl S,S-diphenyl phosphorodithioate in rice hulls. The renewal was requested by Mohay Chemical Corp. This rule will permit the marketing of rice hulls while further data is collected on the subject pesticide.

EFFECTIVE DATE: Effective July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTAL INFORMATION: On May 24, 1976, the EPA announced (41 FR 21166) that in response to a food additive petition (PAP 545608) submitted by Chemagro Agricultural Div., Mohay Chemical Corp., PO Box 4913, Kansas City MO 64120, 21 CFR 561.31 was being established to permit the use of the fungicide O-ethyl S,S-diphenyl phosphorodithioate on growing rice with a tolerance of 0.3 part per million (ppm) for residues of the fungicide in rice hulls in accordance with an experimental use permit that was being issued concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (21 Stat. 979; 7 U.S.C. 136(a) et seq.). This experimental program expired May 13, 1977.

Mohay Chemical Corp. has requested a one-year renewal of this temporary tolerance both to permit continued testing to obtain additional data and to permit the marketing of food commodities affected by the application of the fungicide to the growing raw agricultural commodity rice.

The scientific data reported and other relevant material have been evaluated, and it has been determined that the pesticide may be safely used in accordance with the provisions of the experimental use permit which is being issued concurrently under FIFRA. It has further been determined that since residues of the pesticide may result in rice hulls from the agricultural use provided for in the experimental use permit, the food additive regulation should be renewed along with the tolerance limitation. (A related document concerning the renewal of a temporary tolerance for residues of the subject pesticide in or on rice grain appears elsewhere in today's Federal Register.)

Accordingly, a feed additive regulation is established as set forth below.

Any person adversely affected by this regulation may, on or before August 8, 1977, file written objections with the Hearing Clerk, EPA, Rm. 1019, East Tower, 401 M St., SW, Washington, D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by the grounds legally sufficient to justify the relief sought.

Effective July 8, 1977, 21 CFR 561.31 is amended as set forth below.

DATED: June 29, 1977.

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

(Sec. 409(c)(1) Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(1).)

Section 561.231 is amended as follows: § 561.231 (Amended)

In § 561.231, the date at the end of the last line in paragraph (a) is changed from "May 13, 1977" to June 20, 1978.

Title 22—Foreign Relations

CHAPTER V—UNITED STATES INFORMATION AGENCY, DEPARTMENT OF STATE

PART 501—APPOINTMENT OF FOREIGN SERVICE INFORMATION OFFICERS

Revisions Reflecting Current Procedures

AGENCY: U.S. Information Agency.

ACTION: Final rule.

SUMMARY: These revisions reflect the changed eligibility requirements regarding maximum age, and the elimination of reference to citizenship of spouse in the examination and appointment of applicants for employment in the Foreign Service. An administrative change in rules and settlement of a complaint necessitated the revisions. These changes will eliminate requirements that are no longer considered necessary.

EFFECTIVE DATES: December 6, 1976 (age requirements), May 20, 1977 (citizenship requirements), as published in the Agency's Manual of Operation and Administration.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: The following revisions update Part 501 of the Agency's regulations to reflect current procedures being followed by the Board of Examiners for the Foreign Service.

1. In §501.6, paragraph (b) is revised to read as follows:

§ 501.6 Written examination.

(b) Designation to take written examination. No person will be permitted to take a written examination for appointment as a Foreign Service officer or Foreign Service information officer who has not been specifically designated by the Board of Examiners to take that particular examination. Prior to each written examination, the Board will establish a closing date for the receipt of applications for designation to take the examination. No person will be designated for the examination who has not, as of that closing date, filed an application with the Board. To be designated for the written examination, a candidate, as of the date of the examination, must be a citizen of the United States and shall be at least 21 years of age.

2. In §501.9, paragraph (a) is revised to read as follows:

§ 501.9 Certification for appointment.

(a) Eligibility. A candidate will not be certified as eligible for appointment as a Foreign Service information officer of class 8 unless the candidate is at least 21 years of age, and is a citizen of the United States. A candidate may be certified as eligible for direct appointment to class 7 if, in addition to meeting these specifications, the candidate also has additional qualifications of experience, education, and age which the Board of Examiners for the Foreign Service currently defines as demonstrating ability and special skills for which there is a need in the Foreign Service. Recommended candidates who meet these requirements will be certified for appointment, in accordance with the needs of the Service, in order of their standing on their respective registers.

3. In §501.13, paragraph (c)(1) is revised as follows:

§ 501.13 Lateral entry appointment of Foreign Service information officers.

(c) Eligibility requirements.—(1) Citizenship. Each person appointed as a Foreign Service information officer must be a citizen of the United States.

4. In §501.14, paragraph (a)(1) is revised to read as follows:

§ 501.14 Reappointment of Foreign Service information officers.

(a) Requirements for reappointment. (1) On the date of application, each applicant must be a citizen of the United States.

Effective date: These provisions and amendments were effective December 6, 1976, and May 20, 1977, as published in the Agency's Manual of Operations and Administration.

JOHN E. REINHARDT, Director.

Title 24—Housing and Urban Development

CHAPTER XX—OFFICE OF THE ASSISTANT SECRETARY FOR CONSUMER AFFAIRS AND REGULATORY FUNCTIONS, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

PART 3282—MOBILE HOME PROCEDURAL AND ENFORCEMENT REGULATIONS

Certification Label—Elimination of Deadline for Use of Original Language

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.
SUMMARY: This amendment eliminates the June 30, 1977, deadline for use of the original version of the mobile home certification label established at the time the original language of the label was changed. This amendment will permit the existing stock of labels to be exhausted.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:
Russell H. Dawson, Director, Mobile
Home Standards Division, Office of the
Assistant Secretary for Neighborhoods,
Voluntary Associations and Consumer
Protection, Department of Housing
and Urban Development, Washington,
D.C., 20410. Phone number 202-775-7076.

SUPPLEMENTARY INFORMATION:
If the June 30, 1977, deadline remained in effect, the excess labels would have to be destroyed at a cost of approximately $30,000.00. This would be an optics of the Department and ultimately passed on to the industry or the taxpayer. The elimination of deadline will permit use of all of the original labels.

The January 12, 1977, rule stated that all labels in the inventories of Production Inspection Primary Inspection Agencies (PIAs), as of December 31, 1976, shall be used up before labels with the new language may be used. This date is being changed to March 15, 1977. This is necessary because the December 31, 1976, date was chosen on the basis of incorrect information. The Department believed that no labels containing the original language would enter IPIA inventories after March 15, 1977. However, it now appears that some such labels, ordered before the January 12 rule, may have entered IPIA inventories as late as March 15, 1977. Therefore, the Department is changing the relevant date to March 15, 1977. On inventories held by PIAs as of March 15, 1977, are exhausted, only labels containing the language stated above shall be used.

Accordingly, 24 CFR 3282.362(c) (2) (i) (C) is amended to read as follows:

§ 3282.362. Production Inspection Primary Inspection Agencies (PIAs). 

(2) (i) (C) The label shall read as follows:

As evidenced by this label No. ABC 000 001, the manufacturer certifies to the best of this label No. ABC 000 001, the manufacturer certifies to the best of the manufacturer's knowledge and belief that this mobile home has been inspected in accordance with the requirements of the Department of Housing and Urban Development and is constructed in conformance with the Federal Mobile Home Construction and Safety Standards in effect on the date of manufacture. See Data Plate.

However, labels containing the language specified in 24 CFR 3282.362 as issued on May 13, 1976, at 41 FR 19869, shall be used until inventories held by PIAs as of March 15, 1977, are exhausted. After such inventories are exhausted, only labels containing the language stated above shall be used.


GENE C. BAXON,
Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

[FR Doc.77-19557 Filed 7-7-77; 8:45 am]

Title 32—National Defense
CHAPTER I—OFFICE OF SECRETARY OF DEFENSE
SUBCHAPTER P—RECORDS
PART 290—DEFENSE CONTRACT AUDIT AGENCY, PRIVACY ACT OF 1974
Implementation; Correction
AGENCY: Defense Contract Audit Agency, DOD.

ACTION: Correction.

SUMMARY: The Defense Contract Audit Agency corrects its Privacy Act regulations to reflect delegation to the Director, Defense Contract Audit Agency, authority to exempt from disclosure certain information to the public. This provision was published in the final adoption of rules; however, through oversight, it was published in the pream-

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

FREDERICK NEUMANN, Director.

MAURICE W. ROCHÉ, Director, Correspondence and
Directives, Office of the Assistant Secretary of Defense (Comptroller).

JULY 5, 1977.

[FR Doc.77-19482 Filed 7-7-77; 8:45 am]
Title 39—Postal Service
CHAPTER 1—U.S. POSTAL SERVICE
PART 601—PROCUREMENT OF PROPERTY AND SERVICES

Addition of New Section to Postal Contracting Manual

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: A recent amendment to the Postal Contracting Manual (Transmittal Letter 24) added, among other things, a new section 26 dealing with transportation and traffic management policies and procedures in the procurement of supplies and services. This makes necessary the following revision of 39 CFR 601.103, which lists and describes each section of the Manual.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:

William J. Jones (202-245-4603).

Accordingly, 39 CFR is amended as follows:

In § 601.103 paragraphs (t), (u), (v), and (w) are redesignated (tu), (v), (w), and (x) respectively; new paragraph (t) is added and redesignated paragraph (v) is revised to read as follows:

§ 601.103 Content of Postal Contracting Manual.

(t) Section 26 prescribes policies and procedures for the application of transportation and traffic management considerations in procurement of supplies and services. Sections 4, 13, 17, 21, 23, and 25 are reserved for future use.

(5 U.S.C. 552(a) (39 U.S.C. 401)).

W. Allen Sanders, Assistant General Counsel, Legislative Division.
[FR Doc.77-19464 Filed 7-7-77;8:45 am]

PART 601—PROCUREMENT OF PROPERTY AND SERVICES

Miscellaneous Amendments to Postal Contracting Manual

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service hereby announces revisions of the Postal Contracting Manual. The revisions add a new section dealing with transportation and traffic management policies and procedures in the procurement of supplies and services. The new section, which adopts policies similar to those found in the Armed Services Procurement Regulations, treats in depth matters not previously fully covered in the Manual. Three other parts of the Manual are also revised to be consistent with the provisions of the added section.

EFFECTIVE DATE: July 8, 1977.

RULES AND REGULATIONS

FOR FURTHER INFORMATION CONTACT:

William J. Jones (202-245-4603).

SUPPLEMENTARY INFORMATION: The Postal Contracting Manual, which has been incorporated by reference in the Federal Register (see 39 CFR 610.100), has been amended by the issuance of Transmittal Letter 24, dated June 10, 1977.

In accordance with 39 CFR 610.105 notice of these changes is hereby published in the Federal Register as an amendment to that section and the text of the changes is filed with the Director, Office of the Federal Register. Subscribers to the basic Manual will receive these amendments from the Government Printing Office. (For other availability of the Postal Contracting Manual, see 39 CFR 610.14.)

Description of these amendments to the Postal Contracting Manual follows:

SECTION 1—GENERAL PROVISIONS

1. Paragraph 1-102 has been revised to clarify the provisions concerning applicability of the Manual.

SECTION 2—PURCHASE BY FORMAL ADVERTISING

2. Paragraph 2-203.3 has been revised to update the provisions on the place and method of delivery of supplies, and to add a cross-reference to new section 28.

SECTION 7—CONTRACT CLAUSES

3. Paragraph 7-203.38 has been added to set forth a new required clause, Commercial Bill of Lading Notation, for cost reimbursement type contracts. The purpose of this clause is to insure that the Postal Service receives the benefit of any existing special freight rates for transportation of supplies.

SECTION 26—TRANSPORTATION OF SUPPLIES AND EQUIPMENT

4. Section 26 has been added to prescribe policies and procedures for the application of transportation and traffic management considerations in the procurement of supplies and equipment.

In consideration of the foregoing, 39 CFR 601.105 is amended by adding the following to § 601.105:

§ 601.105 Amendment to the Postal Contracting Manual.

Amendments to postal contracting manual

Transmittal letter | Dated | Federal Register publication
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W. Allen Sanders, Assistant General Counsel, Legislative Division.
[FR Doc.77-19464 Filed 7-7-77;8:45 am]

Title 40—Protection of Environment
CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY
SUBCHAPTER E—PESTICIDE PROGRAMS
[FRL 750-2; OPP-300011A]

PART 380—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE USE ON RAW AGRICULTURAL COMMODITIES

Certain Inert Ingredients in Pesticide Formulations

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes exemptions from the requirement of a tolerance for certain inert ingredients used in pesticide formulations. The exemptions were requested by six firms. This rule will permit the use of these inert ingredients in pesticide formulations applied to growing crops or raw agricultural commodities after harvest.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On March 14, 1977, the EPA published a notice of proposed rulemaking in the Federal Register (42 FR 13942) to amend 40 CFR 180.1001 by exempting certain pesticide chemicals which are additional (or occasionally active) ingredients in pesticide formulations from tolerance requirements under provisions of Section 408(e) of the Federal Food, Drug, and Cosmetic Act. Two comments were received in response to this notice. One comment pointed out a typographical error in connection with polyoxyethylated primary amine. The range given was C12-C13 instead of C10-C13.

A second comment stated that 1,2-benzisothiazolin-3-one is very closely related to saccharin, a suspected carcinogen, and that a referral to an advisory committee were requested in response to this notice. It has been concluded that the amendment will protect the public health and, therefore, that the amendment to the regulations should be adopted with the recommended changes.

Any person adversely affected by this regulation may, on or before August 8, 1977, file written objections with the Hearing Clerk, EPA, Room 1019, East Tower, 401 M Street SW., Washington,
RULING ON Docket No. 76-01

PART 258—REGULATIONS GOVERNING SECTION 505 OF THE RAILROAD RE-VITALIZATION AND REGULATORY RE- FORM ACT OF 1976, AS AMENDED

Final Standards for Evaluation and Other Miscellaneous Amendments

Correction

In FR Doc. 77-15923 appearing at page 28976 in the issue of June 8, 1977, on page 28985, third column, in the first line of § 258.27, correction should be made as follows:

The phrase “Are located in a corridor” should read “Are not located in a corridor”.

CHAPTER X—INTERSTATE COMMERCE COMMISSION

PART 1033—CAR SERVICE

Investigation of Adequacy of Railroad Freight Car Ownership, Utilization, Distribution, Rules and Practices


FOR FURTHER INFORMATION CONTACT:

This document (order) also stated that no further action was contemplated with respect to the show cause order 566 L.C. 497. That order required the carriers to show cause why they should not be required to purchase specified amounts of equipment. The Commission indicated that a number of its proceedings designed to encourage voluntary acquisition of freight cars has made the direct approach envisioned in the show cause order inappropriate and unnecessary.

The order also discontinued this proceeding. The proceeding had been held open by the report 335 L.C. 286, in order that weaknesses in the prescribed car service rules and the car ownership formulas might be exposed and corrected. The Commission reasoned that the rules and formulas had been in effect sufficient time to discover and correct such flaws as the proceeding had been held open to expose. The parties were informed that the closing of the proceeding would not affect the previously prescribed car service rules presently in effect or the fleet adequacy reporting requirements imposed at 335 L.C. 286.

H. G. Homme, Jr., Acting Secretary.

PART 1063—REGULATIONS GOVERNING THE ADEQUACY OF INTERCITY MOTOR COMMON CARRIER PASSENGER SERVICE

Interstate Transportation of Passengers by Motor Common Carriers; Adequacy of Service, Equipment, and Facilities; Correction

AGENCY: Interstate Commerce Commission.

ACTION: Correction of final rule.

SUMMARY: By notice published in the Federal Register (42 FR 29309-29311 (1977)), the Interstate Commerce Commission announced that it had adopted certain regulations designed to improve the adequacy of service provided by intercity motor common carriers of passengers. The purpose of this document is to notify interested persons that paragraph (f) (1) of §1063.4, appearing at 42 FR 29310 contains an inadvertent error, namely "*" such forms shall be considered as the same as a claim in accordance with the provisions of 49 CFR 1005. The ten day period specified in the above-quoted phrase shall have read "15 day period" so that, corrected, paragraph (f) (1) reads as set forth below.

FOR FURTHER INFORMATION CONTACT:

Mr. Michael Eremberg, Assistant Deputy Director, Section of Operating Rights, Interstate Commerce Commission, 12th and Constitution Avenue NW., Washington, D.C. 20423 (202-265-7892).

SUPPLEMENTARY INFORMATION: Section 1063.4(f) (1) is corrected to read as follows:

§ 1063.4 Baggage service.

   * * * * *

(f)(1) Checked baggage which cannot be located within one hour after the arrival of the bus as is supposed to be transported shall be designated as lost baggage. The passenger shall be notified by the carrier at that time and appropriate tracing forms shall be furnished to the passenger for completion and filing with the carrier or its agent. Such forms shall be considered the same as a claim in accordance with the provisions of 49 CFR Part 1065 in the event the baggage is not recovered within 15 days after filing.

   * * * * *

   H. G. Homme, Jr., Acting Secretary.

PART 1065—REGULATIONS GOVERNING THE ADEQUACY OF INTERCITY MOTOR COMMON CARRIER PASSENGER SERVICE

Interstate Transportation of Passengers by Motor Common Carriers; Adequacy of Service, Equipment, and Facilities; Correction

AGENCY: Interstate Commerce Commission.

ACTION: Correction of final rule.

SUMMARY: By notice published in the Federal Register (42 FR 29309-29311 (1977)), the Interstate Commerce Commission announced that it had adopted certain regulations designed to improve the adequacy of service provided by intercity motor common carriers of passengers. The purpose of this document is to notify interested persons that paragraph (f) (1) of §1063.4, appearing at 42 FR 29310 contains an inadvertent error, namely "*" such forms shall be considered as the same as a claim in accordance with the provisions of 49 CFR 1005. The ten day period specified in the above-quoted phrase shall have read "15 day period" so that, corrected, paragraph (f) (1) reads as set forth below.

FOR FURTHER INFORMATION CONTACT:

Mr. Michael Eremberg, Assistant Deputy Director, Section of Operating Rights, Interstate Commerce Commission, 12th and Constitution Avenue NW., Washington, D.C. 20423 (202-265-7892).

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   H. G. Homme, Jr., Acting Secretary.

PART 661—SALMON FISHERY

Amendment to Emergency Regulations Repromulgated

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Amendment to Emergency Regulations Repromulgated.

SUMMARY: This rule extends the amendments to emergency regulations adopted on May 24, 1977 to the emergency regulations of the commercial and recreational salmon fisheries off the coasts of Washington, Oregon, and California for an additional 18 days from July 9 to July 24, 1977 inclusive. This extension is consistent with the termination date of the initial emergency regulations published in the Federal Register on April 26, 1977 and repromulgated for an additional 45 days until July 24, 1977.

EFFECTIVE DATE: 0001 hours July 9, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. R. Neal Moore, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301) 492-7984.

SUPPLEMENTARY INFORMATION:

Section 70.1 of the Atomic Energy Act, U.S.C. 2085, authorizes the Commission to "* exempt certain classes or quantities of special nuclear material or things of special nuclear material (or special nuclear material) from the requirements of the Atomic Energy Act, any regulations prescribed thereunder or any license issued under the Atomic Energy Act, which would not be inimical to the common defense and security and would not constitute an unreasonable risk to the health and safety of the public". To date, the Commission has not exercised this authority.

Recently, the Commission has received a request from the National Aeronautics and Space Administration to export to the USSR for use in a Joint US/USSR space experiment a 65 gram of uranium (special nuclear material) for use in a joint US/USSR space experiment to take place soon pursuant to the US/USSR Space Cooperation Agreement of 1972 and 1977. Under present regulations, the Commission is precluded from issuing an export license for this material because there is no agreement for cooperation with the USSR pursuant to
to section 123 of the Atomic Energy Act. Recently, another export by Energy Research Development Administration to the USSR of 2.0 milligrams of plutonium-234, for a scientific experiment with U.S. scientists participating, has been withheld in the absence of an agreement for cooperation.

Therefore, the Commission having found that the exemption will not be inimical to the common defense and security and would not constitute an unreasonable risk to the health and safety of the public, has decided to exercise the discretionary authority of the Federal Energy Administration ("FEA") Office of General Counsel pursuant to 10 CFR 205.153 to set forth FEA's determination as to certain issues that have arisen with respect to the proper treatment of separate reservoirs as stripper well properties after September 1, 1976. A written comment on or objection to the appended Ruling may be filed at any time with the FEA Office of General Counsel pursuant to the provisions of 10 CFR 205.153.

DATES: Not applicable.

FOR FURTHER INFORMATION CONTACT:


Dennis M. Moore (Office of General Counsel, 12th and Pennsylvania Avenue, NW., Room 7122, Washington, D.C. 20461, (202) 556-2085.


ERIC J. FRYE,
 Acting General Counsel, Federal Energy Administration.

FEDERAL ENERGY ADMINISTRATION

[Ruling 1977-1]

POST-SEPTEMBER 1, 1976 TREATMENT OF SEPARATE RESERVOIRS AS STRIPPER WELL PROPERTIES

BACKGROUND

Effective September 1, 1976, the Federal Energy Administration ("FEA") amended the definition of "property" in 10 CFR 212.72 so that a producer may, but is not required to, treat as separate properties each separate and distinguished reservoir subject to a single right to produce crude oil, provided that the reservoir is not in communication with any other reservoir subject to the same right to produce: And provided, That the reservoir is recognized as such by the appropriate Ministerial regulatory authority, and where production has been consistently and historically reported as such. The amended definition of property was intended to provide more realistic incentives under the two-tier price system over the longer term of price controls on domestic crude oil. (See 41 FR 45692, August 23, 1976.) (Prior to September 1, 1976, a producer could treat separate reservoirs as separate properties only where there were "separate and distinct rights to produce crude oil from each reservoir." ("FEA Ruling 1976-10", 40 FR 45692, September 4, 1976.)

Subsequent to issuance of the amended definition of property, FEA received comments addressed to certain issues raised by the amendment (as well as issues not relevant to the Ruling) which were resolved in "FEA Ruling 1977-2" (42 FR 4409, January 25, 1977). In "Ruling 1977-2" FEA determined that, with respect to the "right to produce crude oil", once a producer has exercised the option to treat each government-recognized separate reservoir as a separate property, a reservoir-property created by the exercise of that option may not qualify as a stripper well property until it has sustained production levels of 10 barrels or less per well per day for a consecutive 12-month period, commencing after the reservoir has been designated as a separate property. FEA also determined in "Ruling 1977-2" that, subject to certain exceptions not relevant in the context of this Ruling, one a producer has elected to designate a single right to produce crude oil as two or more separate reservoir-properties, the producer may not redesignate any two or more of these separate reservoirs as a single property. However, such a Ruling is subject to the exceptions as described in this Ruling under the election of the reservoirs as separate properties.

The U.S. government agency is exempt from the regulations in this part upon publication in the FEDERAL REGISTER. This regulation should be made effective upon publication in the FEDERAL REGISTER.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1970, as amended, and Sections 582 and 585 of Title 5 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 70 is published as a substantial codification of the rule and effective July 8, 1977.

A new § 70.15 is added to read as follows:

§ 70.15 Intergovernmental cooperative activities.

Any U.S. Government agency is exempt from the regulations in this part and those requirements of the license set forth in section 53 of the Atomic Energy Act to the extent that such agency exports up to three (3) grams of any type of special nuclear material to be used for or in support of activities authorized by intergovernmental cooperative agreements between the U.S. and a foreign nation, group of nations, or international organization, and such agency is required to notify the Nuclear Regulatory Commission of the destination and purpose of the export.

(See 53, 161, Pub. L. 82-703, 68 Stat. 930, as amended, 948, as amended (45 U.S.C. 2073, as amended, and 582 and 585 of Title 5 of the United States Code).)

Dated at Washington, D.C., this 1st day of July 1977

For the U.S. Nuclear Regulatory Commission.

SAMLJ. CHILK,
Secretary for the Commission.

[FR Doc.77-15928 Filed 7-7-77; 8:45 am]
RULES AND REGULATIONS

FEA is aware of the following situations in which a producer might have been placed in a disadvantaged position under the price regulations. The first situation involves the election to treat the reservoir or property as a stripper well property. It is to these situations only that this Ruling is addressed.

**EXAMPLE I**

Facts. Producer X elected to treat a single property as three separate properties effective October 1, 1976, based upon the recognition by the appropriate governmental regulatory authority of three separate reservoirs underlying the property. However, Producer X then decided to treat the separate reservoirs as a single property because it was believed that Reservoir A could be classified as a stripper well property effective October 1, 1976. Producer X would not otherwise have elected to treat the single property as three separate properties, because to do so would have resulted in lower volumes of new crude oil produced and sold from the three separate reservoir properties than would have been produced and sold had Producer X continued to treat the three reservoirs as a single property. Effective October 1, 1976, Producer X certified all the crude oil produced and sold from Reservoir A as stripper well crude oil and charged prices in excess of the upper tier ceiling price.

With the issuance of “Ruling 1977-2”, Producer X learned that the certification of Reservoir A as stripper well crude oil from Reservoir A is improper until such time as the reservoir is recognized as a separate reservoir, as the rate of production of 10 barrels or less per well per day for a 12-month period commencing on or after October 1, 1976.

Issue. May Producer X redesignate the separate reservoirs as a single property prior to the end of the calendar quarter in which it certified产妇 as stripper well crude oil, thereby allowing Producer X to avoid assessment of the resulting reset price?

Ruling. No. As indicated in the October 29, 1976, Notice adopting the stripper well property exemption, this is consistent with the Congressional intent “to do so would have resulted in lower volumes of new crude oil produced and sold from Reservoir A as stripper well crude oil and charged prices in excess of the upper tier ceiling price.” (Emphasis added.)

(3) Yes. “Ruling 1977-2” provides that new crude oil volumes shall not include:

- any number of barrels not certified as new crude oil, pursuant to the provisions of 212.72, that existed before the election to segregate, as new crude oil, Producer X is required to do so, to segregate, or to withdraw that portion of the crude oil volumes mistakenly certified as stripper well crude oil.

Accordingly, any revenues obtained by Producer X as a result of erroneously characterizing Reservoir A as a stripper well property, were in excess of the ceiling prices determined under Subpart D, and must be refunded.

(3). Yes. “Ruling 1977-2” does provide that:

If during that period Producer X had certified as stripper well crude oil a greater number of barrels than those barrels of crude oil that would have been purchased at the price applicable to those barrels of crude oil, Producer X is required to refund to the purchaser the difference between the exempt price paid for those barrels of crude oil and the upper tier ceiling price applicable to those barrels of crude oil in those months, without the payment of any penalty on that difference.

FHA has also determined that such recertification may be necessary and will be permitted by FHA in the manner described above, where a producer wishes to continue separate property treatment for each individual reservoir based upon the additional benefits that accrue under the two tier price system. In other words, for some properties a producer may not wish to redesignate the separate reservoirs as the single property that existed before the election to segregate separate reservoirs, because the aggregate volumes of new crude oil and oil sold would be greater if each separate reservoir underlying the property were treated as a separate property than if the entire right to produce crude oil were treated as a single property.

**EXAMPLE II**

Facts. Producer Y elected to treat a single property as three separate properties effective October 1, 1976, either because to do so would have resulted in lower volumes of new crude oil produced and sold from the three separate reservoir properties than would have been produced and sold had Producer Y continued to treat the three separate reservoirs as a single property, as a result of erroneously characterizing Reservoir A as stripper well crude oil effective October 1, 1976. Producer Y has elected to treat separate reservoirs as single properties subject to the same right to produce as a result of erroneously characterizing Reservoir A as a stripper well property effective October 1, 1976, based upon the recognition by the appropriate governmental regulatory authority of three separate reservoirs underlying the property. However, Producer Y then decided to treat the separate reservoirs as a single property because it was believed that Reservoir A could be classified as a stripper well property effective October 1, 1976. Producer Y would not otherwise have elected to treat the single property as three separate properties, because to do so would have resulted in lower volumes of new crude oil produced and sold from the three separate reservoir properties than would have been produced and sold had Producer Y continued to treat the three separate reservoirs as a single property, as a result of erroneously characterizing Reservoir A as stripper well crude oil effective October 1, 1976. Producer Y certified all the crude oil produced and sold from Reservoir A as stripper well crude oil and charged prices in excess of the upper tier ceiling price.

With the issuance of “Ruling 1977-2”, Producer Y learned that the certification of Reservoir A as stripper well crude oil from Reservoir A is improper until such time as the reservoir is recognized as a separate reservoir, as the rate of production of 10 barrels or less per well per day for a 12-month period commencing on or after October 1, 1976.

Issue. May Producer Y redesignate the separate reservoirs as a single property prior to the end of the calendar quarter in which it certified Producer X, as a single property?

Ruling. No. As indicated in the October 29, 1976, Notice adopting the stripper well property exemption, this is consistent with the Congressional intent “to do so would have resulted in lower volumes of new crude oil produced and sold from Reservoir A as stripper well crude oil and charged prices in excess of the upper tier ceiling price.” (Emphasis added.)

(3) Yes. “Ruling 212.72” provides that new crude oil volumes shall not include:

- any number of barrels not certified as new crude oil, pursuant to the provisions of 212.72, that existed before the election to segregate, as new crude oil, Producer X is required to do so, to segregate, or to withdraw that portion of the crude oil volumes mistakenly certified as stripper well crude oil.

Accordingly, any revenues obtained by Producer X as a result of erroneously characterizing Reservoir A as a stripper well property, were in excess of the ceiling prices determined under Subpart D, and must be refunded.

(3). Yes. “Ruling 1977-2” does provide that:

If during that period Producer X had certified as stripper well crude oil a greater number of barrels than those barrels of crude oil that would have been purchased at the price applicable to those barrels of crude oil, Producer X is required to refund to the purchaser the difference between the exempt price paid for those barrels of crude oil and the upper tier ceiling price applicable to those barrels of crude oil in those months, without the payment of any penalty on that difference.
tion of projects designed to increase production from any such reservoir, and where such investments were based upon the mistaken assumption that crude oil produced and sold from such a reservoir could be sold at prices above the upper tier ceiling price, and where producers or operators invested additional funds which cannot adequately be recovered, even by the recertification permitted by this Rule, FEA will consider relief, on a case-by-case basis, under FEA Office of Exceptions and Appeals, on grounds of gross inequity or serious hardship.

REINSTITUTION OF SUPPLIER/PURCHASER RELATIONSHIP

In situations similar to one of the examples above, a producer may have erroneously certified production from one or more reservoir properties as stripper well crude oil and, on that basis, terminated a supplier/purchaser relationship with the original purchaser under 10 CFR 211.63(d)(1)(i) or (ii). Such a termination would be improper if based solely on what the producer believed to be the status of the reservoir as a stripper well property. Accordingly, unless the termination was otherwise permitted by the provisions of § 211.63(d), the obligation imposed on the supplier by its supplier/purchaser relationship under 10 CFR 211.63 would require prompt resumption of the supply relationship with the original purchaser.


Eric J. Percy, Acting General Counsel, Federal Energy Administration.

[FR Doc. 77-13998 Filed 7-7-77; 3:45 am]

PART 460—GRANTS FOR OFFICES OF CONSUMER SERVICES

Establishment of Guidelines

AGENCY: Federal Energy Administration.

ACTION: Final rule.

SUMMARY: The Federal Energy Administration hereby establishes guidelines for a program of discretionary grants for the establishment or operation of State consumer services to assist the representation of consumer interests before electric utility regulatory commissions. Any State, the District of Columbia, any territory or possession of the United States and the Tennessee Valley Authority are eligible to apply for a grant under this program. Grants will be awarded on a competitive basis to a limited number of States.

DATES: The effective date is July 3, 1977. A State must submit an application to FEA on or before August 26, 1977.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

A. Introduction.

B. Elements of the Program.

1. Award of Funds.

2. Statutory Requirements.

3. Eligible Consumer Groups.

4. Allowable Expenditures.

5. Minimum Program Requirements.

6. Application.

7. Selection of Grantees.

8. Termination of Grants.

A. INTRODUCTION

With the issuance of this final rule, the Federal Energy Administration (FEA) amends Chapter II of Title 10, Code of Federal Regulations, to establish Part 460 which provides for a program of grants for offices of consumer services, pursuant to Section 205 (42 U.S.C. 6807) of the Energy Conservation and Production Act (Act), Pub. L. 94-385, 90 Stat. 1125 et seq., 42 U.S.C. 6801 et seq.

The purpose of this program is to establish or operate State offices of consumer services (Office) to support consumer representation in proceedings before an electric utility regulatory commission (commission). A consumer, for the purpose of this rule, is a person who buys electricity for purposes other than resale. Congress has appropriated $2 million for this program in the current fiscal year. For this reason, FEA can only consider applications for no more than 15 states, the number of States able to participate in any one year. The purpose of this rule is to have a reasonable likelihood of providing effective assistance for consumers.

On May 18, 1977, FEA published an advance notice of proposed guidelines (advance notice), 42 FR 24768, which described the grant program for State Offices being developed by FEA and solicited comments from interested persons. FEA received and carefully considered hundreds of substantive comments, most of which endorsed the basic concepts and goals of the program. These comments are summarized and discussed below.

Pursuant to Section 553(a)(2) of the Administrative Procedure Act, 5 U.S.C. 553, exempting grant programs from the requirements of the Federal Register, FEA published a final rule because it considers that consumer interests will best be served by making program funds available as soon as practicable.

In developing and implementing this program, FEA considered, among other resources, the following materials: law review articles and reports including "Report to the Nuclear Regulatory Commission: Policy Issued in Answer to Interlocutor Requests for Financial Assistance in NRC Proceedings," prepared by Bonsberg, Hewes, Klucel and Kaas ("The Bonsberg Report"); 1976; Federal Regulation and Regulatory Reform, Report by the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce ("Subcommittee Report") (1976); Cramton, "Where and How of Broadened Public Participation in the Administrative Process," 60 Geo. L.J. 525 (1972); Gelhorn, "Public Participation in Administrative Proceedings," 81 Yale L.J. 359 (1972); Bloch and Stein, "The Public Counsel Concept in Practice: The Rail Reorganization Act of 1970," 16 William and Mary L. Rev. 211 (1975); Nota, "Federal Agency Assistance of Impecunious In-
or will in a timely manner satisfy these requirements. Within six months of the date of grant award, an Office must be empowered and authorized under local law—(A) to assist consumer groups or to advise, on its own behalf or through its agents, on the presentation of their positions in a commission proceeding; and (C) to advocate on its own behalf a position which it determines represents the position most advantageous to consumers. Accordingly, an Office must perform at least one of these functions. Of course, an Office is empowered to carry out any combination of the three functions it is empowered to carry out.

3. Eligible Consumer Groups.—The definition provided in the advance notice of “eligible consumer” elicited twenty-three comments. The majority of comments concluded that the proposed definition was unnecessarily restrictive. On the other hand, four comments expressed the opinion that the definition should be narrowed to exclude all but residential consumers. The guidelines express FEA’s conclusion that a State should have considerable flexibility in determining which consumer groups are most in need of representation. Accordingly, the final definition does not restrict eligibility to a specific commission class or group. At the same time, FEA believes an Office should represent residential consumers and the guidelines in § 460.12(a) (2) (A) and (C) so provide.

The adequacy of representation provided in a proceeding, which is necessary to contribute to a fair determination of the proceeding taken as a whole. This “necessity test” is a restatement of standards developed by Federal agencies to decide claims for reimbursement by intervenors in agency proceedings in the absence of a statutory directive authorizing broad consumer participation. Under the necessity test, a Federal agency has implied authority to allow reimbursement to a consumer group as a necessary ancillary function of carrying out a regulatory program. The necessity test appears unduly restrictive in light of Section 205’s statutory directive to encourage consumer participation.

For this reason, § 460.14 provides more flexible standards. FEA has decided to use a “fairness test.” This test requires that a consumer group represent a consumer’s interest, though substantial, the economic consequences of which would substantially contribute to a full and fair determination of the issues to be considered in the proceeding. FEA considers that the fairness test is more likely to result in a broad spectrum of views being incorporated in a commission’s decisionmaking process. Thus, the fairness test increases the likelihood that consumer groups will provide a commission with access to the information it needs to identify and evaluate accurately and impartially the costs and benefits that alternative resolutions of a given issue entail.

The advance notice required a consumer group to demonstrate that, but for the assistance to be provided, it lacked sufficient resources to participate effectively in the proceeding. Upon reconsideration, FEA finds this “but for” test too restrictive. The guidelines provide that a consumer group must show that it does not have reasonably available and cannot reasonably obtain sufficient resources to participate effectively in a proceeding. The distinction is that the “but for” test requires an Office to be virtually without resources, with the result that only the “poorest of the poor” could be certain of qualifying. The guidelines now permit a consumer group to obtain assistance if needed resources are not reasonably available. Thus, if a consumer group could raise funds to participate in a proceeding by drastically reducing its staff or their salaries, it would fail the “but for” test. However, where an Office concludes that such a solution is unreasonable, funding could be provided under § 460.14.

The “reasonably obtainable” test is designed to prevent an Office from concluding, for example, that a group of consumers who own or have equity in their homes are ineligible for assistance on the theory that the consumers could not carry a heavier burden of proving financial need than incorporated organizations where the assets of members are screened by the corporate veil. An Office is thus precluded from looking behind a consumer group to inquire into the wealth of its individual members regardless of any ad hoc association.

The guidelines in § 460.14 (b) (2) establish an alternative test of need employing a class action standard. Under this class action test, a consumer group may be eligible for funding if an Office finds, on the one hand, that the economic interest of both the consumer group and any consumer is small in relation to the costs of effective participation in a proceeding; and, on the other hand, that the costs of the consumer group’s effective participation are small in relation to the social, economic or environmental consequences for consumers of the outcome of the proceeding. In this situation, the interest, though substantial, will remain unrepresented because no individual or group has a sufficiently strong financial incentive to intervene.

The class action test does not take financial need into consideration. A consumer group may qualify for financial or technical assistance irrespective of the extent of its financial resources. Where the cumulative consequences of the outcome of the proceeding are shown to be of substantial importance, the consumer interest should be protected regardless of ability to pay.

The utility of the class action test can be illustrated as follows: A small investor (in this case reimbursement of an intervenor’s out-of-pocket expenses) is clearly justified if it can be expected to yield a substantial return (either a achievement or for economic, social or environmental consequences) and if that outlay is also a
necessary element of the intervenor's decision to participate.

An example in which the class action concept may be appropriate is the case where a utility company requires a $10 deposit from new consumers as a condition of service. The deposit will be refunded when service is discontinued, provided that a consumer has paid his bill. If the average period of service is six months, the utility pays no interest on deposits, the dollar value of interest not received by a consumer is insubstantial. Therefore, the benefits to be gained from an intervention by an individual or group of individuals in a proceeding is too insignificant to recover the costs. However, if a consumer group representing an Office's reliance on outside experts is minimal, an Office is empowered to perform the three statutory functions and is independent of the commission and this restriction is set forth in § 460.13(b).

Seventeen comments responded to the question of whether a consumer group's action will have generated enormous economic benefits or will have at most incurred minimal costs. Ten comments stated that the costs of participating in Federal utility regulatory proceedings will be able to receive financial assistance and consultancies should be raised substantially. FEA considers that the 45 percent limit, which is provided in § 460.13(a)(3) is appropriate. It furthers the twin goals of promoting an Office's long-term viability by requiring it to develop its own expertise and operational capacity, and at the same time ensuring that it has access to additional manpower and expertise needed to effectively perform its functions. These goals are reinforced by limiting, in § 460.13(a)(3), the amount that may be paid to an individual consultant to 20 percent and by allowing expenses incurred by an Office to provide technical assistance to eligible consumer groups. Such assistance includes making data, technical analyses, or other information available to eligible consumer groups, preparing testimony on their behalf, for use in a commission proceeding and providing them with legal assistance or expert testimony.

The amount that may be spent to contract for the use of computers and other equipment for storing and analyzing data is limited to 20 percent in § 460.13(a)(3) which defines administrative expenses, exclusive of compensation paid to its staff for which there is no limit, may not exceed 10 percent of its grant funds. The guidelines also specify and limit the other expenditures that an Office may incur with program funds. In developing these limits, FEA considered comparable provisions in rulesmaking procedures. Two comments stated that the amount of the rate increase proposed for an Office in its application, the dollar value of interest not received by a consumer, and consultants should be raised substantially.

The guidelines provide criteria that an Office shall consider in establishing priorities among eligible consumer groups. The final comment focused on such factors as the group's size, the importance of the interest it represented, and the amount of the rate increase proposed for an Office in its application, the dollar value of interest not received by a consumer, and consultants should be raised substantially.

To the extent practicable, FEA urges an Office to establish procedures which will enable it to identify in advance and establish priorities.
participate in those commission proceedings most likely to achieve its goals and objectives.

**B. APPLICATIONS**

Application procedures are set forth in § 460.15. To be eligible for a grant, a State must submit an application to FEA not later than August 26, 1977. Since FEA will accept only one application per State, a State must designate the department or agency which shall apply to FEA for a grant.

The guidelines require an application to include information on how the State proposes to establish, where none currently exists, and operate an Office. The application must include a description of the goals and objectives of the proposed Office; a discussion of how it proposes to meet the minimum program requirements; a description of the functions the Office will perform; a program budget and a description of the Office's proposed organizational structure and staffing; a schedule of tasks, sequence and a timetable. The application also shall include an assurance that the proposed budget for the Office exceeds by the amount of the grant award, the amounts expended by the State, if any, in the prior fiscal year or appropriated to be expended in the current fiscal year, whichever is greater, to perform functions similar to those to be conducted for this program. A State must also provide information concerning any State department or agency which represents consumers with respect to commission proceedings.

In addition, the application shall contain information concerning a State's need for an Office, which shall be evaluated by FEA as described in Section 460.15(c).

**C. SELECTION OF GRANTEEES**

Grantees will be selected on the basis of FEA's evaluation of their applications through the use of the rating system set forth in § 460.15. An application may receive up to 50 points for the feasibility and quality of the proposed Office, taking into account the overall concept of the proposal and the feasibility of implementation. An application may receive up to 50 points for a State's demonstration of its need for an Office. Of this, up to 20 points will be awarded on the basis of the magnitude of need demonstrated with respect to the information provided in response to Section 460.11(b)(11). The remaining 30 points will be awarded on the basis of FEA's analysis of the following three factors: first, the average revenue per KWH calculated for all electric utilities in the State, as an indication of the number of persons or families who are likely to receive a grant; second, the percentage of per capita income of a State's residential consumers with respect to the extent to which a State is able to provide electricity to consumers; and third, the extent to which a State's electrical energy usage is for residential use, as an indication of the impact of an average electric bill on a typical family; and third, the extent to which a State's residential population is likely to be served by electric utilities.

In § 460.19, FEA provides for suspension and termination of grants upon written notice to a grantee in the event FEA determines there has been a substantial failure to comply with the requirements of this guidelines.

**D. TERMINATION OF GRANTS**

In § 460.19, FEA provides for suspension and termination of grants upon written notice to a grantee in the event FEA determines there has been a substantial failure to comply with the requirements of this guidelines.

**6. Environmental and Inflationary Revis**

In accordance with FEA's obligations under the National Environmental Policy Act of 1969 (NEPA) 42 U.S.C. 4321 et seq., an evaluation of the potential environmental impacts of this program has been made by FEA. FEA finds that this program does not entail a major federal action that will have a significant impact on the environment.

FEA cannot anticipate nor will it restrict the position which may be advocated by an Office or subgrantee and therefore cannot foresee the environmental consequences of such advocacy. Copies of this analysis are available during normal business hours at FEA's Freedom of Information Office.

As required by section 7(c)(2) of the Federal Energy Administration Act of 1974, Pub. L. 93-275, a copy of this notice has been submitted to the Administrator of the Environmental Protection Agency (EPA) for his comments concerning the impact of this program on the quality of the environment. The Administrator has no comments.

The guidelines have also been reviewed in accordance with Executive Order 11211 and OMB Circular A-110, issued November 27, 1974, and have been determined not to be a major proposal requiring an evaluation of its inflationary impact.

In consideration of the foregoing, Chapter II of Title 10 of the Code of Federal Regulations, is amended by establishing Part 460 as set forth below, effective July 5, 1977.


**Eric J. Flyn**, Acting General Counsel, Federal Energy Administration.

Subpart D, Chapter II of Title 10, Code of Federal Regulations, is amended by establishing Part 460 as set forth below:

**Sec. 460.1 Purpose and scope.**

460.2 Administration of grants.
(1) Treasury Circular 1075, entitled "Regulations Governing Withdrawal of Cash from the Treasury for Advances under Federal Grant and Other Programs;" and
(2) Such procedures applicable to this part as FEA may from time to time prescribe for the administration of grants.
§ 460.3 Definitions.
As used in this part—
"Administrator" means the Administrator of the Federal Energy Administration.
"Commission" means a utility regulatory commission.
"Consultant" means a person who contracts to provide personal services for an Office and includes an attorney, accountant, economist, or other expert witness.
"Consumer" means a person who buys electricity for purposes other than resale.
"Consumer Group" means an association or organization consisting of not less than three individuals that represents a consumer interest, and may include a corporation, nonprofit corporation, unincorporated association, unit of general purpose local government, tribal organization, law firm, committee, or association of concerned consumers.
"Consumer Interest" means a potential benefit or detriment to a consumer from the social, economic or environmental consequences of the outcome of a proceeding.
"Consumer-Interest Office" means a department, agency, or office of a State which engages in activities on behalf of a consumer interest.
"Electric Utility" means a person, political subdivision of a State, or other entity empowered to generate, supply, transmit, or sell electric energy for purposes of resale in interstate or foreign commerce.
" rebellor" means the Federal Energy Administration.
"Federal Agency" means an agency or instrumentality of the United States.
"Fuel Adjustment Clause" means a clause in a rate schedule that provides, for an adjustment of the consumer's bill if the cost of the fuel used for electrical generation varies from a specified unit of cost.
"Governor" means the chief executive officer of a State or territory, the Mayor of the District of Columbia, or the Chairman of the Tennessee Valley Authority.
"Grant" means the State or other entity named in the notification of grant award as the recipient.
"Kilowatt-Hour" means a unit of measuring electricity usage which represents a unit of work or energy equal to that expended by one kilowatt in one hour.
"KWH" means a kilowatt hour.
"Local Law" means the laws in force in a State and includes the statutes, rules and regulations, judicial decisions, administrative findings and determinations, and executive orders and proclamations, as enforced by the State and its judicial system.
"Office" means an Office of Consumer Services.
"Person" means an individual, partnership, corporation, unincorporated association or any other group, entity or organization.
"Proceeding" means a proceeding before a utility regulatory commission.
"State" means the District of Columbia, American Samoa, Guam, Puerto Rico, the Virgin Islands, the Trust Territory of the Pacific Islands and the Tennessee Valley Authority.
"Sub-grantee" means the eligible consumer group named as the recipient in a grant which shall be made by an Office.
"Tribal Organization" means the recognized governing body of an Indian Tribe, or any legally established organization of Native Americans which is controlled, sanctioned or chartered by such governing body.
"TVA" means the Tennessee Valley Authority.
"Unit of General Purpose Local Government" means any city, county, town, parish, village or other general purpose political subdivision of a State.
"Utility Regulatory Commission" means an Office or a regulatory authority empowered by Federal or local law to fix, modify, approve or disapprove rates, charges, terms and conditions for the sale of electric energy by an electric utility other than itself.
§ 460.10 Grant awards.
(a) FEA shall provide financial assistance to a State, from sums appropriated for any fiscal year, only upon annual application.
(b) Grants shall be awarded to States, selected at the discretion of FEA, for the establishment or operation of an Office.
§ 460.11 Application.
(a) To be eligible to receive a grant under this part, a State shall submit an application, in conformity with paragraph (b) of this section, which shall be received by FEA on or before 5:30 p.m. e.d.t. on August 26, 1977. FEA shall send a copy of each application to the Governor of every State and invite him or her to submit an application.
(b) Each application shall include—
(1) An overview statement of the specific goals and objectives of the proposed office and an explanation of how they relate to the goals and objectives of an existing State Consumer-Interest Office and any commission before which the Office intends to assist the representation of consumer interests;
(2) A legal opinion setting forth the manner in which the State has compiled, or will, in a timely manner, comply with the requirements of § 460.12(a);
(3) Where applicable, an explanation of the authority, functions, organization, activities, budget and financial resources of an Office operating within the State;
(4) An assurance that the final proposed budget for the Office exceeds, by at least 10 percent of the grant award, the amount expended by the State, if any, in the prior fiscal year or appropriated to be expended in the current fiscal year, whichever shall be greater, to perform functions to assist consumers similar to those set forth in § 460.12(a));
(5) A statement of which of the functions set forth in § 460.12(a)(2) are proposed to be carried out by the Office with financial assistance under this part and the reasons for choosing to perform those functions;
(6) A detailed description of how the Office will meet the minimum program requirements prescribed by § 460.12(b) and a timetable for satisfying those requirements;
(7) The amount of Federal financial assistance being applied for under this part, which shall not exceed $200,000, and a budget including an identification and a description of resources or financial assistance which shall be provided to an Office from sources other than the financial assistance provided under this part.
§ 460.12 Minimum program requirements.
(a) Prior to the expenditure of any grant funds and no later than 6 months from the date of a notification of grant award made under this part, a grantee...
shall have in existence or establish an Office which—

1. Is a consumer-interest office;
2. Is empowered and has authority under local law to—
   (1) Make general factual assessments of the impact of proposed electric utility rate changes and other proposed regulatory actions upon consumers, including residential consumers;
   (2) Provide technical or financial assistance to an eligible consumer group meeting the requirements of § 460.14 in the presentation of its position in a proceeding; and
   (3) Is independent of a commission with respect to the following—
      (a) The Commission has no direct control over the Office's budget or its disbursement of funds;
      (b) The commission has no authority over the hiring, management, or dismissal of the personnel employed by an Office; and
      (c) Employees of the Office do not perform services for, report to, or act on behalf of, the commission.
3. Each Office shall develop and publish within 6 months of the date of a grant award or 3 months from the date upon which the Office meets the requirements of paragraph (a) of this section, whichever shall be later, procedures to be approved by FEA to—
   (1) Determine whether a consumer group is an eligible consumer group in accordance with the requirements of this part;
   (2) Provide technical assistance to an eligible consumer group, and financial assistance on a full funding or cost sharing basis to a sub-grantee to make one or more presentations in a proceeding;
   (3) Establish priorities for providing technical and financial assistance to eligible consumer groups taking into consideration—
      (a) Consumer interests;
      (b) The consumer interest of, or represented by, an eligible consumer group;
      (c) The composition, diversity and number of members of an eligible consumer group;
      (d) The relative effectiveness of an eligible consumer group's proposed presentation including the extent to which—
         (1) The eligible consumer group is familiar with and understands the subject matter and issues involved in the proceeding;
         (2) Its proposed presentation is feasible and well-conceived; and
         (3) The eligible consumer group can effectively represent a consumer interest in a proceeding;
      (e) The uniqueness or novelty of an eligible consumer group's position or point of view; and
      (f) Where financial assistance is to be provided, the experience and expertise of a consultant which an eligible consumer group intends to engage;
   (4) Advocate on its own behalf a position in a proceeding which it determines represents the position most advantageous to consumers which shall involve the performance of activities including—
      (i) Consideration of views and data obtained from consumers through the use of such information gathering techniques as a public hearing, survey, analysis and consideration of developments in innovative utility rate design reform;
      (ii) Obtaining qualified witnesses and preparing testimony and other submissions for presentation in a proceeding;
      (iii) Analysis and consideration of developments in innovative utility rate design reform;
      (iv) Making general factual assessments of the impact of proposed rate changes and other proposed regulatory actions upon consumers; and
      (v) Identifying consumer groups and providing them with information concerning this program and its operation.
   (5) After complying with the requirements of paragraphs (a), (b) and (c) of this section, an Office shall carry out activities for the functions prescribed in § 460.12(a) and (b) or (ii) FEA may upon application of an Office or upon good cause shown extend the time limit set to meet the requirements of paragraphs (a) and (b) of this section.
§ 460.13 Allowable expenditures.
(a) Financial assistance provided under this part shall be used for the establishment or operation of an Office, and grant funds awarded in any year shall only be expended for the following—
(b) Compensation of employees of the Office;
(c) No more than 10 percent shall be used for administrative expenses of an Office, exclusive of compensation provided under paragraph (a)(1) of this section;
(d) No more than 45 percent may be paid for the services of consultants, provided that no consultant shall receive in excess of 20 percent; and
(e) No more than 20 percent may be paid to contract for the use of computers and similar equipment for the storage and analysis of data;
(f) Payments to sub-grantees to carry out the functions described in § 460.12(a) and (b) in accordance with the requirements of this part, provided that total payments to sub-grantees shall not exceed 45 percent of the grant funds awarded in any year;
(g) Payments to a consultant by an Office or sub-grantee shall not exceed the prevailing market rate for the level and quality of professional service but not to exceed $75 dollars per hour exclusive of reasonable costs for travel and incidental disbursements such as mailing and photocopying; and
(h) Reasonable costs of an Office or sub-grantee for travel and transportation for an employee, consultant, or a person performing services, such as a volunteer, provided that such costs are incurred in connection with preparing or making a presentation at a proceeding.
§ 460.14 Eligible consumer group.
No consumer group shall receive financial or technical assistance from an Office unless—
(a) The consumer group is—
   (1) Representing a consumer interest with the capacity, financial and technical capability to substantially contribute a full and fair determination of the issues to be considered in the proceeding.
   (2) Participation in the proceeding is necessary to the effective presentation of the consumer interest;
   (b) The consumer interest would not be effectively represented because—
   (1) The consumer group does not have reasonably available and cannot reasonably obtain sufficient resources to participate effectively in the proceeding; or
   (2) The economic gain or loss to the consumer group and any consumer with regard to the outcome of the proceeding is small relative to the costs of effective participation in the proceeding; and
   (3) The costs of effective participation are small relative to the social, economic or environmental consequences of the outcome of the proceeding.
§ 460.15 Selection of grantees.
(a) FEA shall evaluate an application submitted in accordance with § 460.11 through the use of a rating system with a total of 100 points under which to
§ 460.16 Oversight responsibility.
(a) The Administrator shall monitor and evaluate the establishment and operation of Offices receiving financial assistance under this part through on-site project reviews, or through other means, in order to insure the effective performance of Offices under the grants.
(b) The Administrator and the Controller General of the United States, or their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, information, and records of Offices receiving financial assistance under this part.
(c) Each grantee shall conduct, on an annual basis, an audit of the pertinent records of any sub-grantee receiving financial assistance under this part.

§ 460.17 Recordkeeping.
Each grantee or sub-grantee receiving Federal financial assistance under this part shall keep such records as FEA shall require, including records which fully disclose the amount and disposition of funds received, the source and amount of funds not supplied by FEA for an Office, and such other records as FEA deems necessary for an effective audit and performance evaluation. Such recordkeeping shall be in accordance with Federal Management Circular 74-7 and any further requirements of this regulation or which FEA may otherwise establish under the terms and conditions of a grant.

§ 460.18 Reporting requirements.
Each grantee receiving financial assistance under this part shall submit a quarterly program performance report and a quarterly financial report to the Administrator. The program performance report shall contain such information as the Administrator may prescribe in order effectively to monitor the progress of a grantee.

§ 460.19 Grant termination.
(a) FEA shall give notice to a grantee in the event FEA finds there is a failure by the grantee to comply substantially with the provisions of this part.
(b) FEA shall issue such notice in the form of a written notice mailed by registered mail, return receipt requested, to the grantee and shall include (1) a statement of the reasons for the finding referred to in paragraph (a) of this section together with an explanation of any remedial action which, if undertaken, would result in compliance; and (2) the date upon which the grant will be terminated.
(c) A grantee which receives the notice referred to in paragraph (a) of this section may file a written response containing an explanation of how it will comply with the requirements of this part, or a statement of its views and supporting data explaining why the grant should not be terminated. This response shall be made by registered mail, return receipt requested, not later than 10 days after the receipt of the notice referred to in paragraph (b) of this section.
(d) Within 20 days after the grantee’s receipt of notice in accordance with the procedure set forth in paragraph (b) of this section, the Administrator, after consideration of any response filed by the grantee, shall issue such notice in the event FEA finds there is a failure by the grantee to comply substantially with the requirements of this part and issue a written statement explaining the reasons for this determination.

(e) Upon issuance of the notice referred to in paragraph (a) of this section, FEA may suspend payments to any grantee pending a final determination. If the Administrator makes a final determination of substantial failure to comply, the grantee will be ineligible to participate in the program unless and until FEA is satisfied that the failure to comply has been corrected.
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 rulemaking prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

[9 CFR Part 381]

TRANSPORTATION OF INEDIBLE MATERIAL

Withdrawal of Proposed Regulation

AGENCY: Food Safety and Quality Service, Agriculture.

ACTION: Notice of withdrawal.

SUMMARY: This notice withdraws a notice of proposed rulemaking which would have allowed the movement in commerce, for uses other than human food, of certain unadulterated, inedible poultry products under a system involving permits, seals, and invoices. The Meat and Poultry Inspection Program has determined that instead of the permit system, a more efficient method of controlling shipments of inedible poultry products can be devised.

EFFECTIVE DATE: July 8, 1977.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

On July 28, 1975, the Meat and Poultry Inspection Program of the Department of Agriculture published a proposed rule (40 FR 31616-31617) to amend 9 CFR 381.175 and 381.193 of the poultry products inspection regulations, that would have allowed the movement in commerce, for uses other than human food, of certain unadulterated, inedible poultry products under a system involving permits, seals, and invoices. The proposal was intended to control the movement in commerce of unadulterated, inedible poultry products in the same manner as unadulterated, inedible meat and meat products (9 CFR 356.11(d)).

The Acting Administrator has determined that a more effective method of controlling the shipment of inedible product than the permit system can be developed. Several other methods are being considered for both meat and poultry products. A more comprehensive and less complicated proposal will be published at a later date. In consideration of the foregoing, the proposal published in the Federal Register (40 FR 31616-31617) on July 28, 1975, is hereby withdrawn.

Note.—The Food Safety and Quality Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11291 and OMB Circular A-107.

Done at Washington, D.C. on: June 29, 1977.

HARRY C. MOSSMAN,
Acting Administrator,
Food Safety and Quality Service.

[FR Doc.77-19518 Filed 7-7-77;8:45 am]

FEDERAL ENERGY ADMINISTRATION

[10 CFR Parts 211, 212]

POST-EXEMPTION MONITORING OF MIDDLE DISTILLATE PRICES

Rescheduling of Public Hearing

AGENCY: Federal Energy Administration.

ACTION: Notice of rescheduling of public hearing.

SUMMARY: The Federal Energy Administration ("FEA") hereby extends the previously announced date of the Washington hearing on the post-exemption monitoring of middle distillate prices to August 2, 1977, to provide additional time for preparation of comments. The deadline for requests to speak has been extended to July 18, 1977. No other dates are changed.

FOR FURTHER INFORMATION CONTACT:

Laura Kuitunen or Dennis M. Moore, (Program Office), Federal Energy Administration, 12th and Pennsylvania Avenue NW., Room 5138, Washington, D.C. 20461 (202-566-8567 or 9566-2985).

SUPPLEMENTARY INFORMATION:

On May 16, 1977, FEA issued a Further Notice of Proposed Rulemaking and Public Hearing on the post-exemption monitoring of middle distillate prices (42 FR 27837, June 1, 1977). The further notice announced FEA's intent to provide an opportunity for receipt of comments and testimony on the manner in which the FEA middle distillate price monitoring system operated during the post heating season and on what action, if any, ought to be taken by FEA with respect to possible further monitoring of or re-imposition of controls on middle distillates through the next heating season. National and regional hearings were scheduled by the further notice for dates in mid-July 1977.

To allow additional time for analysis of the information presented at the regional hearings and to provide additional time for preparation of comments, FEA hereby extends the date previously announced for the Washington hearing to Tuesday, August 2, 1977, 9:30 a.m. The Washington hearing will be held, as originally announced, in Room 3000A, 12th and Pennsylvania Avenue NW, Washington, D.C. 20461. In accordance with this extension of the Washington hearing date, requests to speak at the Washington hearing must be submitted by July 18, 1977.

All hearing dates, times, and locations for the regional hearings announced in the May 26, 1977, further notice remain unchanged and such regional hearings will take place as scheduled. The final date for filing comments is July 6, 1977, but FEA will continue to consider comments submitted up to the time of the Washington hearing.


Eric J. Fry, Acting General Counsel, Federal Energy Administration.

[FR Doc.77-19368 Filed 7-7-77;8:45 am]

ENERGY CONSERVATION PROGRAM FOR APPLIANCES

Proposed Rulemaking Regarding Test Procedures for Conventional Ranges, Conventional Cooking Tops, Conventional Ovens, and Microwave Ovens; Corrections

AGENCY: Federal Energy Administration (FEA).

ACTION: Proposed rulemaking; corrections.

SUMMARY: This document corrects errors made in the proposed rulemaking regarding test procedures for conventional ranges, conventional cooking tops, conventional ovens, and microwave ovens which appeared at 30627 and following of the June 16, 1977, Federal Register.

FOR FURTHER INFORMATION CONTACT:


FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
SUPPLEMENTARY INFORMATION: A number of provisions of Appendix I contained in the proposed regulation, pages 30653 and following, were incorrectly stated and are corrected below. In all other respects the proposed rulemaking remains as published on June 16, 1977.


In consideration of the foregoing, the proposed regulation for test procedures for conventional ranges, conventional cooking tops, conventional ovens, and microwave ovens published in 42 FR 30627 et seq. (June 16, 1977) is corrected as set forth below.

Issued in Washington, D.C., July 1, 1977.

ERIC J. FYGI,
Acting General Counsel,
Federal Energy Administration.

Section 4.5.2 of Appendix I is deleted and sections 4.1.4, 4.1.9, 4.5.3 and 4.5.4 are corrected to read as follows:

APPENDIX I—UNIFORM TEST METHOD FOR MEASURING THE ENERGY CONSUMPTION OF CONVENTIONAL RANGES, CONVENTIONAL COOKING TOPS, CONVENTIONAL OVENS, AND MICROWAVE OVENS

4.1.4 Conventional oven annual self-cleaning energy consumption of a basic model. Calculate the conventional oven annual self-cleaning energy consumption, Eo, of the basic model tested, expressed in kWh per year for electrical energy and Btu's per year for gas, and defined as:

\[ E_o = \frac{365}{n} \left( (E_s \times X) + (E_h \times X_h) \right) \times S \]

where

- \( E_s \) = Energy consumption in cubic feet of gas per oven tested according to 3.2.1.
- \( E_h \) = Electrical energy consumed by an ignition device for the self-cleaning operation of a conventional gas oven.
- \( H_o = \text{Conversion factor of wait-hours to Btu's (8.42 Btu/Wh)} \)
- \( H_s = \text{Elapsed time or hours, the heating value of the gas used in the test as specified in 2.2.2.1 and 2.2.2.2 in Btu's per standard cubic foot.} \)

4.3.4 Microwave oven test procedure. Calculate the microwave oven rated efficiency, \( \eta \), and defined as:

\[ \eta = \frac{E_m}{P_i \times S \times C} \]

where

- \( E_m \) = Energy consumption in watt-hours per oven tested according to 3.1.1.2.
- \( S \) = As defined above.
- \( C \) = Conversion factor of watt-hours to kilowatt-hours (0.001 Wh/KWh).

4.2.2 Gas heating element efficiency. Calculate the efficiency, \( \eta \), of the gas heating element under test, and defined as:

\[ \eta = \frac{W_s \times C_s \times T_s}{E} \]

where

- \( W_s \) = Measured weight of test block according to 3.3.2.1, in pounds.
- \( C_s \) = Specific heat of aluminum, 0.20 Btu/\( \text{lb} /\text{deg} \langle F \rangle \)
- \( T_s \) = Temperature rise of the test block/oven or test temperature, \( T_s \) as determined in 2.2.2, minus the initial test block temperature, \( T \).
- \( E = \frac{1}{(E_s + E_h) \times X} + (E_s + E_h) \times X_s \)

SUPPLEMENTARY INFORMATION: On June 29, 1973, the EPA, published in the Federal Register (38 FR 16418) a notice that the United States Department of the Interior (USDI), Bureau of Reclamation, Washington, D.C. 20240, had submitted a petition in a proceeding under the Federal Insecticide, Fungicide, and Rodenticide Act, 32 U.S.C. 136 et seq., for establishment of a food additive tolerance for residues of the herbicide dalapon (2,2-dichloropropionic acid) in potable water at 0.2 part per million (ppm) when present therein as a result of the application of dalapon sodium—sodium salts mixtures to irrigation channel and ditch banks.

The data submitted in the petition and all other relevant material have been evaluated, and it is concluded that the pesticide may be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (68 Stat. 913, 89 Stat. 751; 7 U.S.C. 136(a) et seq.). The toxicological data considered in support of the proposed tolerance were two mutagenicity tests in rats with a no-effect level of 3,000 ppm for each. two 2-year rat feeding studies to investigate tumor formation, a 1-year chronic dog-feeding study, and a rat teratology study. An adequate analytical method (gas chromatography) is available to enforce the proposed tolerance. Tolerances have previously been established (40 CFR 180.150) for residues of dalapon from 15 ppm to 0.1 ppm (negligible residue) on a wide variety of crops. (A related proposed rulemaking document to amend 40 CFR 180.150 by establishing tolerances for residues of dalapon in or on a variety of crops and crop groupings appears elsewhere in today's Federal Register.) Therefore, it is proposed that 21 CFR 193 be amended as set forth below.

Any person who has registered, or submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act which contains any of the ingredients listed herein may request, on or before August 8, 1977, that this proposal be referred to an advisory committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Three copies of the comments should be submitted to facilitate the work of the Agency and of others interested in inspecting them. The comments must be a notation indicating both the subject and the petition/document number, "Dalapon, P03960/PT". All written comments filed in response to this notice of proposed rulemaking will be available for public inspection in the office of the Federal Register Section from 8:30 a.m. to 4 p.m. Monday through Friday.


DOUGLAS D. CAMPE, Acting Director, Registration Division.
PROPOSED RULES

FOR FURTHER INFORMATION CONTACT:

Paul J. Traina, Director, Enforcement Division, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street, NE., Atlanta, Georgia 30308 (404/881-2211)

SUPPLEMENTARY INFORMATION:

On December 17, 1976, John Quarles, Acting Administrator of EPA, issued compliance date extensions (41 FR 55191) to the Savannah Electric and Power Company's Port Wentworth Generating Station for Units 1, 2, and 3, located in Chatham County, Georgia.

Each unit was required to be equipped with air pollution control devices by specific dates, before converting to coal burning. The Savannah Electric and Power Company informed EPA on March 4, 1977, that the construction time for the control equipment for Units 1 and 2 would have to be extended three months and the construction of control equipment for Unit 3 would be completed one month ahead of the date originally scheduled. EPA is considering the approval of the modification of the construction dates and is reviewing the documentation submitted by Savannah Electric. This documentation indicated that the schedule had to be adjusted because a new contractor was selected to install the control equipment.

All other conditions of the original compliance date extension will remain in effect, including the requirement to maintain compliance with all applicable air pollution regulations by continuing to burn oil until the construction of the control equipment is completed.

Accordingly, it is proposed that Part 55 of Chapter I, Title 40, Code of Federal Regulations, be amended by revising subdivisions (iii), (iv), (v), and (vii) of § 55.570(a)(1) to read as follows:

Subpart L—Georgia
§ 55.570 Compliance date extensions.

(a) * * *

(1) * * *

(iii) August 1, 1977. Initiate on-site construction or installation of particulate emission control equipment for Units 1, 2, and 3.

(iv) April 1, 1978. Initiate on-site construction or installation of particulate emission control equipment for Units 1, 2, and 3.

(vi) August 1, 1978 (Unit 1), September 1, 1978 (Unit 2), October 1, 1978 (Unit 3). Complete on-site construction or installation of particulate emission control equipment and initiate use of such equipment.

(vii) October 15, 1978 (Unit 1), November 15, 1978 (Unit 2), December 31, 1978 (Unit 3). Complete shake-down operations and performance tests on the control equipment required by this subparagraph; also, demonstrate compliance with section 391-3-1-02(2)(d) of the Georgia Rules and Regulations for Air Quality Control and certify such compliance to the Director of the EPA Region IV Enforcement Division.

* * *

(40 CFR Part 180)

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

Proposed Amendment to Tolerance Regulation for Pesticide Chemical Naled

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes that established tolerances for naled be amended to (1) correct errors in the regulations, (2) update the regulations, and (3) editorially revise the format. This proposed amendment will provide the public with more accurate information in an easier to read style.

DATE: Comments must be received on or before August 6, 1977.


FOR FURTHER INFORMATION CONTACT:

Jan B. Wine, Federal Register Section, at the address above or by telephone at 202-755-4854.

SUPPLEMENTARY INFORMATION:

As announced on October 27, 1976 (41 FR 47076), the Environmental Protection Agency (EPA) is reformatting the pesticide tolerance regulations contained in 40 CFR Part 180. The current narrative paragraphs are being put into an alphabetized columnar listing for the purpose of providing orderly development of and/or amendments to the regulations, furnishing ample room for expansion in the years ahead, and providing the public and affected parties with regulations that are easier to read. In addition to editorial revisions, certain, section titles are being amended by substituting acceptable common names for antiquated and unacceptable pesticide chemical names where appropriate, and the regulations are being updated and corrected where necessary.

It is proposed that (1) § 180.315 be renumbered, (2) § 180.319 be amended to correct an error in the regulations, and (3) § 180.215 be amended to update the regulation.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
In June 1974, the Agency amended 40 CFR 180.215 in response to a petition (1P71078) by Sections Co., 949 Hensley Street, Richmond, CA 94804. Interim tolerances for nased residues in or on certain raw agricultural commodities were established pending review and completed action on this petition and others submitted to the Agency. In addition, the petition submitted by Chevron also included a proposal for permanent tolerances for residues of nased in or on soybeans which was subsequently withdrawn by the petitioner. Therefore, § 180.319 should have been amended to delete the interim tolerances for beans, peas, and soybeans at the time § 180.215 was amended (39 FR 22423) by establishing permanent tolerances for residues of nased in or on the raw agricultural commodities beans (succulent) and peas (succulent) at 0.5 part per million.

On January 29, 1975, the Agency amended 40 CFR 180.215 (40 FR 4279) in response to two petitions (PP23211 and PP24144) also filed by Chevron Chemical Co. Permanent tolerances were established for all remaining interim tolerances found in Section 180.215. However, amendments to 40 CFR 180-319 were once again overlooked.

Therefore, it is proposed at this time that § 180.319 be amended to delete all interim tolerances shown for the pesticide naled.

It is also proposed that § 180.215 be amended to eliminate a contradiction contained in the regulation pertaining to the established tolerance of 0.05 ppm for almonds (hulls) and almonds (nuts) and the established tolerance of 0.5 ppm for "all raw agricultural commodities, except those otherwise listed in this section," from the pesticide for area pest (mosquito and fly) control. To make the minimum tolerance uniform for residues of nased on growing crops, regardless which registered use of nased causes such residues, the established tolerances for almonds (hulls) and almond (nuts) are being increased from 0.05 to 0.5 ppm. Furthermore, to clarify the situation regarding established tolerances of 0.05 ppm for eggs, milk, and the fat, meat, and meat byproducts of livestock and poultry with respect to 40 CFR 180.215, the introductory paragraph to § 180.215 is being revised to include residues which may result from direct application to livestock and poultry. In addition, since available toxicity data now include long-term feeding studies which were used to support non-negligible residues of nased in or on raw agricultural commodities such as oranges, spinach, and turnips at 3 ppm, the negligible residue determinant "N" is being removed. It has been determined that these proposed changes and clarifications will protect the public health.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act which contains any of the ingredients listed herein may request, on or before August 8, 1977, that this proposal be referred to an advisory committee in accordance with Section 406 of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Three copies of the comments should be submitted to facilitate the work of the Agency and of others interested in inspecting them. The comments should bear a notation indicating the subject and the control number "OPP-260025". All written comments filed pursuant to this notice will be available for public inspection in the office of the Federal Register Section from 8:30 a.m. to 4 p.m. Monday through Friday.


DOUGLAS D. CAMPE, Acting Director, Registration Division.

It is proposed that Section 180.215 be amended by revising the entire section to read as follows:

§ 180.215 Naled; tolerances for residues.

Tolerances are established for residues of the insecticide naled (1,2-dihydro-2, 2-dichloroethyl dimethyl phosphate) and its conversion product 2,2-dichlorovinyl dimethyl phosphate, expressed as naled, resulting from the application of the pesticide to growing crops or from direct application to livestock and poultry, in or on the following raw agricultural commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almonds (hulls)</td>
<td>0.5</td>
</tr>
<tr>
<td>Almonds (nuts)</td>
<td>0.5</td>
</tr>
<tr>
<td>Beans (dry)</td>
<td>0.5</td>
</tr>
<tr>
<td>Beans (exceeding)</td>
<td>0.5</td>
</tr>
<tr>
<td>Beets, sugar, roots</td>
<td>0.5</td>
</tr>
<tr>
<td>Beets, sugar, tops</td>
<td>0.5</td>
</tr>
<tr>
<td>Broccoli</td>
<td>0.5</td>
</tr>
<tr>
<td>Brussels sprouts</td>
<td>0.5</td>
</tr>
<tr>
<td>Cabbage</td>
<td>0.5</td>
</tr>
<tr>
<td>Cattle, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Cattle, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Cattle, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Cauliflower</td>
<td>1</td>
</tr>
<tr>
<td>Collards</td>
<td>3</td>
</tr>
<tr>
<td>Cottonseed</td>
<td>0.5</td>
</tr>
<tr>
<td>Courgettes</td>
<td>0.5</td>
</tr>
<tr>
<td>Eggplant</td>
<td>0.5</td>
</tr>
<tr>
<td>Eggs</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, sbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Goats, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>0.5</td>
</tr>
<tr>
<td>Grapes</td>
<td>0.5</td>
</tr>
<tr>
<td>Grasses, forage</td>
<td>0.5</td>
</tr>
<tr>
<td>Hogs, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Hogs, mbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Hogs, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Hops</td>
<td>0.5</td>
</tr>
<tr>
<td>Horses, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, sbyp</td>
<td>0.05</td>
</tr>
<tr>
<td>Horses, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Kale</td>
<td>0.5</td>
</tr>
<tr>
<td>Legumes, forage</td>
<td>10</td>
</tr>
<tr>
<td>Lemons</td>
<td>3</td>
</tr>
<tr>
<td>Lettuce</td>
<td>0.5</td>
</tr>
<tr>
<td>Melons</td>
<td>0.5</td>
</tr>
<tr>
<td>Milk</td>
<td>0.05</td>
</tr>
<tr>
<td>Mushrooms</td>
<td>0.5</td>
</tr>
<tr>
<td>Onions</td>
<td>0.5</td>
</tr>
<tr>
<td>Peaches</td>
<td>0.5</td>
</tr>
<tr>
<td>Peas (succulent)</td>
<td>0.5</td>
</tr>
<tr>
<td>Peppers</td>
<td>0.5</td>
</tr>
<tr>
<td>Poultry, fat</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Commodity:  
Poultry, mbyp  0.05  
Poultry, meat  0.05  
Punnut  0.5  
Rice  0.5  
Saltwater, seed  0.5  
Sesew, fat  0.05  
Sheep, mbyp  0.05  
Sheep, meat  0.05  
Spinach  0.5  
Squash, summer  0.5  
Squash, winter  0.5  
Strawberries  1  
Swiss chard  0.5  
Tangorines  0.5  
Tomatoes  0.5  
Turnips, tops  3  
Walnuts  0.5

A tolerance of 0.5 part per million is established for the pesticide naced in or on all raw agricultural commodities, except those otherwise listed in this section, from the use of the pesticide for area pest (mosquito and fly) control.

§ 180.319 [Amended]  
It is proposed that § 180.319 be amended by deleting the substance naced and corresponding tabular material from the regulation.

[FR Doc. 77-119145 Filed 7-17-77; 8:45 am]

[40 CFR Part 180 ]  
[FFD 13518/P437; FRL 758-8 ]

PESTICIDE PROGRAMS

Tolerances and Exemption of Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; Proposed Tolerances for the Pesticide Chemical Dalapon

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes that tolerances be established for residues of the herbicide dalapon in or on a variety of crops and crop groupings. This proposal was submitted by the U.S. Department of the Interior. This proposal will permit the safe use of dalapon on irrigation ditch banks in the western United States in programs of the Bureau of Reclamation.

DATE: Comments must be received on or before August 8, 1977.

ADDRESS: Send comments to: Federal Register Section, Technical Services Division (WH-569), Office of Pesticide Programs, EPA, Rm. 401, East Tower, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Ms. Patricia Critchlow, Registration Division (WH-567), Office of Pesticide Programs, EPA, (202) 260-1000.

SUPPLEMENTARY INFORMATION: The United States Department of the Interior (USDI), Bureau of Reclamation, Washington, D.C. 20240, has submitted a pesticide petition (FP 3E1365) to the EPA. This petition requests that the Administrator, pursuant to section 406(e)
of the Federal Food, Drug and Cosmetic Act, propose that 40 CFR 180.150 be amended by the establishment of tolerances for residues of the herbicide dalapon (2,2-dichloropropionic acid) resulting from application of dalapon sodium-magnesium salt mixtures to irrigation ditch banks in the United States in programs of the USDA Bureau of Reclamation in or on the following raw agricultural commodities and commodity groups:

- Flaxseed, forage grasses, forage legumes, and wheat at 2 parts per million (ppm).
- Cucurbits, grain crops (except wheat), leafy vegetables, hops, nuts, pome fruits, root crop vegetables, small fruits, and stone fruits at 0.5 ppm.
- Avocados, citrus fruits, cottonseed, fruiting vegetables, hops, nuts, pome fruits, root crop vegetables, small fruits, and stone fruits at 0.2 ppm.
- All other relevant material at 0.1 ppm.
- Cottonseed at 0.01 ppm.

The data submitted in the petition and all other relevant material having been evaluated, it has been concluded that the tolerances established for these commodity groups at the levels proposed will protect the public health. The toxicological data considered in support of the proposed tolerances were two mutagenic tests in rats with & /no-effect level of 3,000 ppm for each, two 2-year rat feeding studies to investigate tumor formation, a 1-year chronic dog-feeding study, and an Ames study. An adequate analytical method (gas chromatography) is available to enforce the proposed tolerances. Tolerances have previously been established for residues of dalapon from 75 ppm to 0.1 ppm (negligible residue) on a wide variety of crops. In addition, it is being proposed that the negligible residue designator ("N") be removed from the existing tolerances as paragrap(§ 180.150) by designating the existing tolerances as paragraphs (a), (b), (c), and (d) by editorially restructuring paragraph (a) into a tabular 'alphabetized listing, to read as follows:

§ 180.150 Dalapon; tolerances for residues.

(a) Tolerances are established for residues of the herbicide dalapon (2,2-dichloropropionic acid) resulting from application of dalapon sodium salt or sodium-magnesium salt mixtures in or on the following raw agricultural commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almonds, hulls</td>
<td>5.0</td>
</tr>
<tr>
<td>Apples</td>
<td>2.0</td>
</tr>
<tr>
<td>Apricots</td>
<td>1.0</td>
</tr>
<tr>
<td>Banana, juice</td>
<td>1.0</td>
</tr>
<tr>
<td>Beans</td>
<td>1.0</td>
</tr>
<tr>
<td>Beets, sugar (roots)</td>
<td>1.0</td>
</tr>
<tr>
<td>Beets, sugar (tops)</td>
<td>1.0</td>
</tr>
<tr>
<td>Cattle, meat</td>
<td>0.5</td>
</tr>
<tr>
<td>Cattle, meat</td>
<td>2.0</td>
</tr>
<tr>
<td>Coffee beans</td>
<td>2.0</td>
</tr>
<tr>
<td>Corn, n.e.</td>
<td>10.0</td>
</tr>
<tr>
<td>Corn, forage</td>
<td>5.0</td>
</tr>
<tr>
<td>Corn, fresh (including sweet K-CWHR)</td>
<td>5.0</td>
</tr>
<tr>
<td>Corn, grain</td>
<td>10.0</td>
</tr>
<tr>
<td>Cottontreated</td>
<td>35.0</td>
</tr>
<tr>
<td>Currants</td>
<td>5.0</td>
</tr>
<tr>
<td>Eggs</td>
<td>3.0</td>
</tr>
<tr>
<td>Flaxseed</td>
<td>75.0</td>
</tr>
<tr>
<td>Goats, meat</td>
<td>2.0</td>
</tr>
<tr>
<td>Grapes</td>
<td>5.0</td>
</tr>
<tr>
<td>Grasses, pasture</td>
<td>10.0</td>
</tr>
<tr>
<td>Grasses, range</td>
<td>10.0</td>
</tr>
<tr>
<td>Hops, spray</td>
<td>2.0</td>
</tr>
<tr>
<td>Hops, meat</td>
<td>1.0</td>
</tr>
<tr>
<td>Lemons</td>
<td>5.0</td>
</tr>
<tr>
<td>Limes</td>
<td>5.0</td>
</tr>
<tr>
<td>Macadamia nuts</td>
<td>1.0</td>
</tr>
<tr>
<td>Milk</td>
<td>1.0</td>
</tr>
<tr>
<td>Oranges</td>
<td>5.0</td>
</tr>
<tr>
<td>Peaches</td>
<td>15.0</td>
</tr>
<tr>
<td>Pears</td>
<td>3.0</td>
</tr>
<tr>
<td>Pears, cored</td>
<td>2.0</td>
</tr>
<tr>
<td>Pears, seeded</td>
<td>2.0</td>
</tr>
<tr>
<td>Peas, with pod</td>
<td>1.0</td>
</tr>
<tr>
<td>Peas, without pod</td>
<td>1.0</td>
</tr>
<tr>
<td>Pineapples</td>
<td>2.0</td>
</tr>
<tr>
<td>Plums</td>
<td>0.1</td>
</tr>
<tr>
<td>Potatoes</td>
<td>1.0</td>
</tr>
<tr>
<td>Poultry, (excluding kidney)</td>
<td>5.0</td>
</tr>
<tr>
<td>Soybeans</td>
<td>1.0</td>
</tr>
<tr>
<td>Soybeans, straw</td>
<td>1.0</td>
</tr>
<tr>
<td>Sugarcanes</td>
<td>1.0</td>
</tr>
<tr>
<td>Tangerines</td>
<td>5.0</td>
</tr>
<tr>
<td>Walnuts</td>
<td>5.0</td>
</tr>
</tbody>
</table>
| (b) Tolerances are established for residues of dalapon (2,2-dichloropropionic acid) resulting from application of dalapon sodium-magnesium salt mixtures to irrigation ditch banks in the western United States in programs of the USDA Bureau of Reclamation, in or on the following raw agricultural commodities. Where tolerances are established at higher levels from other uses of dalapon on the subject crops, the higher tolerance applies also to residues from the irrigation ditch bank use.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avocados</td>
<td>0.3</td>
</tr>
<tr>
<td>Citrus fruits</td>
<td>2.0</td>
</tr>
<tr>
<td>Cottonseed</td>
<td>2.0</td>
</tr>
<tr>
<td>Cucubits</td>
<td>5.0</td>
</tr>
<tr>
<td>Flaxseed</td>
<td>0.3</td>
</tr>
<tr>
<td>Fruits, pome</td>
<td>2.0</td>
</tr>
<tr>
<td>Fruits, small</td>
<td>2.0</td>
</tr>
<tr>
<td>Fruits, stone</td>
<td>2.0</td>
</tr>
<tr>
<td>Grain crops (exc wheat)</td>
<td>5.0</td>
</tr>
<tr>
<td>Grapes, forage</td>
<td>2.0</td>
</tr>
<tr>
<td>Hops</td>
<td>0.3</td>
</tr>
<tr>
<td>Legumes, forage</td>
<td>2.0</td>
</tr>
<tr>
<td>Nuts</td>
<td>2.0</td>
</tr>
<tr>
<td>Vegetables, fruiting</td>
<td>3.0</td>
</tr>
<tr>
<td>Vegetables, leafy</td>
<td>2.0</td>
</tr>
<tr>
<td>Vegetables, root crop</td>
<td>2.0</td>
</tr>
<tr>
<td>Vegetables, seed and pod</td>
<td>2.0</td>
</tr>
<tr>
<td>Wheat</td>
<td>2.0</td>
</tr>
</tbody>
</table>

INTERSTATE COMMERCE COMMISSION

[49 CFR Parts 1047, 1082]

[Nos. MC-C-3479, MC-C-3400]

MOTOR TRANSPORTATION OF PROPERTY INCIDENTAL AND PASSENGERS INCIDENTAL TO TRANSPORTATION BY AIRCRAFT

Extension of Comment Period

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rule.

SUMMARY: At the request of Todd A. Peterman, Representative of American Trucking Associations, Inc., the time for filing comments in the above-referenced proceeding (42 FR 26667, May 25, 1977) has been extended from August 8, 1977, to September 7, 1977. No further extensions.

DATES: Comments must be received on or before September 7, 1977.

FEDERAL REGISTER, VOL. 42, NO. 371—FRIDAY, JULY 8, 1977
POLLUTION CONTROL DEPARTMENT

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

PROPOSED RULES

ADDRESS:

Send comments to: Interstate Commerce Commission, 12th and Constitution Avenue, Washington, D.C. 20423. All written submissions will be available for public inspection during regular business hours at the same address.

FOR FURTHER INFORMATION CONTACT:

Michael Erenberg, Assistant Deputy Director, Section of Operating Rights, Office of Procedings (202-275-7292).

H. J. Homme, Jr., Acting Secretary.

[FR Doc. 77-19537 Filed 7-7-77; 8:45 am]

49 CFR Part 1331

NOTIFICATION OF RATE PROPOSALS FOLLOWING PRIOR INDEPENDENT ACTION

Petition for Rulemaking

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rule.

SUMMARY: On petition by the U.S. Department of Justice the Commission is considering whether to prescribe a rule prohibiting rate bureaus from publishing changes or modifications to independently established rates and related matters of member carriers without the specific consent of such carriers. This rule will have the effect of eliminating the practice of changing or modifying independently established rates without the specific consent of carriers.

DATES: Statements of intent to participate in support or opposition are due on or before July 28, 1977.

ADDRESS: Send statements of intent to participate to: Office of Proceedings, Room 5342, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT:

Deputy Director Rosenak or Assistant Deputy Director Gobetz, Section of Rates, Interstate Commerce Commission, Washington, D.C. 20423, 202-275-7693.

SUPPLEMENTARY INFORMATION:
The United States Department of Justice has petitioned the Interstate Commerce Commission to prescribe a proposed rule reading as follows:

No rate bureau may publish any tariff which has the effect of changing or modifying any rate, term, or condition of an existing rate which, rate, term or condition was a result of the exercise of independent action by a member of the rate bureau, unless the rate bureau shall have first notified such member that a proposed tariff will change or modify the rate, term or condition which resulted from that member's exercise of independent action and shall have obtained the member's written consent to the change or modification.

Petitioner alleges that rate bureaus often cancel or change independently established rates of member carriers without the acquiescence or knowledge of such carriers. It will submit evidence illustrat-
ACTION: Advance notice of proposed rulemaking.

SUMMARY: Announcement is made of five of a number of public hearings to consider the desirability of rulemaking and other possible courses of action under the Fishery Conservation and Management Act of 1976 ("the Act") for dealing with business arrangements involving the purchase of fish by foreign buyers from U.S. fishermen. These particular hearings will be held jointly by the National Marine Fisheries Service (NMFS) and the North Pacific Regional Fishery Management Council. These hearings will assist the Secretary of Commerce in establishing a national policy regarding such business arrangements, whose potential effects appear in some cases consistent and in other cases inconsistent with the purposes and policies of the Act.

DATES, TIMES, AND LOCATIONS: Public hearings will be held:


On August 5-6, 1977, at Sea-Tak Hilton Hotel (Conference Room to be posted), 17820 Pacific Highway, South, Seattle, Washington 98188.

On August 22, 1977, at Supreme Court Chambers, State Court Building, 3rd and K Streets, Anchorage, Alaska 99501.

On August 23, 1977, at Sand Point City Hall, Sand Point, Alaska 99611.


Hearings will begin at 9:00 a.m. and will continue until all testimony is received. The hearings will terminate, however, by 5:00 p.m.

In addition to oral testimony, written comments also are solicited. These may be submitted to the address shown below no later than September 2, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Phillip Clitwood, Fisheries Research Administrator, Alaska Region, P.O. Box 1668, Juneau, Alaska 99801, Telephone: (907) 586-7221.

SUPPLEMENTARY INFORMATION: During the hearings we will seek to evaluate transactions at sea between foreign support vessels and U.S.-fishing vessels, particularly the foreign purchase of U.S. caught fish. Possible courses of action would include, among other things:

(a) Modifying existing preliminary management plans and regulations during 1977;
(b) Changing optimum yield statements with, or without, new biological, social, or economic data;
(c) Adjusting existing foreign allocations;
(d) Modifying existing permits and issuing new ones;
(e) Establishing a long-range policy for U.S. and foreign joint participation in fishing ventures under both preliminary and fishery management plans; and
(f) Taking such other related steps as may be appropriate.

A detailed explanation of the issues and options to be discussed at these public hearings may be found at 42 FR 30875, 30876, Friday, June 17, 1977. The NMFS presently has no additional information which would be helpful to the public in updating or expanding upon that explanation.

Dated: July 6, 1977.

WINFRED H. MEIDHORN, Associate Director, National Marine Fisheries Service.

[F.R. Doc. 77-19626 Filed 7-7-77; 8:45 a.m.]
ADMINISTRATOR, EMERGENCY NATURAL GAS ACT OF 1977

[Docket No. E77-125]

AMINOL, U.S.A.

Emergency Order

On June 21, 1977, Aminol, U.S.A. (Aminol) filed, pursuant to section 6 of the Emergency Natural Gas Act of 1977 (Act), Pub. L. 95-2 (91 Stat. 4 (1977)) a petition seeking assistance in obtaining the transportation charges of Pacific Gas and Electric Company (PG&E) which are necessary prior to the approval of the sale of natural gas from Aminol to Natural Gas Pipeline Company (Natural). Specifically, Aminol requests that PG&E provide the following information:

1. The information necessary to establish a point of connection on PG&E's line in section 8, 3 3/4 N., 2 E. near the Union Scapes well on its lines in Contra Costa County, California.

2. The information necessary to establish another point of connection on PG&E's lines in Solano County, California on the east side of section 6, 6 N., 2 E.

3. A determination by PG&E as to the day on which delivery of gas can commence.

Pursuant to section 6(d)(1) of the Act, I hereby order PG&E to submit the requested information to Aminol within 48 hours of issuance of this order. Further, should Aminol determine that either or both of these connections are feasible, pursuant to section 6(d)(1) of the Act, I order PG&E to transport said gas for Aminol's account.

This order is issued pursuant to the authority delegated to me by the President in Executive Order No. 11969 (February 2, 1977), and shall be served upon Aminol, Natural, and PG&E. This order shall also be published in the Federal Register.

This order and authorization granted herein are subject to the continuing authority of the Administrator under Pub. L. 95-2 and the rules and regulations which may be issued thereunder.

RICHARD L. DUNHAM,
Administrator.

[Docket No. E77-121]

TUCO, INC., AND LLANO, INC.

Supplemental Emergency Order; Correction

In FR Doc. 77-17765, appearing on page 31611 in the issue of Wednesday, June 22, 1977, please change the word "Eddy" to "Lea," Line 5 in the second complete paragraph on page 31611 of the order issued June 15, 1977, in Docket No. E77-121, TUCO, Inc., and Llano, Inc. Please change the words "TUCO—Natural delivery point" to "delivery point on TUCO's line at Section 12, Township 18 South, Range 27 East, Eddy County, New Mexico" line 6 in the second complete paragraph on page 31611.

That sentence should read: "Llano will transport up to 10,000 Mcfd of the subject gas from TUCO's storage in Lea County, New Mexico, to the delivery point on TUCO's line at Section 12, Township 18 South, Range 27 East, Eddy County, New Mexico."

RICHARD L. DUNHAM,
Administrator.

[FR Doc.77-19162 Filed 7-7-77;8:45 am]

DEPARTMENT OF AGRICULTURE
Food Safety and Quality Service

EXPERT PANEL ON NITRITES AND NITROSAMINES

Meeting and Agenda

Notice is hereby given of a meeting of the Expert Panel on Nitrates and Nitrosamines to be held in Room 218A, Administration Building, Department of Agriculture, 12th and Independence Avenue SW., Washington, D.C., July 25, 1977, at 9:30 a.m. The meeting will reconvene in the same room on July 26 at a time announced during the July 25 session.

The agenda of the meeting is (1) consideration of carcinogenicity issue in relation to nitrates and nitrosamines, (2) final reports of Panel's subcommittees, (3) further discussions on recommendations relating to use of nitrite in cured meats, especially bacon, and residual nitrite allowances in such products, and (4) other business as appropriate.

The meeting will be open to the public and under the direction of the Panel Chairperson or her designee. Written statements may be filed with the Panel before or after the meeting. Any member of the public who has further questions should contact the Issuance Coordination Staff, Technical Services, Food Safety and Quality Service, U.S. Department of Agriculture, Room 4905, South Agriculture Building, Washington, D.C. 20250, Area Code 202-447-8188. Any person who wishes to file a statement may send such statement to the Issuance Coordination Staff at the above address.

Done at Washington, D.C., on July 5, 1977.

HARRY C. MUSSMAN,
Acting Administrator.
Food Safety and Quality Service.

[FR Doc.77-19519 Filed 7-7-77;8:45 am]

Rural Electrification Administration

ALLEGHENY ELECTRIC COOPERATIVE, INC.

Final Environmental Impact Statement

Notice is hereby given that the Rural Electrification Administration (REA) has adopted the generating plant portion of the associated 230 kV transmission portion of the 1975 Final Environmental Statement prepared by the Atomic Energy Commission (presently the Nuclear Regulatory Commission (NRC)) for the Susquehanna Steam Electric Station currently under construction by the Pennsylvania Power & Light Company in Salem Township, Luzerne County, Pennsylvania. These portions of NRC's statement adopted by REA, together with independent determinations made by REA, constitute REA's Final Environmental Impact Statement for the plant and the associated 230 kV facilities.

This action on the part of REA is in accordance with section 102(2) (C) of the National Environmental Policy Act and is in connection with the review of an application for a loan guarantee commitment from the Allegheny-Electric Cooperative, Inc., 212 Locust Street, Harrisburg, Pennsylvania 17101. The application is for the financing of a ten percent ownership interest by Allegheny Electric Cooperative, Inc., in the Susquehanna Steam Electric Station, Units No. 1 and No. 2, and for the financing of $230,361 of 500 kV transmission facilities also associated with the station.

Additional Information may be secured upon request, if submitted to Mr. Richard P. Richter, Assistant Administrator, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250. The REA Final Environmental Impact Statement on the plant and associated 230 kV facilities may be examined during regular business hours at the offices of REA in the South Agriculture Building, 12th Street and Independence Avenue SW., Washington, D.C., Room 4310, or at the borrower's address indicated above. Final REA action with respect to this matter, including any release of funds, may be taken after August 8, 1977.
Copies of the REA Final Environmental Impact Statement have been sent to various Federal, State, and local agencies, as outlined in the Council on Environmental Quality Guidelines. Any loan guarantee commitment which may be made pursuant to this matter will be subject to, and release of funds thereunder will be contingent upon, REA’s reaching satisfactory conclusions with respect to its environmental effects and compliance with the National Environmental Policy Act of 1969.

A separate Draft Environmental Impact Statement has been prepared by REA for all of the 500 kV transmission facilities associated with the Susquehanna Steam Electric Station.

Dated at Washington, D.C., this 1st day of July 1977.

DAVID A. HAMILL, 
Administrator, Rural Electrification Administration.

[FR Doc. 77-19156 Filed 7-7-77; 8:45 am]

ALLEGHENY ELECTRIC COOPERATIVE, INC.

Draft Environmental Impact Statement

Notice is hereby given that the Rural Electrification Administration (REA) has prepared a Draft Environmental Impact Statement for the 500 kV transmission facilities associated with the Susquehanna Steam Electric Station, Units No. 1 and No. 2, in accordance with section 102(2) (C) of the National Environmental Policy Act of 1969. This notice is given in connection with an application for a loan guarantee commitment from the Allegheny Electric Cooperative, Inc., 212 Locust Street, Harrisburg, Pennsylvania 17101, for the financing of a ten percent ownership interest by Allegheny Electric Cooperative, Inc., in the Susquehanna Steam Electric Station, Units No. 1 and No. 2, and for the financing of 42.3 miles of the 128 miles of 500 kV transmission facilities also associated with the station. The 500 kV transmission facilities are located in Luzerne, Lackawanna, Columbia, Montour, Northumberland, Snyder, Carbon, and Northampton Counties in Pennsylvania.

Additional information may be secured upon request, if submitted to Mr. Richard F. Richter, Assistant Administrator—Electric, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250. Comments are particularly invited from State and local agencies which are authorized to develop and enforce environmental standards and from Federal agencies having jurisdiction by law or special expertise with respect to any environmental impact involved from which comments have not been requested specifically. Comments concerning the environmental impact of the construction proposed should be addressed to Mr. Richter at the address given above and must be received by September 6, 1977.

Copies of the aforementioned REA Draft Environmental Impact Statement have been sent to various Federal, State, and local agencies, as outlined in the Council on Environmental Quality Guidelines. The Draft Environmental Impact Statement may be examined during regular business hours at the offices of REA in the REA Building, 12th Street and Independence Avenue SW., Washington, D.C., Room 4310, or at the borrower’s address indicated above.

Any loan guarantee commitment which may be made pursuant to this matter will be subject to, and release of funds thereunder will be contingent upon, REA’s reaching satisfactory conclusions with respect to its environmental effects and compliance with the National Environmental Policy Act of 1969.

Dated at Washington, D.C., this 1st day of July 1977.

DAVID A. HAMILL, 
Administrator, Rural Electrification Administration.

[FR Doc. 77-19157 Filed 7-7-77; 8:45 am]

COOPERATIVE POWER ASSOCIATION AND UNITED POWER ASSOCIATION

Negative Determination for Environmental Impact Statement

Notice is hereby given that the Rural Electrification Administration (REA) has made a negative determination on the need for an environmental impact statement by REA in connection with construction approval by the Rural Electrification Administration for Cooperative Power Association of Minnesota (Co-OPA) and United Power Association of Elk River, Minnesota (CPA-UPA), in the relocation of a 7.7-mile segment of the existing U.S. Bureau of Reclamation Garrison-Jamestown 230 kV Transmission Line in the vicinity of Underwood, North Dakota.

CPA-UPA have prepared an Environmental Report of the proposed action in which REA has had extensive input. The Environmental Report is in compliance with REA’s environmental guidelines and numerous commitments have been made by CPA-UPA to satisfy Federal, State, and local requirements.

Our independent evaluation of the proposed project leads us to conclude that REA’s financial assistance for this project does not represent a major Federal action that would significantly affect the quality of the human environment.

Based on REA’s independent evaluation, our review of the Environmental Report and REA experience with installations of this type and the subsequent environmental effects, a negative determination was made under section 5K of REA Bulletin 20-21.

Additional information may be secured on request, submitted to Mr. Richard F. Richter, Assistant Administrator—Electric, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250.

Final REA action with respect to this matter may be taken after fifteen (16) days, but only after REA has reached satisfactory conclusions with respect to its environmental effects and compliance with the National Environmental Policy Act of 1969.

Dated at Washington, D.C., this 29th day of June 1977.

JOSEPH VELLONE,
Acting Administrator, Rural Electrification Administration.

[FR Doc. 77-19176 Filed 7-7-77; 8:45 am]

CIVIL SERVICE COMMISSION

DEPARTMENT OF LABOR

Revocation of Authority To Make a Noncareer Executive Assignment

Under authority of § 9.20 of Civil Service Rule IX (5 CFR § 9.20), the Civil Service Commission revokes the authority of the Department of Labor to fill by noncareer executive assignment in the excepted service the position of Executive Assistant to the Secretary of Labor, Office of the Secretary.

UNITED STATES CIVIL SERVICE COMMISSION,
James C. Brey,
Executive Assistant to the Commissioners.

[FR Doc. 77-10562 Filed 7-7-77; 8:45 am]

DEPARTMENT OF COMMERCE

Economic Development Administration

ABE LEVINE KNITTING MILLS, INC.

Petition for a Determination of Eligibility To Apply for Trade Adjustment Assistance

A petition by Abe Levine Knitting Mills, Inc., 1329 Willoughby Avenue, Brooklyn, New York 11237, a producer of women’s knit outerwear, was accepted for filing on June 30, 1977, pursuant to section 251 of the Trade Act of 1974 (Pub. L. 93-618) and section 315.23 of the Adjustment Assistance Regulations for Firms and Communities (13 CFR part 315). Consequently, the United States Department of Commerce has initiated an investigation to determine whether increased imports into the United States of articles like or directly competitive with those produced by the firm contributed importantly to total or partial separation of the firm’s workers, or threat thereof, and to a decrease in sales or production of the petitioning firm.

Any party having a substantial interest in the proceedings may request a
NOTICES

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

35179

public hearing on the matter. A request for a hearing must be received by the Chief, Trade Act Certification Division, Economic Development Administration, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of the tenth calendar day following the publication of this notice.

JACK W. OSBURN, Jr., Chief, Trade Act Certification Division, Office of Planning and Program Support.

[FR Doc.77-19399 Filed 7-7-77; 8:45 am]

Economic Development Administration, Office of Planning and Program Support

ARDMORE FASHIONS, INC.

Petition for Determination of Eligibility To Apply for Trade Adjustment Assistance

A petition by Ardmor Fashions, Inc., 550 Sproul Street, Chester, Pennsylvania 19013, a producer of women's knit outerwear, was accepted for filing on July 1, 1977, pursuant to Section 202 of the Trade Act of 1974 (Pub. L. 93-418) and Section 315.23 of the Adjustment Assistance Regulations for Firms and Communities (CFR Part 315). Consequently, the United States Department of Commerce has initiated an investigation to determine whether increased imports into the United States of articles like or directly competitive with those produced by the firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of the petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by the Chief, Trade Act Certification Division, Economic Development Administration, U.S. Department of Commerce, Washington, D.C. 20230, no later than the close of business of the tenth calendar day following the publication of this notice.

JACK W. OSBURN, Jr., Chief, Trade Act Certification Division, Office of Planning and Program Support.

[FR Doc.77-19400 Filed 7-7-77; 8:45 am]

National Oceanic and Atmospheric Administration

PROPOSED ESTUARINE SANCTUARY, ROCKERY BAY, FLA.

Public Hearing on the Draft Environmental Impact Statement

Notice is hereby given that the Office of Coastal Zone Management, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, will hold a public hearing for the purpose of receiving comments on the draft environmental impact statement for the proposed estuarine sanctuary in Rockery Bay, Florida.

The public hearing will be held at the Collier County Courthouse (Building C), in the Board Room, East Tamiami Trail and Airport Road in Naples, Florida, at 7:30 p.m. to 10:30 p.m., on Tuesday, July 25, 1977.

The views of interested persons and organizations are solicited. These may be expressed orally or in written statements. Presentations will be scheduled on a first-come, first-served basis or as otherwise agreed upon. An opportunity to be heard will be given to those with written statements. Time will be available at the end of the meeting for persons without statements to present their views orally. The Office of Coastal Zone Management will allow any speaker following presentation of his/her statement. No verbatim transcript of the hearing will be maintained; but staff present will record the general thrust of the remarks.

Persons or organizations wishing to be heard on this matter should contact the Office of Coastal Zone Management as soon as possible so that an appearance schedule may be drawn up and definite terms established for presentations.

Please contact: June Condack, Office of Coastal Zone Management, 3200 Whitney Street NW., Washington, D.C. 20235; phone 202-634-2422.

Written comments may also be submitted by mail to the Office of Coastal Zone Management. Such comments should be received before August 8, 1977, to assure adequate consideration for inclusion in the final environmental impact statement.

Copies of the draft environmental impact statement may be obtained by contacting the Office of Coastal Zone Management at the above address.

The statement is also available for inspection by the public, both at the Office of Coastal Zone Management and at the following Collier County Free Public Library Branches: Naples, Everglades, Golden Gate, Immokalee, and Marco Island.

Comments may address the adequacy of the impact statement and/or the nature of the proposed sanctuary.

Following consideration of the comments received at this hearing, as well as written comments submitted, the Office of Coastal Zone Management will prepare the final environmental impact statement pursuant to the National Environmental Policy Act of 1969 and implementing guidelines.

Dated: June 29, 1977.

T. P. GLITZER, Assistant Administrator for Administration.

COUNCIL ON ENVIRONMENTAL QUALITY

ENVIRONMENTAL IMPACT STATEMENTS

Availability

The following is a list of environmental impact statements received by the Council on Environmental Quality from June 27 through July 1, 1977. The date of receipt for each statement is noted in the statement summary. Under Council Guidelines the minimum period for public review and comment on draft environmental impact statements is forty-five (45) days from this Federal Register notice of availability. (As of August 22, 1977.) The thirty (30) day period for each final statement begins on the day the statement is made available to the Council and to commenting parties.

Copies of individual statements are available for review from the originating agency. Back copies are also available at 10 cents per page from the Environmental Law Institute, 1346 Connecticut Avenue, Washington, D.C. 20036.

DEPARTMENT OF AGRICULTURE

Contact: Mr. Errett Deck, Coordinator, Environmental Quality Activities, U.S. Department of Agriculture, Room 101A, Washington, D.C. 20250; 202-445-4527...

FOREST SERVICE

Draft

Prairie Dogs, Nebraska National Forest, South Dakota, and Nebraska, June 30: Proposed is implementation of a management plan for prairie dogs on public lands in Nebraska National Forest system and Nebraska. Reductions in prairie dog colonies will be done with use of chemical and mechanical methods. Anticipated effects will be a reduction in habitat available for species associated with prairie dogs other than black-footed ferret. Anticipated effects will result due to the mix of user groups able to enter Little Kern. Comments made by: USDA. DOI. EPA. AHP. State and local agencies, and interested groups and persons. (ELQ Order No. 70607.)

Final

Little Kern Unit Plan, Sequoia National Forest, Tulare County, Calif., June 27: This statement proposes a land use plan for 111,763 acres within the Sequoia National Forest, Tulare County, California. The plan, when implemented, will replace the existing Multiple Use Plan for this area and direct the management of the National Forest land within this plan-management were considered for implementation. The selected alternative increases the area proposed for wilderness to 49,440 acres and reduces the trail mileage from 18,160 to 18,150. Some impacts will result due to the mix of user groups able to enter Little Kern. Comments made by: USDA. DOI. ESY. EPA. DOT. GOI. AHP. State and local agencies, and interested groups and persons. (ELQ Order No. 70561.)

Salmon River Wild and Scenic Rivers Pro- posal, Idaho, June 29: Proposed is the inclusion of 237 miles of the Salmon River in the National Wild and Scenic Rivers System. The segment under consideration runs from North Fork, Idaho, to its confluence with the Snake River through Nemerce, Lewis, Idaho, and Lemhi Counties, Idaho. The purpose of the action is to control the impacts of development and increased recreation use within the river corridor. There are approximately 5,521 acres of private lands involving 160 owners within the proposed boundaries. Comments made by: USDA. DOI. USA. HUD. DOC. DOT. EGA. FPC. WRC. State and local agencies, and concerned citizens. (ELQ Order No. 70612.)

Proposed Pere Marquette Wild and Scenic River, Lake, and Mason Counties, Mich., June 29: This proposed act would establish a Federal designee of 65.4 miles of the Pere Marquette River and 13,090 adjoining acres as
part of the National Wild and Scenic Rivers System. The action is intended to protect the natural resources of the area. Comments made by: DOI, USA, HUD, HFD, HPA, EPA, state and local agencies, and concerned citizens. (ELR Order No. 70804.)

**RURAL ELECTRIFICATION ADMINISTRATION**

Supplement

Reid Power Station (S-1), Kentucky, June 30: This statement supplements a final EIS filed with CEQ in April 1976. The proposed action is the authorization to construct the Reid Power Station, located near Marvin, Kentucky, on the South Fork of the Kentucky River. The project includes construction of a 1050 MW generating plant with 4 units of 262.5 MW each, a 125 MW solar power plant, and associated facilities. The project is designed to provide for the development of hydroelectric power for the area. Comments made by: EPA, USDA, HFD, DOE, DOE, EPA, state and local agencies, and concerned citizens. (ELR Order No. 70805.)

**SOIL CONSERVATION SERVICE**

**Final**

April Brook Watershed, Hartford County, Conn., July 1: Proposed is a watershed project for watershed protection and flood prevention located in the town of South Windsor, Connecticut. The plan encompasses an area of 25 square miles and proposes conservation land treatment supplemented by two floodwater retarding structures and floodproofing. Comments made by: USDA, HFD, DOI, DOE, EPA, state and local agencies, and concerned citizens. (ELR Order No. 70808.)

**DEPARTMENT OF DEFENSE, ARMY CORPS**

Contact: Dr. Grant Ash, Office of Environmental Policy Department, Attn: MWP, CWR-P, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 100 Independence Avenue, SW, Washington, D.C. 20314, 202-693-0793.

**Draft**

Upper White Oak Bayou, Harris County, Tex., June 27: The proposed action consists of constructing flood control improvements in Upper White Oak Bayou and its tributaries, Cole and Vogel Creeks, in Harris County, Texas. The project is intended to improve drainage by construction of 2 culverts along Cole Creek and 5 culverts along Vogel Creek. Comments made by: USDA, HFD, DOI, DOE, EPA, state and local agencies, and concerned citizens. (ELR Order No. 70811.)

**DEPARTMENT OF HUMAN SERVICES**

Contact: Mr. Richard H. Brown, Director, Office of Environmental Quality, Department of Health and Human Services, 550 7th Street, SW, Washington, D.C. 20210, 202-755-6308.

**Draft**

Cape Cod Canal, Bourne and Sandwich, O & M, Bourne County, Mass., June 28: Proposed is the maintenance and operation of the Cape Cod Canal, including intermittent dredging of the shipping basins and boat basins. In addition, the project includes maintenance and operation of a breakwater, a jetty, a railroad bridge, two highway bridges, three docks, maintenance and administration buildings, floating plant, electronic traffic control system, and service roads and recreation areas. This project would allow for continued safe navigation by commercial and recreational vessels. Permanent elimination of some benthic habitats is anticipated. (New England Division) Comments made by: DOI, EPA, AHP, HUD, HFD, state and local agencies, and concerned citizens. (ELR Order No. 70803.)

**NOTICES**

Bald Head Island Marina (permit), Brunswick County, N.C., July 1: Proposed is the authorization to construct the Bald Head Island Corporation for the construction of a boat marina and access facilities adjacent to the Bald Head River on Bald Head Island, North Carolina. The project includes the construction of a marina basin, service facilities, and access channel. The direct impacts associated with the discharge of effluents from the second unit, including the results of air quality modeling. (ELR Order No. 70804.)

**ENVIRONMENTAL PROTECTION AGENCY**


**Supplement**

W. Contra Costa Co, Wastewater Management (S-1), Contra Costa County, Calif., July 1: This statement supplements a final EIS filed with CEQ in January 1977. The project is proposed to provide treatment for wet weather inflow into the San Pablo Sanitary District treatment plant, rehabilitate or replace some treatment facilities and provide a sludge transport pipeline from the Richmond treatment plant to the SPSD and rehabilitation of two treatment facilities at the SPSPD. Construction impacts will result. (Region 9) (ELR Order No. 70810.)

**FEDERAL POWER COMMISSION**

Contact: Dr. Jack M. Heinemann, Acting Assistant Director for Environmental Quality, 225 North Capitol Street, NE, Washington, D.C. 20426, 202-275-4791.

**Draft**

Matagorda Bay Project, several counties in Texas, July 1: Proposed is the approval of applications filed by El Paso Eastern Co., El Paso LNG Terminal Co., El Paso Natural Gas Co., United LNG Co., and United Gas Pipe Line Co. These applications relate directly or indirectly to a proposal by El Paso Eastern Co. to import LNG from Algeria to a terminal to be located in the vicinity of Port La Fourche, La., on the Matagorda Bay. Approval would authorize construction and operation of facilities necessary to unload, store, regasify, and distribute the imported LNG. (ELR Order No. 70814.)

**DEPARTMENT OF HUMAN SERVICES**

Contact: Mr. Richard H. Brown, Director, Office of Environmental Quality, Department of Housing and Urban Development, 451 7th Street, SW, Washington, D.C. 20210, 202-755-6308.

**Draft**

Greengate Place and Birnam Wood, Harris County, Tex., June 27: The proposed action is acceptance of, for HUD/FHA home mortgage insurance purposes, some 723 acres of land (368-acre tract of Greengate Place and 355-acre tract of Birnam Wood) located in the northern part of Harris County, Texas. The development of the two tracts located within a mile of each other will be composed primarily of single family dwellings consisting of approximately 3000 units. Adverse effects are expected, as well as noise and air pollution. Comments made by: USDA, HFD, DOE, EPA, state and local agencies, and concerned citizens. (ELR Order No. 70804.)

**Indian Oaks Subdivision, Will County, Ill., June 27: Proposed is the approval of a mortgage insurance 241(d)(4) for 318 multi-family apartment units that comprise an intermediate stage of a planned unit development that already comprises 1400 units and will eventually total 2250 units. Few adverse effects are anticipated due to the fact that the natural environment has already been altered on the southern portion of the site, having been cleared years ago. The northern portion of the site is still wooded and will remain so even after development. Comments made by: DOI, FFC, DOT, USDA, state and local agencies, concerned citizens. (ELR Order No. 70795.)

**Memorial Parkway Subdivision, Harris County, Tex., June 30: The proposed action is the approval of mortgage insurance purposes of the 1,109-acre Memorial Parkway Subdivision located in Harris County, Texas. When completed, the subdivision will contain 3,842 single-family homes plus some attached single-family housing, and shopping and recreational facilities. Adverse Impacts will be removal of agricultural land from production and an increased demand for fossil fuels through heavy dependence on the automobile for transportation. Comments made by: DOT, USDA, EPA, state and local agencies, interested groups and persons. (ELR Order No. 70809.)

**Supplement**

West Side Housing (S-2), Denver County, Colo., June 29: This statement supplements a final EIS submitted to CEQ in January 1973. The proposed project, the West Side Housing, is a development that already comprises 1100 acres of medium-high density high-rise apartments for low-income and very-low-income families due to lack of funds. The addendum describes the present proposal which consists of acquisition of 11 acres for the annexation of 12 structures. Redvelopment plans include construction of 80 units of medium-density high-rise apartments and 90 units of medium-density garden apartments. (ELR Order No. 70802.)

The following are Community Development Block Grant statements prepared and circulated directly by applicants pursuant to section 104(h) of the 1974 Housing and Community Development Act. Copies may be obtained from the office of the appropriate local chief executive. (Copies are not available from HUD.)

**Section 104(h)**

**Draft**

Denver, Colo.—Sloan Lake Sanitary Sewer, Denver County, Colo., June 27: Proposed are plans for the existing Sloan Lake Sanitary Sewer System in Denver, Colorado. Plans call for the replacement of existing aged or damaged main sanitary sewer lines in the drainage basin. Construction-related impacts are expected, as well as socio-economic impacts due to increased population. (ELR Order No. 70602.)

High Point, N.C.—Big Ditch, North Carolina, June 27: Proposed are improve-
ments to Big Ditch stream in High Point, North Carolina. Corrective methods proposed for the Big Ditch include: (1) piping the stream from West Ward Avenue to West Ward Avenue; (2) retaining open flow but improving the stream channel for the same length of stream; or (3) a combination of piping and channel improvements. The action will result in increased erosion and stream sedimentation, removal of trees, and flooding of adjacent structures. (ELR Order No. 70764.)

Tarrant County, Tex.—County Water Project, June 27: Proposed is the adoption of a water project for Bedford, Euless, Collyville, Grapevine, and North Richland Hills in northeast Tarrant County, Texas. Plans call for the expansion of the existing plant, along with completion of the following items: raw water transmission line near Little Tonoloway Creek, Maryland, a distance of approximately 8.7 miles. Adverse impacts include the taking of wildlife management land, and the noise disruption of predominately tranquil surroundings. (Region 3.) Comments made by: AEP, EPA, DOI, USDOT, DOT, COE, state and local agencies, concerned citizens. (ELR Order No. 70767.)

Arkansas Nuclear One, Unit 2, Pope County, Ark., June 30: Proposed is the issuance of an operating license to the Arkansas Power and Light Company for the startup and operation of Arkansas Nuclear One, Unit 2, located on Lake Dardanelle, 2 miles southeast from the village of London and 6 miles northwest from the City of Bauxville, Arkansas. The unit will employ a pressurized-water reactor to produce up to 2,620 megawatts thermal. A steam-turbine-generator will use this heat to produce up to 950 megawatts electrical of electrical power capacity. The exhaust steam will be cooled by a closed-cycle cooling system using a natural-draft tower to dissipate waste heat to the atmosphere. Comments made by: USDA, COR, EPA, HEW, DOI, DOT, state and local agencies, concerned citizens. (ELR Order No. 70808.)

Final

Tarrant County, Tex.—County Water Project, June 27: Proposed is the adoption of a water project for Bedford, Euless, Collyville, Grapevine, and North Richland Hills in northeast Tarrant County, Texas. Plans call for the expansion of the existing plant, along with completion of the following items: raw water transmission line near Little Tonoloway Creek, Maryland, a distance of approximately 8.7 miles. Adverse impacts include the taking of wildlife management land, and the noise disruption of predominately tranquil surroundings. (Region 3.) Comments made by: AEP, EPA, DOI, USDOT, DOT, COE, state and local agencies, concerned citizens. (ELR Order No. 70767.)

Supplement

Appalachian Highway, North Georgia. Several states in North Carolina, July 1: Proposed is the extension of the Appalachian Highway in Forsyth, Cherokee, Fiddens, Gilmer, Fannin, Union, and Towns Counties in northeastern Georgia. The route would extend from S.R. 336 in Forsyth County approximately 100 miles generally in a northern direction along the Black Hawk Creek Greenbelt. Comments made by: AEP, EPA, DOI, USDOT, DOT, COE, state and local agencies, concerned citizens. (ELR Order No. 70815.)

Draft

Shalott Creek Bridge, Brunswick County, N.C., July 1: Proposed is issuance of a permit to construct a bridge across Shalott Creek, Brunswick Co., North Carolina. Plans call for construction of a fixed bridge approximately 90 feet in length and 15 feet in width to connect two parcels of property owned by the applicant. Adverse impacts will occur with respect to water quality, wetlands, wildlife, and vegetation. (ELR Order No. 70816.)

Final

West Bank Expressway, Jefferson Parish, La., July 1: Proposed is the upgrading of the existing West Bank Expressway in Jefferson Parish, Louisiana, to a 6-lane limited access expressway. The expressway route extends from U.S. Highway 90 on the west to Terry Parkway/General DeGaulle on the east, and follows the existing corridor which is 9.7 miles long with 20 feet of right-of-way. Adverse impacts include loss of 14 acres of swamp hardwoods for right-of-way purposes. Comments made by: DOI, AHP, USDOT, DLAB, DOT, COE, EPA, state and local agencies, interested groups and persons. (ELR Order No. 70817.)

Nicholas C. Yost,
Acting General Counsel.

[FR Doc.77-19477 Filed 7-7-77; 8:45 am]

DEPARTMENT OF DEFENSE

WINTER NAVIGATION BOARD ON GREAT LAKES-ST. LAWRENCE SEAWAY

Open Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of a meeting of the Winter Navigation Board to be held on 26 and 27 July 1977 in the Sheraton-Chicago Hotel at 505 N. Michigan Avenue in Chicago, Illinois. The meeting will be in session from 10:30 a.m. until approximately 4:30 p.m. on the 26th and from 8:30 a.m. until approximately 11:30 a.m. on the 27th.

The Winter Navigation Board is a multi-agency organization which includes representatives of Federal agencies and non-Federal public and private interests. It was established to direct the Great Lakes-St. Lawrence Seaway navigation season extension investigations and negotiations with Canada. Pursuant to Public Laws 91-611, 92-251, and 94-587.

The primary purpose of the meeting is to review efforts in preparation of Interim Feasibility Report No. 2. This report is to address requirements for a permanent, Federally funded year-round navigation program on the entire Great Lakes-St. Lawrence Seaway System. Efforts to be reviewed include those in the engineering, economic, environmental and social aspects of the winter navigation program. Other topics to be discussed include program direction and funding status, U.S.-Canadian coordination, and FY-77 activities.

The meeting will open to the public, subject to the following limitations:

a. As the seating capacity of the meeting room is limited, it is desired that advance notice or intent to attend be provided. This will assure adequate and appropriate arrangements for all attendants.

b. Written statements, to be made part of the minutes, may be submitted prior to, or up to 10 days following, the meeting, but oral participation by the public is limited because of the time schedule.

Inquiries may be addressed to Mr. David Westheuer, U.S. Army Engineer District, Detroit, Corps of Engineers, P.O. Box 1027, Detroit, Michigan 48231, telephone (313) 226-6770.


By Authority of The Secretary of The Army.

ROXIE D. SMITH,
Colonel, United States Army,
Director, Admin. Mgt., TAGCEN.

[FR Doc.77-19387 Filed 7-7-77; 8:45 am]

DEFENSE MAPPING AGENCY

PRIVACY ACT OF 1974

New System of Records

The Defense Mapping Agency systems of records notices as prescribed by the
NOTICES

Privacy Act of 1974 have been published in the Federal Register as follows:
FR Doc. 75-82707 (40 FR 23517) August 18, 1975.

Notice is hereby given that the Defense Mapping Agency submitted a proposed new record on July 27, 1976, pursuant to the Privacy Act of 1974 (Pub. L. 93-579, 5 U.S.C. 552a(o)). This OMB guidance was set forth in the Federal Register (40 FR 41677) on October 3, 1975.

The Defense Mapping Agency invites public comments concerning the proposed new record system. Interested persons are invited to submit written data views and arguments to Headquarters, Defense Mapping Agency, Attn.: Civilian Personnel Office, Building 56, Naval Observatory, Washington, D.C. 20305, or before August 10, 1977. The system will become effective, within 30 days (August 10, 1977), as proposed without further notice unless comments are received which result in a contrary determination.

B-0601-03 H0THASI
System name: Advanced Personnel Data System—Civilian (APDS-C).

System location:
Director, DMA Aerospace Center, Attn.: PO, St. Louis Air Force Station, Missouri 63113.
Director, DMA Hydrographic School, Attn.: PO, St. Louis Air Force Station, Missouri 63113.
Director, DMA Topographic Center, Attn.: 20000, 6500 Brooks Lane, Washington, D.C. 20315.
Director, Inter American Geodetic Survey, Attn.: SD, Drawer 894, Ft. Clayton, Canal Zone.

Categories of individuals covered by the system:
Current and former DMA civilian employees.

Categories of records in the system:
Civilians employed in the Department of Defense whose personnel data are processed by computer systems.

Civilian employment information including authorization for position, personnel data, suspense information; position control information; projected information and historical information; civilian education and training data; performance appraisal, ratings, evaluation of potential; civilian historical files covering job experience, training and transactions; civilian awards information; merit promotion plan work files; career programs files for such functional areas as procurement, logistics, civilian personnel, etc., civilian separation and retirement data for reports and to determine eligibility; adverse and disciplinary data for statistical analysis and employee assistance; stand-alone files, as for complaints, employee personnel files; extract files from which to produce statistical reports in hard copy, or for immediate access display on remote computer terminals; miscellaneous files.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

To provide automated system support to DMA officials at all levels from that part of the Civil Service Commission required personnel personnel and records throughout the system that pertains to evaluation, authorization and position control, position management, staffing, skills inventory, career management, training, retirement, employee services, rights and benefits, merit promotions, demotions, reductions in force, complaints resolution, labor management relations, and the suspending and processing of personnel actions; to provide for transmission of such records between employing activities within the Defense Mapping Agency; to provide reports to the Civil Service Commission; to provide reports of military reserve status and other pertinent information to officials of the armed services for contingency planning employment activities; to obtain statistical data on the work force to fulfill internal and external report requirements and to provide DMA offices with information needed to plan for and evaluate manpower, budget and personnel programs, to provide minority group designator codes to the U.S. Civil Service Commission's automated data file, to provide the Office of the Assistant Secretary of Defense, Manpower and Reserve Affairs, with data to assess the effectiveness of the program for employment of women in executive level positions; to provide data to DMA officials to facilitate the assessment of the DMA Affirmative Action Plan for minorities and women; to obtain listings of employees by function or area for locator and inventory purposes disclosed to officials of labor organizations recognized under Executive Order 11491, as amended, when relevant and necessary to their duties of exclusive representation concerning personnel policies and practices and matters affecting working conditions.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:
Maintained in visible file binders/cabinets.
Maintained in card files.
Maintained on computer magnetic tapes.
Maintained on disks or drums.
Maintained on computer paper printouts.
Maintained on microfiche.

Retrievability:
Filed by name.
Filed by Social Security Account Number (SSAN).
Filed by other identification number or system identifier.

The primary individual record identifier in APDS-C is SSAN.

There is the added capability of selecting an individual's record or certain preformatted information by SSAN on an immediate basis using a teletype or cathode ray tube display device.

Safeguards:
Records are accessed by custodian(s) of the record system.
Records are accessed by person(s) responsible for servicing the record system.
Records are accessed by authorized personnel who are properly screened and cleared for need-to-know.
Records are stored in secure file containers/cabinets.
Records are stored in safes.
Records are stored in secure vaults.
Records are stored in locked cabinets or rooms.
Records are protected by guards.
Records are controlled by computer system software.

Retention and disposal:
Analog output products are retained in office files until superseded, obsolete, no longer needed for reference, or inactivated. They are then destroyed by tearing into pieces, shredding, macerating, or burning. Data stored digitally within system is retained only for the period required to satisfy recurring processing requirements and/or historical requirements.

The Notification of Personnel Action, Standard Form 50, is disposed of as directed by the Civil Service Commission's instructions.

The record is maintained in the Defense Mapping Agency Automated System for Personnel Action—Civilian (APDS-C).

The primary Individual record identifier in APDS-C is SSAN.

There is the added capability of selecting an individual's record or certain preformatted information by SSAN on an immediate basis using a teletype or cathode ray tube display device.

Safeguards:
Records are accessed by custodian(s) of the record system.
Records are accessed by person(s) responsible for servicing the record system.
Records are accessed by authorized personnel who are properly screened and cleared for need-to-know.
Records are stored in secure file containers/cabinets.
Records are stored in safes.
Records are stored in secure vaults.
Records are stored in locked cabinets or rooms.
Records are protected by guards.
Records are controlled by computer system software.

Retrievability:
Filed by name.
Filed by Social Security Account Number (SSAN).
Filed by other identification number or system identifier.

The primary individual record identifier in APDS-C is SSAN.

There is the added capability of selecting an individual's record or certain preformatted information by SSAN on an immediate basis using a teletype or cathode ray tube display device.

Safeguards:
Records are accessed by custodian(s) of the record system.
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Records are accessed by authorized personnel who are properly screened and cleared for need-to-know.
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Retrievability:
Filed by name.
Filed by Social Security Account Number (SSAN).
Filed by other identification number or system identifier.

The primary individual record identifier in APDS-C is SSAN.

There is the added capability of selecting an individual's record or certain preformatted information by SSAN on an immediate basis using a teletype or cathode ray tube display device.
Notification procedure:
Information may be obtained from above.
Record access procedure:
Requests from individuals should be addressed to above.
Written requests for information should contain the full name of the individual, Social Security Number, current address and telephone number.
For personal visits, the individual should be able to furnish personal identification containing his/her full name, Social Security Number, physical description containing his/her full name, are related to the internal rules and practices of the Department of Defense.

Contesting record procedures:
The Agency rules for contesting contents and appealing initial determination may be obtained from System Manager.

Record source categories:
Digest of information from existing Personnel Files and management employees, source documents.

System Exempted from certain provisions of the Act:
None.

B. C. WIMBERLY,
Counsel, Defense Mapping Agency.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Office of the Assistant Secretary of Defense (Comptroller).


[FR Doc. 77-19483 Filed 7-7-77; 8:45 am]

Office of the Secretary
WAGE COMMITTEE

Closed Meetings
Pursuant to the provisions of section 10 of Pub. L. 92-463, the Federal Advisory Committee Act, effective January 5, 1973, notice is hereby given that a meeting of the Department of Defense Wage Committee will be held on Tuesday, September 6, 1977; Tuesday, September 13, 1977; Tuesday, September 20, 1977; and Tuesday, September 27, 1977, at 9:45 a.m. in Room 18301, The Pentagon, Washington, D.C.
The Committee's primary responsibility is to consider and submit recommendations to the Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics) concerning all matters involved in the development and authorization of wage schedules for Federal prevailing rate employees pursuant to Pub. L. 92-392. At this meeting, the Committee will consider wage survey specifications, wage survey data, local wage survey committee reports and recommendations, and wage schedules derived therefrom.

Under the provisions of section 10(d) of Pub. L. 92-463, the Federal Advisory Committee Act, meetings may be closed to the public when they are "concerned with matters listed in section 552b of Title 5, United States Code." Two of the matters so listed are those "related to the internal personnel rules and practices of an agency," (5 U.S.C. 552b.(c)(2)), and those involving "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (5 U.S.C. 552b.(c)(4)).

Accordingly, the Deputy Assistant Secretary of Defense (Civilian Personnel Policy) hereby determines that all portions of the meeting will be closed to the public because the matters considered are related to the internal rules and practices of the Department of Defense (5 U.S.C. 552b.(c)(2)) and the detailed wage data considered by the Committee during its meetings have been obtained from officials of private establishments with a guarantee that the data will be held in confidence (5 U.S.C. 552b.(4)).

However, members of the public who may wish to do so are invited to submit material in writing to the Chairman concerning matters believed to be deserving of the Committee's attention. Additional information concerning this meeting may be obtained by contacting the Chairman, Department of Defense Wage Committee, Room 3D281, The Pentagon, Washington, D.C.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Office of the Assistant Secretary of Defense (Comptroller).


[FR Doc. 77-19483 Filed 7-7-77; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[OFF-42016A; (FRL 758-2)]

ALKASK

Approval of State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides

Section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 975; 7 U.S.C. 136), requires that the contamination of the raw milk of livestock by chemical substances required by section 8(b) of the Toxic Substances Control Act (90 Stat. 2601 et seq.) on the establishment and records regulations of 40 CFR Part 171 require each State desiring to certify applicators to submit a plan for its certification program. Any State certification program will be maintained in accordance with the State plan approved under this section.

On May 9, 1977, notice was published in the Federal Register (42 FR 22534) of the intent of the Regional Administrator, EPA Region X, to approve, on a contingency basis, the Alaska Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides (Alaska State Plan). Contingent approval was requested by the State of Alaska pending promulgation of implementing regulations. Complete copies of the Alaska plan were made available for public inspection at the Alaska Department of Environmental Conservation, Juneau, Alaska; EPA Region X Office, Seattle, Washington; and the Office of Pesticide Programs, EPA, Washington, D.C.

It has been determined that the Alaska State Plan will satisfy the requirements of section 4(a)(2) of the amended FIFRA and of 40 CFR Part 171, if the regulations described in the plan, which are necessary for its implementation, are promulgated by the Alaska Department of Environmental Conservation. Accordingly, the Alaska plan is approved contingent upon promulgation of implementing regulations in accordance with and as prescribed in the State plan.

The contingent approval shall expire September 21, 1977 if these terms and conditions are not satisfied by that time. On or before the expiration of the period of contingent approval, a notice shall be published in the Federal Register concerning the extent to which these terms and conditions have been satisfied, and the approval status of the Alaska plan as a result thereof.

Effective date: Pursuant to section 4(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), the Agency finds that there is good cause for providing that the contingent approval granted herein to the Alaska plan shall be effective immediately. Neither the Alaska plan itself nor this Agency's contingent approval of the plan create any direct or immediate obligations on pesticide applicators or other persons in the State of Alaska. Delays in starting the work necessary to implement the plan, such as may be occasioned by providing some later effective date for this contingent approval, are inconsistent with the public interest. Accordingly, this contingent approval shall become effective immediately.

Dated: June 27, 1977.

L. ELLSWORTH COATES,
Acting Regional Administrator, U.S. Environmental Protection Agency, Region X.

[FR Doc. 77-19377 Filed 7-7-77; 8:45 am]

[OTS-081004A; FRL 758-5]

COMPUTER-READABLE CANDIDATE LIST

Availability
An April 23, 1977, the Environmental Protection Agency (EPA) announced (42 FR 21639) the availability of the candidate list of chemicals intended to aid in compilation of the initial inventory of chemical substances required by section 8(b) of the Toxic Substances Control Act (90 Stat 2601 et seq.). This notice detailed, in part, the procedures for obtaining a copy of the candidate list.

The EPA intended the computer tape to aid persons required to report a significant number of chemical substances for the initial inventory. Therefore, effective immediately, requests for magnetic tape copies of the candidate list will be honored only if, in addition to meeting the requirements set forth at 42 FR 21639-21640, the manufacturer anticipates reporting more than ten (10)
NOTICES

chemical substances under the inventory reporting regulations. The request must contain a certification to that effect, and be signed by a responsible representative of the requesting organization. The computer-readable version of the candidate list may be obtained by written request to: Computer List, OTS (TS-557), Attn: Kenneth Olsen, Environmental Protection Agency, Room 315, 401 M Street SW., Washington, D.C. 20460. For additional information you may call Mr. Olsen (202) 382-9819.

Dated: June 29, 1977.

KENNETH L. JOHNSON, Acting Assistant Administrator for Toxic Substances.

[F.R. Doc. 77-19223 Filed 7-7-77; 8:45 am]

[PP 5G1617/T120; FRL 756-6]

PESTICIDE PROGRAMS
Renewal of a Temporary Tolerance for O-Ethyl S,S-Diphenyl Phosphorodithioate

On May 24, 1976, the Environmental Protection Agency (EPA) announced (41 FR 21218) an extension of a temporary tolerance for residues of the fungicide O-ethyl S,S-diphenyl phosphorodithioate in or on the raw agricultural commodity rice grain at 0.1 part per million (ppm). This tolerance was established (40 FR 41834) in response to a pesticide petition (PP 5G1617) submitted by Mobay Chemical Corp., Chemagro Agricultural Div., P.O. Box 4913, Kansas City, Mo. 64120. This extension expired May 13, 1977.

Mobay Chemical Corp., Chemagro Agricultural Div., has requested a one-year renewal of this temporary tolerance both to permit continued testing to obtain additional data and to permit the marketing of the above raw agricultural commodity when treated in accordance with the provisions of an experimental use permit that is being renewed concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (85 Stat. 179; 7 U.S.C. 136 et seq.) and the regulations thereunder (40 CFR 162). Notice of receipt of this application is given in accordance with Section 3(c)(4) of FIFRA (40 CFR 162.2(b)(6)) and does not indicate a decision by this Agency on the application. Any Federal agency or other interested persons are invited to submit written comments on this application referred to in this notice to the FEDERAL REGISTER Section, Technical Services Division (WH-567), Office of Pesticide Programs, Room 315, East Tower, 401 M Street SW., Washington, D.C. 20460 (202-725-1851).

Dated: June 20, 1977.

DOUGLAS D. CAMPY, Acting Director, Registration Division.

[FR Doc. 77-19223 Filed 7-7-77; 8:45 am]

[OPP-31010; FRL 759-1]

REGISTRATION OF PESTICIDE PRODUCT ENTAINING A CHANGED USE PATTERN

Receipt of Application

Application to register a pesticide product entailing a changed use pattern has been made to the Environmental Protection Agency (EPA) pursuant to the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (85 Stat. 179; 7 U.S.C. 136 et seq.) and the regulations thereunder (40 CFR 162). Notice of receipt of this application is given in accordance with Section 3(c)(4) of FIFRA (40 CFR 162.2(b)(6)) and does not indicate a decision by this Agency on the application. Any Federal agency or other interested persons are invited to submit written comments on this application referred to in this notice to the FEDERAL REGISTER Section, Technical Services Division (WH-567), Office of Pesticide Programs, Environmental Protection Agency, Room 401, East Tower, 401 M St. SW, Washington DC 20460. Three copies of the comments should be submitted to facilitate the work of the Agency and others interested in inspecting them. The comments must be received on or before August 8, 1977, and should be notarized indicating the EPA File System number of the application to which the application to which the comments pertain. Comments received within the specified time period will be considered before a final decision is made with respect to the pending application: Comments received after the specified time period will be considered only to the extent possible without delaying processing of the application. Specific questions concerning the following application should be directed to the designated Product Manager (PM), Registration Division (WH-567), Office of Pesticide Programs, at the above address or by telephone (202) 226-2464.

Notice of approval or denial of this application to register the pesticide product listed will be announced in the Federal Register. The label furnished by each applicant as well as all written comments filed pursuant to this notice will be available for public inspection in the office of the Federal Register Section from 8:30 a.m. to 4 p.m. Monday through Friday.


DOUGLAS D. CAMPY, Acting Director, Registration Division.

APPLICATION RECEIVED

EPA File Symbol 21127-4, EM Laboratories Inc., Pesticides Div., 500 Executive Blvd., Elmsford NY 10523. FUNGINEX. Active Ingredients: Triforine (N-[(1,4-piperazinediyl)-N-(2,2,6,6-tetramethylpiperidinyl-1-carboxamide)] 18.2%. This application proposes a significant new use pattern, since the proposed use patterns entail an outdoor application, whereas this pesticide chemical is now registered only for use on roses in greenhouses. Application also proposes that the product be classified for restricted use. PM21

[FR Doc. 77-19276 Filed 7-7-77; 8:15 am]

[OPP-42034; FRL 760-1]

STATE OF CALIFORNIA

Submission of State Plan for Certification of Pesticide Applicators

In accordance with the provisions of Section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136 et seq.) and 40 CFR 171 (39 FR 24542 (October 9, 1974) and 40 FR 11658 (March 12, 1975)), the Governor of the State of California, has submitted to EPA a State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides to the Environmental Protection Agency (EPA) for approval on a contingency basis.

Contingency approval is being requested pending promulgation of additional regulations. Copies of pertinent laws, regulations, proposed regulations, and other related documents are attached to the plan.

Notice is hereby given of the intention of the Regional Administrator, EPA, Region IX to approve the plan on a contingency basis.

A summary of the plan follows. The entire plan, together with all attached appendices, may be examined during normal business hours at the following locations:

Department of Food and Agriculture, 1220 "N" Street, Room A170, Sacramento, CA 94815 (916) 425-2742.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
Legal authority for the certification program is contained in the following statutes and regulations: Food and Agricultural Code Divisions 1, 2, 6, & 7; California Administrative Code Title 3; and Structural Pest Control Act Sections 475-491; 8620, 8647.

The plan indicates that the State lead agency and cooperating agencies have sufficient qualified personnel and funds necessary to undertake the programs described in the State Plan. Certain EPA funds have been provided to the lead agency to support the certification program. In FY 1976-77 a grant of $325,000 was awarded to the Department of Food and Agriculture for this purpose. Additionally, the Cooperative Extension Services, University of California, has received funding to train and conduct private applicator training during FY 1976 and FY 1977.

The State lead agency will submit an annual report to EPA on or before March 15 of each year concerning the previous calendar year to include the information specified in 40 CFR 171.7.

The certification requirements for private and commercial applicators will be met by the restricted materials control system. All private and commercial applicators intending to possess or use restricted pesticides to comply with permit requirements, and by other pesticide regulatory activities.

PRIVATE APPLICATOR CERTIFICATION

Private applicators will be certified by completion of an oral interview between the County Agricultural Commissioner and the private applicator. The oral interview will cover the standards of competency as specified in 40 CFR 171.5 and 171.6. All other categories must meet the competency standards for certification in EPA Category 7 (Industrial, Institutional, Structural, and Health Related Pest Control). The license category covers fourteen specific pest control areas which are identified in the plan. Additionally, individuals who operate aircraft in the business of pest control must hold an agricultural pilot's certificate and an agricultural pest control operator's license. There are provisions for both apprentice and journeyman certification.

During 1976, the lead agency issued over 1,800 agricultural pest control operator licenses. In that same year, over 600 apprentice pilots and over 600 journeyman pilots were licensed by the Department.

PUBLIC HEALTH APPLICATORS

The Department of Health, Vector and Waste Management Control Section certifies local public health vector control personnel who use or supervise the use of chemicals or biological agents training. Certification programs meet or exceed the standards of competency for Category 8 (public health pest control). As of July 1976, 824 vector control technicians were certified in mosquito control and vertebrate vector control subcategories. Certification in the third subcategory "terrestrial vertebrate vector control" will be offered during 1977. The training program for the certified technician is comprehensive and designed to upgrade employees of local public health programs. A written certification examination covering the approved standards is included in the training course.

The certification examination includes a code section on general pesticide use, safety, laws and regulations, vector-disease relationships, and specialty sections on biology and control of the vectors in each of these three subcategories. Continued competence will be maintained by means of mandatory personnel training. Each certified technician certificate will expire two years after issuance. As a condition for renewal, the completion of a prescribed refresher training course is required prior to expiration. Each refresher course is six months following the date of expiration.

STRUCTURAL PEST CONTROL APPLICATORS

The Structural Pest Control Board, Department of Consumer Affairs, is responsible for the examination and licensing of structural pest control operators and field representatives. To obtain a license for either, a person must successfully pass written examinations which meet the competency standards for certification in EPA Category 7 (Industrial, Institutional, Structural, and Health Related Pest Control). The license categories utilized include: Operator Branch 1 (fumigation), Operator Branch 2 (general pest control), Operator Branch 3 (wood-destroying pests and organisms), Field Representative Branch 1 (fumigation), Field Representative Branch 2 (general pest control), and Field Representative Branch 3 (wood-destroying pests and organisms). Discussion of compliance with the lead agency's regulatory requirements and supervision of non-certified individuals is included in the Plan.
NOTICES

OTHER COMMERCIAL APPLICATORS

Commercial applicators not included in the previous categories will be certified by the Department of Food and Agriculture to use restricted use pesticides after passing a written examination to demonstrate the ability to conduct pest control operations safely and to demonstrate a knowledge of the principles and practices of pest control. The examinations will include all of the general standards and specific category standards applicable to the type(s) of pest control to be conducted with the exception of those relating to pest recognition in certain categories (Forest Pest Control, Seed Treatment, Aquatic Pest Control, and Right-of-way Pest Control) which is adequately regulated through the licensing of agricultural pest control advisors discussed elsewhere in the plan.

The commercial categories to be utilized, in addition to those licensing programs discussed previously, include: (1) Agricultural Pest Control, (2) Forest Pest Control, (3) Ornamental and Turf Pest Control, (4) Aquatic Pest Control, (5) Right-of-way Pest Control, (6) Industrial and Institutional Pest Control, and (7) Regulatory Pest Control.

The Demonstration and Research Pest Control category was deleted and the Agricultural Pest Control category was added in an amendment to the State Plan submitted April 28, 1977.

The applicant must successfully pass a written examination on each type of pest control to be conducted in addition to the basic core examination on laws, regulations, safety, and general practices. Examinations will consist of approximately 100 multiple choice questions. The minimum passing score is 70 percent for each examination. Training and study guides are available from the University of California, Cooperative Extension Service for the specific applicator certification categories. In addition, each applicant will be sent a study guide on California's pest control laws and regulations plus information on sources of other appropriate materials. A certificate will be issued to each certified commercial applicator by an embossed plastic card similar to a common credit card. Each certificate will be valid indefinitely unless suspended or revoked by the Director, Department of Food and Agriculture. It is estimated that there will be between 3,000 to 20,000 applicants in this group, the size of this group being dependent on the final list of restricted use pesticides by EPA.

Provisions for suspension or non-certified applicators are discussed in the plan. There are no provisions in the plan for the certification of applicators who do not read English.

The Plan indicates that applicators employed by Federal agencies and applicators on Indian reservations will be required to comply with the same contamination standards and restricted materials permit requirements that pertain to other commercial applicators who possess or apply restricted materials.

The Plan also indicates that reciprocity agreements are not in place at the present time. As certification programs are established in neighboring states, it will be possible to determine if reciprocity agreements can be established.

Other regulatory program activities described in the California State Plan to maintain and supplement the certification program include the following:

1. Pesticide product registration,
2. Experimental use permits,
3. Pesticide product quality control,
4. Restricted materials,
5. Agricultural pest control advisor licensing,
6. Pesticide dealer licensing,
7. Pesticide worker safety regulations,
8. Storage, handling, transportation, and disposal of pesticides and used containers regulations,

Each of these programs is discussed in the plan.

Maintenance of the State Plan will be insured by provisions that private and commercial applicants will comply with the standards for use of restricted materials, including those pertaining to supervision of noncertified applicators, and through the enforcement of various measures detailed in the State Plan. An enforcement staff of over 700 lead agents and county agricultural personnel will, on a statewide basis, continue to maintain alictor competence through frequent direct contact and observation of pesticide applications.

Private and commercial applicants, on the basis of changing technology, will routinely be given various refresher courses, technical information, and specialized training as necessary to insure continued training of competency through coordinated programs carried out by the University of California, Department of Food and Agriculture, County Agricultural Commissioners, and other cooperating agencies.

PUBLIC COMMENTS

Interested persons are invited to submit written comments on the proposed Plan for the State of California to the Office of Pesticide Programs, Air and Hazardous Materials Division, Region IX, Environmental Protection Agency, Room 360, 100 California Street, San Francisco, California 94111. The comments must be received on or before August 5, 1977, and should bear the identification notation (OPP-42047). All written comments filed pursuant to this notice will be available for public inspection at the above mentioned location from 8:30 a.m. to 4 p.m. Monday through Friday.

Dated: June 24, 1977.

PAUL DE FALCO, JR.,
Regional Administrator,
Region IX.

[FDB 77-13157 Filed 7-7-77; 8:45 am]

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

Establishment of Temporary Tolerances

Elanco Products Co., Div. of Eli Lilly and Co., P.O. Box 1750, Indianapolis, Ind. 46206, has submitted a pesticide petition (FPP 61680 to the Environmental Protection Agency (EPA). This petition requests that temporary tolerances be established for residues of the herbicide tebuthiuron (N-(1,3-dimethylurea) -1,2-thilindazole-2-yl)N' -dimethylurea and its metabolites in or on the raw agricultural commodities grasses (pasture and rangeland) and grass hay at 20 parts per million (ppm); in kidney and liver of cattle and sheep at 2 ppm; in milk at 0.3 ppm and in the meat, fat, and meat byproducts (except kidney and liver) of cattle, goats, horses and sheep at 0.5 ppm.

Establishment of these temporary tolerances will permit the marketing of the above raw agricultural commodities when treated in accordance with the experimental use permit that has been issued under the Federal Insecticide, Rodenticide Act, as amended (85 Stat. 973, 69 Stat. 751; 1 U.S.C. 135(a) et seq.). An evaluation of the scientific data reported and other information showed that the requested tolerances were adequate to cover residues resulting from the proposed experimental use, and it was determined that the temporary tolerances would protect the public health. The temporary tolerances have been established for the pesticide, therefore, with the following provisions:

1. The total amount of the pesticide to be used must not exceed the amount authorized by the experimental use permit.
2. Elanco Products Co. must immediately notify the EPA of any findings from the experimental use that have any bearing on safety. The firm must also keep records of production, distribution and performance and on request make the records available to any authorized officer or employee of the EPA or Food and Drug Administration.

These temporary tolerances expire June 15, 1978. Residues not in excess of these temporary tolerances remaining in or on the raw agricultural commodities after expiration of these tolerances will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and temporary tolerances. These temporary tolerances may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicates such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to the Special Registrations Section, Registration Division (WH-567), Office of Pesticide Programs, Rm. 315, East Tower, 401 M Street SW, Washington, D.C. 20460 (202-765-4651).
NOTICES

FEDERAL ENERGY ADMINISTRATION

PETROLEUM COMPANY FINANCIAL REPORTING SYSTEM

AGENCY: Federal Energy Administration (FEA).

ACTION: Notice of public panel to discuss the petroleum company financial reporting system.

SUMMARY: The Federal Energy Administration requires financial information regarding petroleum company operations to fulfill its responsibility to formulate energy policy. FEA proposes to implement a Financial Reporting System that will collect detailed information about the financial results for these companies. The proposed reporting form will be a modified version of a previous proposal which was changed and expanded to take account of new data requirements and the receipt of public comments. The public comments were received as part of a public comment period which was announced in 40 FR 43612, dated September 22, 1975. The new requirements implement a part of the National Energy Plan. The public panel discussion announced in this notice provides interested parties the opportunity to offer comments which will help guide FEA's development of this reporting program. Certain topics are highlighted for specific comment.

DATES: Comments by August 3, 1977, 4:30 p.m. Requests to speak by July 22, 1977. Panel date: July 29, 1977, 9 a.m. to 5 p.m.

ADDRESSES: Written comments and requests to participate to David T. Huett, Deputy Assistant Administrator, Data and Analysis, Federal Energy Administration, 12th and Pennsylvania Avenue NW., Room 4420, Washington, D.C. 20461, telephone 202-585-6118.

Panel discussion location: Conference Room B, Departmental Auditorium, Old Labor Department Building, Constitution Avenue between 12th and 14th Streets NW., Washington, D.C. 20461.

Copies of the transcript of the meeting may be purchased from the reporter.

FOR FURTHER INFORMATION CONTACT:


William D. Luck, Office of General Counsel, 12th and Pennsylvania Avenue NW., Room 6144, Washington, D.C. 20461 (202-585-9295).

SUPPLEMENTARY INFORMATION:


II. Objectives of FRS.

III. Previously Published Version of FRS.

IV. Implementation Scheme.

V. Comments Invited, Particularly on Certain Issues.

VI. Panel Discussion Procedures.

Notice is hereby given that the issues related to the development and implementation of the FEA Petroleum Company Financial Reporting System (FRS) will be the topic of a panel discussion to be held on July 29, 1977, from 9 a.m. to 5 p.m. in Conference Room B, Departmental Auditorium, Old Labor Department Building, Constitution Avenue between 12th and 14th Streets NW., Washington, D.C.

I. LEGISLATIVE MANDATE FOR FRS

The Financial Reporting System (FRS) is designed to provide energy information from the petroleum industry to meet two areas of responsibility of the Administrator of the Federal Energy Administration (FEA).

The first of these areas is to assist the Administrator in fulfilling certain of his responsibilities under the FEA Act of 1974, Public Law 93-275, as amended. Pursuant to Section 13 of the FEA Act, the Administrator is required to "collect, assemble, evaluate, and analyze energy information by categorical groupings, established by the Administrator, of sufficient comprehensiveness and particularity to permit fully informed monitoring and policy guidance with respect to the exercise of his functions under this Act." Section 5(v) (5) of the FEA Act further states that the Administrator shall "promote stability in energy prices to the consumer, prevent free and open competition in all aspects of the energy field, prevent unreasonable profits within the various segments of the energy industry, and promote free enterprise." Finally, Section 13(a) of the FEA Act states that "the Administrator shall . . . ensure that the potential economic impacts of proposed regulatory and other actions . . . are evaluated . . . ."

The second area of responsibility which is addressed by FRS is the requirement of Title V, Section 503 of the Energy Policy and Conservation Act (EPCA), Public Law 94-163, as amended, which amends Section 11(e) of the Energy Supply and Environmental Coordination Act of 1974 (ESCA), Public Law 93-319, as amended, to require that the Administrator file quarterly reports with the President and the Congress presenting energy information as specified in Section 506(c) of EPCA. Such quarterly reports are to be made by the Administrator for each calendar quarter which begins 6 months after the date on which the accounting practices became effective pursuant to Title V, Section 503 of EPCA are made effective. Title V, Section 503 of EPCA provides: (1) for the development by the Securities and Exchange Commission, relying on the Financial Accounting Standards Board and in consultation with the FEA, the General Accounting Office and the Federal Power Commission, of accounting practices to be followed in the preparation of accounts by persons engaged in the production of crude oil or natural gas in the United States; (2) that the standards developed, to the greatest extent practicable, permit the compilation, treating domestic and foreign operations as separate categories, of an energy data base consisting of (a) the cost of capital, revenue, and operating cost information pertaining to prospecting, acquisition, exploration, development, and production; (b) the full cost of production of the operation; (c) the accounting treatment of persons engaged in the production of crude oil or natural gas; and (c) such other information, projections, and relationships of collected data as shall be necessary to facilitate the compilation of such data base.

With respect to the scope of energy information which may be collected by FRS, Section 11(e) of EPCA defines "energy information" as including "(A) all information in whatever form on (1) fuel reserves, exploration, extraction, and energy resources (including petrochemical feedstocks) wherever located; (2) production, distribution, and consumption of energy and fuels wherever carried on; and (B) matters relating to energy and fuels, such as corporate structure and proprietary relationships, costs, prices, capital investment, and assets, and other matters directly related thereto, wherever they exist.

Although the subject of this notice is the annual reporting system, quarterly reporting will be compatible with the exploration, development and production sections of the annual FRS.

II. OBJECTIVES OF FRS

The information collected by FRS will enable more informed deliberation as to possible governmental actions with regard to the petroleum industry. FRS information will assist in analysis of the following areas:

(1) What are the revenues, costs, and profits being realized in the different segments of the petroleum industry: Foreign and domestic operations? Production, refining, and marketing? What are the relationships between costs and sales prices?

(2) What is the degree of influence or control exercised by single companies or groups of companies within the context of ownership of reserves, control of pro-
dution and access to foreign sources of oil and of other fuels?

3) Horizontal and vertical integration. Oil companies using funds generated from their sales in the domestic market to finance projects in foreign countries. The competition in the domestic market is reduced by the horizontal integration of the companies (vertical integration is discussed below). The foreign projects may increase the companies' share of the world market, the company's share of a particular region, or its share of a particular product.

III. PREVIOUSLY PUBLISHED VERSION OF FRS

A proposed version of the FRS form and an October 14, 1975, public hearing concerning that proposed form have been the subject of a previous notice (40 FRS 4361, September 22, 1975). The present version of the FRS form responds to many of the comments made at that previous public hearing and to comments received by mail. Specific comments regarding additional data requirements that correspond to many of the comments made on the proposed form were offered at the public hearing and to comments received by mail. Specific comments regarding the burden of preparing the form were also made. The final version of the FRS form will have reached nearly final form. A 30-day pretest will then be conducted, involving approximately 8 firms; the pretest will examine in detail the form and especially those parts of FRS which have changed since the earliest version of the form. The pretest is scheduled to be completed at the end of September 1977 at which time a final version of the form will be prepared for submission to the General Accounting Office (GAO) for clearance.

V. COMMENTS INVITED, PARTICULARLY IN CERTAIN ISSUES

The July 29, 1977, public panel discussion is for the purpose of discussing any issues not previously identified by the FEA staff upon which comment is especially desired.

1. Confidential Information. Some of the information requested on this form may be considered confidential information, because its release would be deemed to cause substantial competitive harm to the companies. If it is believed that any information required by the form is covered by the exemption to the Freedom of Information Act concerning trade secrets and confidential or privileged information obtained from a person and privileged or confidential (5 U.S.C. 552(b)(4)), please provide comment. Such comment should include: (1) a description of the item, (2) an explanation of the competitive injury to the submitting party which would result from public disclosure, (3) an indication whether and why such items of information are customarily treated as confidential within the industry, and (4) an indication when such information might become nonconfidential due to the passage of time. FEA retains the right to make its own determination with regard to any claim of confidentiality.

2. Reporting of financial information, by separate refining and marketing business segments. The proposed modification of the earlier form is the requirement to report the refining and marketing functions of integrated companies as separate business segments. FEA has identified that the return on investment achieved by each segment is desired. FEA recognizes that many companies may never have accounted for their operations in this fashion and therefore may encounter difficulty in implementing this aspect of the form. FEA is seeking comment and information with a view towards refining the instructions and further ascertaining the feasibility of reporting by segment. In particular, there are two aspects of this problem upon which comment is especially desired.

The first area concerns the establishment of revenues for inter-segment sales. In principle this may be done by establishing transfer prices based upon (1) sales of the same quantity of the same product to third parties by the same company in the same locality in the same time period, etc., (2) effecting some compromise with regard to the aforementioned variables, such as using prices from sales at a different geographic location, etc., or (3) calculating a price based upon some preset return on investment for the assets involved in the operation. FEA invites comment on the availability of comparable third party prices for products which would be suitable for the calculation of inter-segment sales and the availability or suitability of alternative methods for establishing transfer prices. Of particular interest would be detailed descriptions of circumstances in which the establishment of a product's transfer price would be difficult, including suggested solutions to the problem.
The implementation of the new financial accounting standards may distort the comparability between currently filed FRS forms, and those filed after the implementation of new standards. Accordingly, FEA proposes to require the future amendment of information filed for previous years to conform to any new accounting practices. FEA seeks comment on this issue.

5. Exploration, development, and production expenditures. FEA invites comment on its plan to collect information about historical expenditures for exploration, development and production of oil and gas, and the additions to oil and gas reserves. These data would cover the years 1962-1971.

6. Burden. Comment is desired concerning the amount of burden which is anticipated to complete each schedule of the form and ways to reduce such burden. Comment should also include information as to whether there is (1) data already supplied to the Federal Government which would be duplicated by the form, or (2) publicly available data which could accomplish the objectives of the form. Data required by the form is which either unavailable or which would require an extraordinary effort to gather.

7. Simplified forms for small companies. The proposed report may represent a substantial burden for small companies. FEA requests specific comments on ways to simplify the form for these companies, without losing essential data.

VI. PANEL DISCUSSION PROCEDURES

The purpose of the panel discussion is to assist the FEA in its decision-making relating to the implementation of the FRS. Members of the public who wish to participate in the panel discussion should inform David T. Hulett, Deputy Assistant Administrator, Data and Analysis, FEA, 12th and Pennsylvania Avenue NW., Room 4426, Washington, D.C. 20460, Phone 202-565-8618, at least 7 days prior to the meeting. Prepared written comments will also be included as part of the public record. Prepared oral presentations will be limited to 5 minutes for each interested party. Written comments may be submitted either before or within 30 days after the meeting.

Copies of the proposed form, Copies of an information package and draft FRS forms may be obtained by calling or writing to FRS Project Office, Room 4420, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461 (202-565-7869).

Transcripts. Approximately two weeks after the panel discussion, the transcript of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room 2107, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C. between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Any person may purchase a copy of the transcript from the reporter.

Issued at Washington, D.C., on July 1, 1977.

Eric J. Fyvol, Acting General Counsel, Federal Energy Administration.

[FIR Doc. 77-19370 Filed 7-7-77, 8:45 a.m]
Certificate No. Owner/Operator and Vessels

09351. Southern Shipbuilding Corp.: Southern Maru No. 174.
07711. AB Vasa Shipping OY: Michael C., N. 23.
08063. Meth Shipping Co. Ltd.: Mountpark.
09717. Kanel Bussan:
12629. Reuniport Co., Ltd.: Vortex Breeze.
12623. Compania Internacional de Pesca:
12630. Compania Internacional de Pesca:
10892. Compania Internacional de Pesca:
10941. Compania Internacional de Pesca:
12667. Compania Internacional de Pesca:
10954. Compania Internacional de Pesca:
10263. Compania Internacional de Pesca:
10088. Compania Internacional de Pesca:
11410. Salen Offshore Drilling Co.:
10831. Salen Offshore Drilling Co.:
12689. Salen Offshore Drilling Co.:
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the statement shall set forth with par-

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of agreement filed by:
Howard A. Levy, Esquire, Suite 727, 17 Bat-

Agreement No. 10501, among the North

fuel expenses which were incurred

go to Kingsport in Docket No. 7Q0, as

In Public Service Company of New

This documentation is a systematic

Kingsport Power Com-

September 21, 1976. APCO
did not change its one-month lag
during the period from September 21, 1976
to October 21, 1976, the first month that
the revised clause became effective.

APCO charged its customers for fuel
under the filed revised clause (with its
updated base fuel costs) for that month.
It now claims that it is entitled to re-
cover revenues for that month under
the old clause's base fuel cost (subtracting
the recovery already received) due to the
one month lag provision in its old clause.

APCO's proposed surcharge is no exception.

As the Commission, stated in the VEFCO case:

It is clear that the Commission never con-
templated that fuel adjustment clauses
should guarantee penny for penny recovery. Although these clauses are designed to re-

A copy of any such statement should also be forwarded to the party filing the agreement (as indicated hereinafter) and the statement should indicate that this has been done.

Notice of agreement filed by:
Howard A. Levy, Esquire, Suite 727, 17 Bat-
ttery Place, New York, New York 10006.

Agreement No. 10501, among the North
Atlantic Westbound Freight Association, Continental North Atlantic Westbound
Freight Conference, Scandinavia Baltic/U.S. North Atlantic Westbound Freight
Conference and South Atlantic North
Europe Rate Agreement, sets forth the
agreement of the member conferences
for the establishment and maintenance
of joint administrative facilities and staff.

DATED: July 5, 1977.

By order of the Federal Maritime
Commission.

[FR Doc.77-19491 Filed 7-7-77;8:45 am]

[FR Doc.77-19450 Filed 7-7-77;8:45 am]

FEDERAL POWER COMMISSION
APPELLACHIAN POWER CO.
Order Rejecting Filing of Proposed Fuel Adjustment Clause Surcharge

On June 7, 1977, Appalachian Power Company (APCO) tendered for filing a
Supplement to its FPC Rate Schedule No. 22, service to Kingsport Power Com-
pany, an affiliate of APCO. The supple-
ment would impose a surcharge of 0.33
mills/kWh on all energy billed to Kings-
port for a 24 month period. APCO claims
that the surcharge is designed to recover
fuel expenses which were incurred by the
Company but which it alleges be-

Public notice of the filing was issued
on June 16, 1977, with protests or peti-
tions due on or before June 29, 1977. No
protests or petitions were filed at the
time of this writing.

APCO's revised fuel clause was sub-
mitted as part of its rate increase filing
to Kingsport in Docket No. ER76-789. It
was accepted by the Commission, sus-
pended, and given an effective date of
September 21, 1976. APCO has request-
ed waiver of the Commission's notice re-
quirements so that the surcharge can be
become effective as of that date.

The alleged revenue deficiency that
APCO proposes to recover involves the
difference in the base cost of fuel be-
tween the old and the revised clauses

1APCO did not change its one-month lag
billing provision but did update the base
fuel cost level substantially in the revised
clause.

FE INITIES, Vol. 42, No. 131—FIFDAY, JULY 8, 1977

NOTICES

Kenneth F. Plumb,
Secretary. 
[FR Doc.77-19450 Filed 7-7-77;8:45 am]

[FR Doc.77-19491 Filed 7-7-77;8:45 am]

INTERSTATE POWER CO.
Application

Take notice that on June 2, 1977, the Interstate Power Company (Applicant)
filed an application with the Commission, pursuant to Section 206 of the Act,
seeking authorization to extend the latest

Applicant is incorporated under the
laws of the State of Delaware, with its
principal business office at Dubuque,
Iowa and is engaged in the electric util-

The net proceeds to be derived from
the notes will be used to provide addi-
tional funds for Applicant's construc-
tion program and to maintain cash
working funds at normal levels.

Any person desiring to be heard or to
make any protest with reference to said
application should, on or before, July 15,
1977, file with the Federal Power Com-
mission, Washington, D.C. 20426, peti-
tions or protests in accordance with the
requirements of the Commission's Rules
of Practice and Procedure (18 CFR 1.8,
1.10). All protests filed with the Commis-
sion will be considered by it in deter-
ing the appropriate action to be taken
but will not serve to make the protestants
parties to the proceeding. Persons wish-
ing to become parties to a proceeding
or to participate as a party in any hearing
therein must file petitions to intervene
in accordance with the Commission's Rules.
The application is on file and available for public inspection.

Kenneth F. Plumb,
Secretary. 
[FR Doc.77-19454 Filed 7-7-77;8:45 am]
NOTICES

MONTANA-DAKOTA UTILITIES CO.

Order Approving Rate Increases and Modification of Tariff PGA Clause


On April 28, 1977, Montana-Dakota Utilities Co. (Montana-Dakota) tendered for filing 1 a proposed rate increase of $269,392 annually for jurisdictional natural gas sales and services. The increase is provided for to offset the unpredictable and widely fluctuating volume of sales to Northern Gas and the recovery of such costs by means of a lump sum charge. The proposed modification appears reasonable in view of the unpredictable and widely fluctuating volume of sales to Northern Gas and accordingly be approved.

Montana-Dakota's proposed increased rates are based on a total cost of service of $60,900,462, representing actual experience for the 12 months ended December 31, 1976, as adjusted, including a rate of return of 9.38 percent and a return on common equity of 13 percent.

Montana-Dakota submitted statements I, J, and K pursuant to Section 154.63 of the Commission's regulations and requests waiver of the regulations so as not to be required to file statements A through K and P. In view of the relatively small amount of additional time and expense which would be required to prepare the additional statements, and the fact that the statements submitted are fully adequate for purposes of the Commission's review and determination, the Commission finds that good cause exists to grant the requested waiver.

Montana-Dakota requests the Commission to approve a modification of its PGA clause to provide for separate calculation of unrecovered purchased gas costs applicable to its sales to Northern Gas and the recovery of such costs by means of a lump sum charge. The proposed modification appears reasonable in view of the unpredictable and widely fluctuating volume of sales to Northern Gas and accordingly be approved.

Public notice of Montana-Dakota's filing herein was issued on May 6, 1977, providing for protests or petitions to intervene to be filed on or before May 25, 1977. No protests or petitions to intervene have been received. However, Montana-Dakota's three jurisdictional customers 2 have entered into written agreements stating their intention not to intervene or otherwise object to Montana-Dakota's proposals. These agreements have been filed with the Commission.

Based upon a review of Montana-Dakota's rate increase application, the Commission finds that the proposed rates have been shown to be just and reasonable and should therefore be approved, as hereinafter ordered.

The Commission orders: (A) Montana-Dakota's rate increase and PGA modification herein approved on April 28, 1977, are accepted for filing and approved, effective July 1, 1977.

(B) Waiver of Section 154.63 of the Commission's regulations with respect to statements A through K and P is granted.

(C) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. FLUMBE, Secretary.

[FR Doc. 77-19453 Filed 7-7-77; 8:45 am]

[Docket No. CP77-449]

NATURAL GAS PIPELINE CO. OF AMERICA

Application and Request for Phased Proceeding


"Take notice that on June 28, 1977, Natural Gas Pipeline Company of America (Applicant), 122 South Michigan Avenue, Chicago, Illinois 60603, filed in Docket No. CP77-449 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation 27.6 miles of 30-inch pipeline and appurtenant facilities from a site near Ingleside, Texas in San Patricio County (Gulf Coast LNG Termination) 3 to a point of interconnection with Applicant's existing main transmission system located near Sinton, Texas in San Patricio County in order to connect vaporized liquefied natural gas (LNG) into its system, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant seeks authorization from the Commission in a two-phase proceeding. In Phase I of such proceeding, Applicant requests that the Commission evaluate the environmental and safety aspects of the proposed facilities and issue a preliminary opinion with respect thereto. In Phase II of the proceeding in this docket, Applicant indicates that it would file additional information necessary for the Commission to evaluate and issue an order authorizing the construction and operation of the particular facilities.

Applicant indicates that in an attempt to alleviate its critical gas supply shortage, it is exploring all reasonable avenues, both traditional and non-traditional, to offset its declining supplies. Applicant states that it is currently negotiating for the purchase of LNG for several sources.

Applicant's affiliate, NGP-LNG, Inc., covers the proposed pipeline and is incorporated herein by reference. Applicant indicates that it anticipates no significant amount of environmental and safety data would be submitted in Phase II.

Applicant states that the estimated cost of the facilities proposed to be constructed and operated in this proceeding is $23,864,000.

Any person desiring to be heard or to make any protest with reference to said application shall file, on or before June 28, 1977, with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.10 and 1.12) 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 procedure to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice prior to the Commission on this application if no petition to intervene is filed within the time required herein. If the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity, if a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required,
Applicant states that the facilities at the proposed Gulf Coast LNG Terminal would be capable of receiving LNG tankers as large as 155,000 cubic meter capacity, transporting foreign sources of supply and that the tankers would enter the Corpus Christi Ship Channel through the Aransas Pass jetty and proceed to a position at the tanker berth. It is indicated that the terminal facilities would consist of (1) a marine transport berth, (2) a system that would transfer the LNG, (3) a storage system for the LNG including three storage tanks with a total storage capacity of 1.65 million barrels of LNG, (4) a system which would convert the LNG into gaseous form for transmission, (5) ancillary support systems and (6) a 0.9 mile of pipeline to transport the vaporized LNG to Natural's proposed 27.5 mile pipeline.

It is stated that all facilities which handle LNG would be constructed of cryogenic materials. It is further stated that On-board ship unloading pumps would pump LNG into the ship's piping headers which provide ship-to-shore tie-ins on a pipe which would carry the LNG to one of the storage tanks, and each tank would be approximately 230 feet in diameter and 130 feet in height and would be capable of receiving 55,000 barrels of LNG. It is said, that it is designed the fill rate for each tank would be 78,000 barrels per hour. Applicant states that the terminal storage system would be capable of handling all the process needs of the LNG during the containment operation. The storage system LNG pumps would supply LNG to the vaporizer system during deliveries, it is further stated that the vaporizer system would receive LNG at pipeline pressure and vaporize the LNG for pipeline transmission.

Applicant indicates that the proposed facilities will be located on a 378-acre tract of undeveloped industrial property on the lower central Gulf Coast, adjacent to the north shore of Corpus Christi Bay, in Matagorda County, Texas, and that the proposed site is immediately adjacent to the Corpus Christi Ship Channel and approximately nine nautical miles from the Gulf of Mexico. The estimate costs of the facilities proposed for this project is $145,073,000.

Applicant indicates that it is requesting the two-phase procedure since actual deliveries of LNG cannot be made until all requisite regulatory approval are obtained and that the Commission's commencement of evaluation of environmental and safety issues, as requested in Phase I of this proceeding would aid in contract negotiations. Applicant further indicates that issues other than those relating to the environment and safety would be reserved for Phase II. Specifically, Applicant indicates that the following exhibits, required by Section 157.14 of the Regulations under the Natural Gas Act (18 CFR 157.14), have been omitted from this application and would be submitted in Phase II of this proceeding:

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<th>Exhibit</th>
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Applicant has submitted with the instant filing Exhibit AA-Environmental Impact Assessment and Exhibit Z-I-LNG Safety Assessment. Applicant indicates that it anticipates no significant amount of environmental and safety data would be submitted in Phase II.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 20, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.79 or 1.101) 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 and will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 16 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required by the foregoing notice. Any such petition to intervene must be filed within 30 days from the date of the publication of this notice.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. LAMB
Secretary.

SOUTHERN NATURAL GAS CO.
Order Accepting for Filing and Suspending Proposed PGA Rate Adjustment, Requiring Modification, Directing Submission of Additional Information, and Rejecting Alternate PGA Rates

On May 17, 1977, Southern Natural Gas Company (Southern) tendered for filing in the above docket a proposed...
rate increase of 10.108 cents per Mcf consisting of (1) an increase of 7.061 cents per Mcf consisting of (1) an increase of 7.061 cents per Mcf or $52,992,170 annually in Southern's current cost of purchase of gas at rates in excess of those for 1.9905 cents per Mcf in the surcharge to recover deferred purchased gas costs of $8,244,408, and (3) an increase of 1.1420 cents per Mcf to recover estimated demand charge credits of $5,854,734, pursuant to section 8(3) of Southern's tariff. Southern requests that the proposed increased rates be permitted to become effective on July 1, 1977.

Southern's filing includes approximately $17.8 million of costs associated with emergency purchases made during the 1976-1977 winter. The bulk of these supplies were obtained pursuant to Commission orders for 60-day emergency purchases under Section 8(3) of Southern's tariff. Southern requests that the proposed increased rates be permitted to become effective on July 1, 1977.

The claimed costs for emergency supplies obtained under Commission orders in Docket Nos. RP77-28, CP77-143, CP77-32, CP77-179, CP77-126, CP77-188, and CP77-188 shall be approved, subject however, to the elimination of certain internal costs, which consists of the following:

- The relationship between purchases and seller;
- The availability of other gas supplies;
- The amount of gas purchased under each 60-day transaction;
- A comparison of each emergency purchase price with appropriate market prices in the same or nearby areas; and
- The Commission finds that the amounts paid to other pipelines for transportation of emergency gas which were not included in its claimed rates are accepted for filing, suspended for one day, and permitted to become effective on July 2, 1977, subject to refund and to the terms of this order.

The Commission orders:

(A) Southern's proposed PGA rates are accepted for filing and suspended for one day, and permitted to become effective subject to refund.

(B) Southern shall, within 15 days from the date of this order, file revised PGA rates excluding (1) all claimed costs of emergency gas which were not paid to other parties and (2) all claimed costs which did not result in obtaining emergency supplies.

(C) Southern shall, within 30 days of the date of this order, file with the Commission and serve on all of its customers and interested state commissions the following information concerning its 60-day emergency purchases under Section 2.68 of the Commission's General Rules, at rates in excess of those established in Opinion No. 770-A:

1. The pipeline's need for the gas;
2. The availability of other gas supplies;
3. The amount of gas purchased under each 60-day transaction;
4. A comparison of each emergency purchase price with appropriate market prices in the same or nearby areas; and
5. The relationship between purchases and seller.

(D) Southern's proposed alternate PGA increase is rejected.

(E) The Secretary shall cause prompt publication of this order to be made in the Federal Register.

By the Commission.

KENNETH F. PLUMIA, Secretary.

[FR Doc. 77-19482 Filed 7-7-77; 8:46 am]

UNITED GAS PIPE LINE CO.

Application


Take notice that on June 16, 1977, United Gas Pipe Line Company (Applicant), P.O. Box 1476, Houston, Texas 77001, filed in Docket No. CP77-48 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of a farm tap on its Boise Southern 8-inch line in Beauregard Parish, Louisiana, as all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that in May 1968 Applicant entered into an agreement with Mrs. Clara Hickman (Hickman) wherein Hickman granted Applicant a right-of-way and easement authorizing the construction of a segment of Applicant's Boise Southern Line across certain lands owned by her in Beauregard Parish, Louisiana. Applicant indicates that in partial consideration for the granting of said right-of-way to Applicant, Hickman was advised that a farm tap would be constructed by Applicant and that a segment of natural gas, to her principal dwelling would be made by Applicant through the distributor in the area, United Gas Corporation, a then affiliate of Applicant. Applicant states that Hickman has requested gas service be extended to her principal dwelling. Consequently, Applicant seeks authorization to construct the required tap and service to Hickman. It is estimated that the total cost of the proposed facilities would be $1,000, it is indicated.

It is stated that Applicant has contracted Entex, Inc. (Entex), the distributor in the Beauregard Parish, Louisiana, area and has been advised that farm tap service to Hickman be provided from within the seasonal volumetric limitations which may be established for its purchases from Applicant by the Commission. Applicant states that it is estimated that deliveries of gas through this farm tap would be approximately 30 Mcf annually, or approximately 0.00001 percent of Applicant's system requirements.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 16, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.16 or 1.10) and the Regu-
NOTICES

The Commission orders: (A) United’s proposed FGA rates herein are accepted for filing and suspended for one day until July 2, 1977, when they shall be permitted to become effective subject to refund.

(B) United shall file revised rates as may be required to give effect to the following:

(1) Any change in Sea Robin’s FGA rates in Docket No. RP73-89 (FGA77-2).

(2) Claimed producer rate increases shall be effective on or before July 1, 1977.

(3) Claimed costs associated with the Delhi purchase in the event a certificate therefor has not been issued on or before July 1, 1977.

(4) Any change in United’s FGA rates associated with alleged non-jurisdictional purchases shall be subject to the outcome of proceedings in Docket Nos. RP74-83 and CP76-238.

(D) United shall, within 30 days of the date of this order, file with the Commission and serve on all of its customers and interested state commissions the following information concerning the rate adjustments which may be required in United’s FGA rates: (1) a statement of individual rate components including base rate, Btu adjustment, gathering or other charges, and taxes; and (5) total cost claimed (volume x total rate).

(E) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. PLUMS, Secretary.

[FEDERAL REGISTER, VOL 42, NO. 131—FRIDAY, JULY 8, 1977]

WISCONSIN ELECTRIC POWER CO. AND WISCONSIN MICHIGAN POWER CO.

[Tariff Change]


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35195

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1 The same or similar circumstances. To assist the Commission in reviewing the reasonableness of the emergency purchases, United shall be required to submit additional, pertinent information as specified in ordering paragraph (D) below.

2 The issue of weather purchased gas costs associated with United’s alleged non-jurisdictional purchases may be included in its FGA rates is an issue in proceedings currently pending in Docket Nos. RP74-83 and CP76-238. The amounts included in the present filing associated with alleged non-jurisdictional purchases shall be accepted subject to refund and subject to the outcome of the proceedings in Docket No. RP74-83, et al., supra. United has not identified the alleged non-jurisdictional purchases included in its present filing. No other information as to these purchases is available, inasmuch as the producers have not made filings with the Commission. The Commission finds that pertinent information concerning the alleged non-jurisdictional purchases included in United’s present filing is required for pursuit of identification and the Commission’s further review. The necessary data is specified in ordering paragraph (E) below.

3 It further appears that United’s filing reflects increased FGA rates of Sea Robin Pipeline Company (Sea Robin), in Sea Robin’s Docket No. RP73-89 (FGA77-2). A review of Sea Robin’s filing indicates that its rates may be predicated in part on purchases which have not been certified by the Commission. Therefore, United’s FGA rates shall be accepted subject to downward adjustment to track adjustments which may be required in Sea Robin’s FGA rates.

4 Finally, in the absence of information pertaining to the alleged non-jurisdictional purchases, the Commission is not able to verify that the effective dates of the alleged non-jurisdictional purchases will occur prior to the proposed effective date of July 1, 1977. United shall therefore be required to file revised lower rates to reflect the exclusion of any increases which are not effective as of July 1, 1977.

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35195
NOTICES

Natural Gas Company (El Paso) for transportation service to Transwestern Pipeline Company (Transwestern) for ultimate delivery to (NGPL). Applicant indicates that no additional facilities would be required to render the proposed service feasible.

Applicant asserts that NGPL needs the additional gas, which it proposes to sell on a short-term basis, in order to help assure that NGPL can continue to provide adequate service to its customers and replenish its storage reserves.

Applicant states that it has a short-term excess annual supply of gas which it can make available to NGPL. A current estimate of Applicant's calendar year 1977 supply and requirements, including the maximum sale under the arrangement proposed herein, is as follows:

CIG TOTAL SYSTEM GAS BALANCE, 1977.
(Volumes in MMcf at 14.65 p.s.L.a.)

<table>
<thead>
<tr>
<th>Gas supply</th>
<th>Sour gas pipeline system</th>
<th>302,032</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wyoming pipeline system</td>
<td>145,601</td>
</tr>
</tbody>
</table>

Total purchases and production: 447,633

Storage withdrawal, exchange gas, and air injection (net): 10,051

Total gas supply: 437,582

Requirements:

Sales to existing customers: 423,627

Proposed short-term sale, maximum volume: 4,020

Company usage: 30,035

Total requirements: 437,582

Applicant states that it has recently experienced significant reductions in the annual requirements of its nonjurisdictional transmission system customers, and that the recent weather in Applicant's general market area has been unusually warm, and Applicant's 1977 deliveries have been correspondingly lower.

It is stated that through negotiation Applicant and NGPL determined that the initial rate for gas sold under the proposed arrangement would be 5.65 cents per Mcf, which is equal to the presently effective rate incorporated in Applicant's FPC Rate Schedule EX-I. The EX-I Rate Schedules provides for the on-system of gas which is in excess of Applicant's volumetric obligations, it is said.

Any person desiring to be heard or to make any protest with reference to said application should file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on the application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, or if any person desiring to be heard is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or to be represented at the hearing.

KENNETH P. FLUM, Secretary.

[Doc No. CP73-95]

COLUMBIA GAS TRANSMISSION CORP.

Petition to Amend Order


Take notice that, on June 15, 1977, Columbia Gas Transmission Corporation (Petitioner), 1709 15th St. N.W., Washington, D.C. 20005, filed in Docket No. CP73-95 a petition to amend the Commission's order of July 20, 1976, issued in the instant docket (60 FPC 380), pursuant to Section 7 of the Natural Gas Act so as to permit the four-year term for development of Artemas-B to its full capacity to apply also to obtaining the necessary storage rights on the average needed to extend the Artemas-B Storage Reservoir, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is indicated that pursuant to the Commission's order of December 6, 1972, in the instant docket Petitioner was granted authorization inter alia, to construct and operate certain facilities in connection with the activation and operation of Artemas-B Storage Field, and that on June 6, 1976, the Commission amended its order of December 6, 1972, to provide an extension of time to June 6, 1976, for Petitioner to construct and operate facilities to extend the Artemas-B Storage Reservoir. It is stated that the extension of Artemas-B Storage Reservoir required the acquisition of additional storage rights on 5,000 acres. Petitioner states that ordering paragraph (D) of the July 20, 1976 order contained...
the provision that the amended certificate authorization and the rights granted thereunder were conditioned upon Petitioner's obtaining the necessary storage rights on the acreage needed to extend the Arteras-B Storage Reservoir within one year from the issuance of the Order, which permit was issued on July 20, 1977.

It is indicated that the areas of the lease acquisition that has not been completed as of June 8, 1977, are as follows:

1. A modification of the present lease from the Commonwealth of Pennsylvania required to include its 1/4 undivided interest in 58 acres situate within the extension area applied for.

2. The 3% undivided interest in 604 acres owned by the United States of America, administered by the United States Department of the Interior, which negotiation has been pursued on a continuing basis since October, 1972.

3. A 58-acre tract on which the private owner has refused to execute a storage lease. If it is determined that a negotiated lease cannot be secured, Petitioner will be forced to obtain storage rights through a condemnation suit.

4. 1,263.31 acres owned by the State of Maryland. The lease has been applied for the Attorney General of Maryland, executed on behalf of Petitioner and mailed to Maryland for execution by the proper authorities.

Petitioner states that areas (1) and (2) may well be leased by July 20, 1977. However, it is doubtful that areas (2) and (3) can be placed under lease in less than an additional three-year period, it is said.

By this petition, Petitioner requests that the Commission amend its order of July 20, 1976 in the instant docket by deleting from ordering paragraph (1) the phrase, "within one year from the issuance of this order," and permit the four-year term for development of Arteras-B to its full capacity to apply also to obtaining the necessary storage rights on the acreage needed to extend the Arteras-B Storage Reservoir.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before July 19, 1977 file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protesting parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing thereon must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMS, Secretary.

[Docket No. ERT7-2641]

DETOUR EDISON CO.

- Order on Rehearing

JUNE 8, 1977.

On May 31, 1977, the Detroit Edison Company (DEC) filed an Application for Rehearing and Reconsideration of the Order Accepting for Filing in Part, Rejecting for Filing in Part, Suspending Proposed Rate Schedules in Part, Granting Intervention and Establishing Procedures, issued April 29, 1977, in Docket No. ERT7-2641, Finding Paragraph (2) of that Order stated that:

"Good cause exists to reject the filing of a proposed rate increase as to the Village of Sebewaing under Section 205, and to instead institute an investigation under Section 206 to determine whether the rate is so low as to adversely affect the public interest as where it might impair the financial stability of the public utility to continue its service, cast upon other customers an excessive burden, or be unduly discriminatory. FPC v. Sierra Pacific Power Co., 350 U.S. 46."

In addition, Ordering Paragraph (C) stated that:

"[I]n Section 206 of the Federal Power Act and the Commission's Rules of Practice and Procedure, an investigation is ordered to determine whether the current rate paid by Sebewaing under its contract of November, 1973 is so low as to adversely affect the public interest."

In its Application for Reconsideration, DEC avers that the above stated standard is not appropriate, as it applies only to fixed rate contracts, according to the Mobile-Sierra doctrine, while the investigation of whether the rate is below the just and reasonable rate, according to the Public Utility Act and the Commission's Rules, is whether the rate is so low as to adversely affect the public interest as where it might impair the financial condition of the public utility to continue its service, cast upon other customers an excessive burden, or be unduly discriminatory, FPC v. Sierra-Pacific Power Co., 350 U.S. 46."

The DEC-Seeboeing contract contains the following provision:

3. Beginning in the effective date of the Agreement, the customer shall be billed by the Company at the rates as approved by the Federal Power Commission, it is expressly understood by the customer that these rates are subject to change by order issued by the Federal Power Commission.

As we stated in our order of April 29, 1977, that contract provision was interpreted in the Order Denying Motion to Reject, Instituting Section 206 Investigation, and Ordering Refunds, issued July 2, 1975 in Docket No. E-9294, and the Commission held that:

"Since the parties provided for changes in rates only by order issued by the Commission, it is clear that they did not contemplate the unilateral filings permitted by Section 205. The only changes in rates which occur by order of the Commission occur pursuant to an order issued pursuant to Section 206. Thus, the parties have provided that changes in rates will only occur pursuant to Section 206. Accordingly, we shall investigate Detroit's current rates and the just and reasonable rates pursuant to Section 206, all changes to be prospective in application.

Having established that changes in rates may occur only pursuant to Section 206, we are presented with the question of whether the appropriate standard for the Commission's investigation is whether the rate is "so low as to adversely affect the public interest as where it might impair the financial stability of the public utility to continue its service, cast upon other customers an excessive burden, or be unduly discriminatory," or whether the rate is below the just and reasonable rate level.

In Docket No. E-7740, Indiana and Michigan Electric Company, the contract between the Companies and the Cooperatives provided that a change in rate was to be made only when ordered by the appropriate regulatory agency. The Commission interpreted this clause to mean that the contracts "are subject to change by order issued by the Cooperatives... under Section 205 of the Federal Power Act." Regarding these procedures, the Commission stated that;

We would note that the procedures under such a Section 205 proceeding would not entail meeting the heavy burden of proof associated with the Mobile-Sierra decisions. As all parties concede, these contracts clearly contemplate that the Commission may order a change in rates; that the rates are not fixed for the term of the contract, only the manner in which such a change may be affected is contractually established. Accordingly, our examination of I&M's proposed rates would still be on a basis of our cost-plus fair return standard. Cf. Southern California Edison Company, Docket No. E-8178, order issued September 21, 1973.

Since the contract between DEC and the Village of Sebewaing states that "rates are subject to change by order issued by the Federal Power Commission," it is similarly clear that while the manner of change in rates is contractually established the rates themselves are not fixed for the term of the contract.

We note that to hold otherwise would imply that it was DEC's intent to contract to provide power at a rate which might yield less than a fair return, and which could only be changed if it were so low as to adversely affect the public interest. It is more reasonable to conclude that the parties intended that the rates could be revised by the Commission.

Since the Sierra-Mobile standard applies only when a public


utility has agreed to a fixed contract rate, affording less than a fair return, it would not be appropriate to use that stricter standard in the case sub judic. Based on the above,

The Commission finds: (1) Good cause exists to amend the Order issued April 29, 1977, in this proceeding as requested by Detroit Edison Company in its Application for Rehearing and Reconsideration, filed May 31, 1977. The Commission orders: (A) Finding Paragraph (2) of the abovementioned Order issued April 29, 1977, in this proceeding is hereby amended to read as follows:

Good cause exists to reject the filing of a proposed rate increase as to the Village of Sebewaing under Section 206 and instead to institute an investigation under Section 206 to determine just and reasonable rates to be charged to the Village of Sebewaing. See Order on Reconsideration, issued June 3, 1974, Indiana and Michigan Electric Company, Docket No. E-7746.

(B) Ordering Paragraph (C) of the Order issued April 29, 1977 is hereby amended to read as follows:

The motion to reject the filing of a rate increase as to the Village of Sebewaing is granted. Pursuant to Section 206 of the Federal Power Act and the Commission's Rules of Practice, an investigation is ordered to determine the just and reasonable rate to be charged to the City of Sebewaing.

(C) In all other respects, our Order of April 29, 1977 remains in full force and effect.

(D) The Secretary shall cause prompt publication of this order to be made in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUMB, Secretary.

[FR Doc.77-19433 Filed 7-7-77; 8:45 am]

[Docket No. CP77-455]

EL PASO NATURAL GAS CO.

Application


Take notice that on June 21, 1977, El Paso Natural Gas Company (Applicant), P.O. Box 1492, El Paso, Texas 79976, filed in Docket No. CP77-455 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the operation of certain existing facilities and an increase as to the Village of Sebewaing is hereby ordered to determine the just and reasonable rate of up to 40,000 Mcf of natural gas per day in interstate commerce for Natural Gas Pipeline Company of America (Natural) for the period up to October 29, 1977, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is noted that Natural has asked Applicant and others for assistance in making available to its system certain short term gas supplies which are available to Natural but not located in close proximity to its system. Natural would utilize the gas made available to it through the instant proposal as a part of its overall supply and storage program to help maintain presently effective customer entitlement level for the 1977-78 winter season, it is said.

Applicant indicates that Natural has contracted with Colorado Interstate Gas Company (Colorado) for the purchase of up to 40,000 Mcf of natural gas per day which would be available for sale by Colorado near Green River, Wyoming, beginning July 1, 1977 and continuing through October 31, 1977. It is stated that pursuant to the terms and conditions of an agreement between Natural and Colorado, Colorado would deliver those volumes of gas purchased by Natural to Northwest Pipeline Company (Northwest) who, in turn, would deliver such volumes to Applicant at an existing point of interconnection between the pipeline systems of Northwest and Applicant in La Plata County, Colorado. Applicant states that it would transport those quantities of gas that it receives from Northwest and deliver equivalent volumes on an Mcf for Mcf basis to Transwestern Pipeline Company (Transwestern) at an existing point of interconnection between Applicant's system and that of Transwestern in Ward County, Texas. It is stated that Transwestern would deliver the volumes of gas so received from Applicant into Natural's pipeline system.

Applicant states that it would render the proposed back-haul transportation service for Natural on a best efforts basis, through the use of otherwise available capacity in Applicant's system, pursuant to a letter agreement between Applicant and Natural dated June 9, 1977. It is stated that Natural would compensate Applicant through the payment of an administrative fee of 1.0 cent for each Mcf delivered by Applicant to Transwestern for Natural's account.

No new or additional facilities would be required by Applicant in connection with the effectuation of such arrangements, it is indicated.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 20, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.10 and 1.11) 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 thereon must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein. If the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity, if a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB, Secretary.

[FR Doc.77-19504 Filed 7-7-77; 8:45 am]

[Docket No. CP77-456]

EL PASO NATURAL GAS CO.

Application


Take notice that on June 21, 1977, El Paso Natural Gas Company (Applicant), P.O. Box 1492, El Paso, Texas 79976, filed in Docket No. CP77-456 an application pursuant to Section 7 of the Natural Gas Act for permission and approval to abandon certain minor facilities and for a certificate of public convenience and necessity authorizing the relocation, and modification of cer-
Applicant seeks permission and approval to abandon and convey, without system utilized in serving its customers. This would be operated and maintained for the present site. Applicant also proposes said application to rebuild the existing metering facilities to make any protest with the City of Mesa would occur as the 4Y-inch OD. sales lateral pipe; necessary for distribution system operation.

Applicant states that as a result of increased contract delivery pressure of not more than 20 psig to a new maximum contract delivery pressure of not more than 250 psig. The City of Mesa had the effect of reducing the rate for these wells to 35 cents per Mcf, plus adjustments.

According to the application, production from these wells has ceased due to a compressor failure. Frio, a small producer, seeks authorization to charge $1.60 per Mcf at 14.65 psig for gas produced from three wells in the Ramerino Field in Liv Oak County, Texas. The gas underlying these wells is dedicated to United Gas Pipe Line Company (United) as a result of a contract amendment of January 1, 1974. On July 27, 1976, Opinion No. 742-A and Order No. 553 issued by the Commission had the effect of reducing the rate for these wells to 35 cents per Mcf, plus adjustments.

Any person desiring to be heard or to make any protest with reference to the City of Mesa would accept from Applicant, upon Applicant's relocation of the subject meter station, approximately 0.42 mile of said 4½-inch O.D. pipeline and approximately 0.42 mile of said 6-inch O.D. pipeline, and the facilities thereon described in the above application. Applicant further states that it would finance the cost of the facilities relocated and rebuilt through use of internally generated funds.

Any person desiring to be heard or to make any protest with reference to the City of Mesa would accept from Applicant, upon Applicant's relocation of the subject meter station, approximately 0.42 mile of said 4½-inch O.D. pipeline and approximately 0.42 mile of said 6-inch O.D. pipeline, and the facilities thereon described in the above application. Applicant further states that it would finance the cost of the facilities relocated and rebuilt through use of internally generated funds.

Any person desiring to be heard or to make any protest with reference to the City of Mesa would accept from Applicant, upon Applicant's relocation of the subject meter station, approximately 0.42 mile of said 4½-inch O.D. pipeline and approximately 0.42 mile of said 6-inch O.D. pipeline, and the facilities thereon described in the above application. Applicant further states that it would finance the cost of the facilities relocated and rebuilt through use of internally generated funds.

Applicant indicates that the relocation of the subject meter to a new location would be considered by the Commission and open to public. Applicant from approximately 6,500 psi to 250 psi, and that under these more desirable operating conditions, Applicant is required to provide the City of Mesa with an increased delivery pressure at the new site. Applicant indicates that the operation of the City of Mesa's distribution system after the proposed realignment requires Applicant to increase the present contract maximum delivery pressure at the said Mesa No. 2 meter station of not more than 200 psig to a new maximum contract delivery pressure of not more than 250 psig. The City of Mesa would accept from Applicant, upon Applicant's relocation of the subject meter station, including over head, contingency and filing fees is $48,344. Applicant further states that it would finance the cost of the facilities relocated and rebuilt through use of internally generated funds.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 20, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority vested in and subject to the jurisdiction conferred upon the Federal Power Commission by section 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) all protests filed with the Commission will be considered by it in determining the proper action to be taken but will not serve to make the protestants parties to the proceeding. Any party wishing to become a party to a proceeding, or to participate as a party in any hearing therein, must file a petition to intervene.
NOTICES

INDIANA & MICHIGAN ELECTRIC CO.
Order Adopting Settlement Agreement

On May 28, 1976, Indiana and Michigan Electric Company (I&M) filed proposed increased rates for service to Northern Indiana Public Service Company (NIPSCO). By Order dated June 25, 1976, the Commission accepted the proposed rate filing and suspended them for 30 days to become effective on July 27, 1976, subject to refund. In addition, the Commission consolidated this docket with proceedings in Docket Nos. ER76-714 1 and ER76-715.2

On February 17, 1977, I&M submitted a negotiated settlement agreement between itself and NIPSCO to the Commission. Notice of the proposed settlement was issued on February 3, 1977 requiring comments prior to or before March 11, 1977. On March 11, 1977, Staff Counsel filed comments supporting the proposed settlement agreement. The proposed settlement provides certain changes to I&M's proposed rate changes as originally filed on May 28, 1976. The agreement provides: (1) the inclusion of a provision mutually agreed upon procedures for the curtailment of power and energy delivery to NIPSCO in the event that there should be a shortage of capacity and or electric energy requiring I&M to curtail power and energy delivery. (2) a reduction in the demand charge from $7.12 to $6.41 per KW reducing the effective rate of $35.13 to $33.10 per Mcf and requests that such rate be made effective subject to refund. Such sales are not to become effective for 30 days to become effective on July 27, 1976, subject to refund.

The Commission finds: The settlement agreement itself, the filings, documents and pleadings submitted, we conclude that the settlement agreement represents a reasonable resolution of the issues in Docket No. ER76-715, and that such settlement is in the public interest. Accordingly, the settlement agreement between I&M and NIPSCO filed on February 17, 1977, should be approved.

The Commission finds: The settlement filed by I&M and NIPSCO on February 17, 1977, as it applies to NIPSCO should be approved and made effective as hereinafter ordered.

The Commission orders: (A) The negotiated Settlement agreement filed by I&M in this docket on February 17, 1977 is hereby approved and made effective as of July 27, 1976.

(B) In accordance with the terms of the settlement agreement and consistent with the Commission's Regulation § 33.19 (a) within 30 days of the date of this order, I&M is hereby directed to refund the difference in revenues collected over and above the rates made effective July 27, 1976, subject to refund and the revenues authorized to be collected pursuant to the terms of the settlement file agreed upon interest rate of 9 percent per annum.

(C) The Commission hereby orders that Section 33.5 of the Commission Regulations be waived in order that the revised supplement to I&M's service agreement with NIPSCO be approved for filing to become effective July 27, 1976 designated as Indiana & Michigan Electric Company, Supplement No. 6 to Rate Schedule FPC No. 22 (Supersedes Supplement No. 5).

(D) I&M is hereby directed to file a compliance report within 15 days after refunds have been made, such reports to show monthly billing determinants and revenues under prior, present, and settlement rates. The report should also show the monthly settlement increase, the monthly revenue refund, and the monthly interest computation together with a summary of such information for the total refund period. A copy of such report shall also be furnished to I&M by the Commission to each State Commission within whose jurisdiction the wholesale customer distributes and sells all electric energy at retail.

(E) This Order is without prejudice to any findings or Order which may have been made or which will hereafter be made by the Commission, and is without prejudice to any claim or contentions which may be made by the Commission, the Staff, or any party or persons affected by the Order against I&M or any person or party.

1 Brown & McKenzie received a small producer certificate in Docket No. C578-49.


1. The filing in Docket No. ER76-714 involves a rate increase for service to Michigan Power Company.
2. The filing in Docket No. ER76-715 involves a rate increase for service to I&M Cooperative and Municipal resale customers.
(F) The Secretary of the Federal Power Commission shall cause prompt publication of this Order in the Federal Register.

By the Commission:

KENNETH F. PLUMB,  
Secretary.

[FR Doc.77-19498 Filed 7-7-77; 8:45 am]

[Docket No. ER76-714]  

INDIANA & MICHIGAN ELECTRIC CO.  
Order Adopting Settlement Agreement  

On May 28, 1976 Indiana & Michigan Electric Company (I&M) filed proposed increased rates for service to Michigan Power Company (MPCO), a wholly-owned subsidiary. By Order dated June 25, 1976, the Commission accepted the proposed rates for filing and suspended them for 30 days to become effective on July 27, 1976 subject to refund. In addition, the Commission consolidated this docket with docket No. ER76-715 of PCO, and ER76-716.


The Settlement Agreement proposes certain changes to I&M's rate filing as originally submitted on May 28, 1976, inasmuch as it provides for (1) a reduction in the original proposed demand charge of $8.17 per KW to $6.95 per KW; (2) an effective date of July 27, 1976; (3) the date I&M's increases were permitted to become effective in one of the amounts indicated by Staff's revised Top Sheet filing based on a 9.16% rate of return and a 12.50% return on common equity. On the basis of the Settlement Cost of Service Top Sheets, Staff, on February 23, 1977, filed comments supporting the Motion of I&M for Approval of the Negotiated Agreement of Settlement and Compromise.

On March 11, 1977, the Michigan Public Service Commission filed comments stating that it was "officially taking no position" with respect to the reasonable-ness of the proposed settlement agreement.

On March 16, 1977, the Michigan Power Users Association filed comments opposing the proposed settlement agreement. In addition to filing comments opposing the settlement, MPUA filed a Motion for Leave to intervene in these proceedings including the settlement agreement itself, the filings, documents and pleadings submitted including MPUA's petition to intervene, we conclude that the settlement agreement represents a reasonable resolution of the issues in Docket No. ER76-715, and that such settlement agreement is in the public interest. Accordingly, the settlement agreement between I&M and MPCO filed on January 23, 1977 should be approved.

The Commission finds: (1) That good cause exists to grant MPUA's Motion for Leave to File Intervention, Time for Intervention Having Expired. (2) That good cause exists to allow MPUA to intervene in this proceeding. (3) That the Settlement Agreement filed by I&M on January 28, 1977, as it applies to service to MPCO should be approved and made effective as hereinafter ordered.

The Commission orders: (A) The negotiated Settlement Agreement filed by I&M in this docket on January 28, 1977, is hereby approved and made effective as of July 27, 1976. (B) In accordance with the terms of the Settlement Agreement and consistent with the Commission's Regulation with regard to the date of the date this order I&M is hereby directed to refund the difference in revenues collected under the rates made effective July 27, 1976, subject to refund and the revenues authorized to be collected pursuant to the terms of the Settlement Agreement filed on January 28, 1977, at an agreed upon interest rate of 9 percent per annum.

(C) The Commission hereby orders that Section 50.3 of the Commission regulations be waived in order that the revised supplement to I&M's service agreement with MPCO be approved for filing to become effective July 27, 1976.

(D) I&M is hereby directed to file a compliant report within 15 days after refunds have been made, such reports to show monthly billing determinant and revenues under prior, present, and settlement rates. The report should also show the monthly settlement increase, the monthly revenue refund, and the monthly interest computation together with a summary of such information for the total refund period. A copy of such report shall also be furnished by I&M to each State Commission within whose jurisdiction the wholesale customer distributes and sells electric energy at retail.

(E) MPUA is hereby permitted to intervene in this proceeding.

(F) This Order is without prejudice to any findings or Order which may have been made or which will hereafter be made by the Commission, and is without prejudice to any claim or contentions which may be made by the Commission, the Staff or any party or persons affected by the Order against I&M or any other person or party.

(G) The Secretary of the Federal Power Commission shall cause prompt publication of this Order in the Federal Register.

By the Commission:

KENNETH F. PLUMB,  
Secretary.

[FR Doc.77-19497 Filed 7-7-77; 8:45 am]

[Docket No. R177-106]  

MARINE CONTRACTORS & SUPPLY, INC.  
Further Amended Petition for Special Relief  

Take notice that on June 17, 1977, Marine Contractors and Supply, Inc. (Marine), P.O. Box 2734, Houston, Texas, filed a further amended petition for special relief in the captioned docket, pursuant to 18 CFR § 2.76.

In Marine's original petition for special relief, filed June 10, 1976, noticed June 30, 1976, in Docket No. R176-151, it sought authorization to charge $1/per Mcf for the sale of gas from the Luce Field, St. Charles Parish, Louisiana to Transcontinental Gas Pipe Line Corporation (Transco). At the time, Marine was selling its gas to Transco for $7.1641 cents per Mcf. Its petition was based on its allegation of the need for well reconditioning in order to prevent its abandonment.

On July 23, 1976, noticed August 6, 1976, Marine filed an amended petition...
NOTICES

[Federal Register Volume 42, No. 131, Friday, July 8, 1977]

NORTHERN NATURAL GAS CO.

Application

June 29, 1977.

Take notice that on June 16, 1977, Northern Natural Gas Company (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP77-443 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to: abandon and remove certain gas measuring facilities located in Iron County, Wisconsin, as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is indicated that pursuant to the Commission's order of June 2, 1965, in Docket No. CP64-255 (Phase II), Applicant installed a sales measuring station, designated Hurley TBS No. 2, in order to sell and deliver natural gas to Lake Superior District Power Company (Lake Superior) for resale to the Lakehead Pipe Line Pumping Station (Lakehead) at Saxon, Wisconsin.

Hurley TBS No. 2 was installed in Iron County, Wisconsin and was placed in service on October 4, 1966. It is stated that the measuring station has been utilized for delivery of volumes on a firm basis to Lake Superior for resale to Lakehead for pump engine fuel, and that on December 31, 1976, Lakehead completed conversion of their pumping station to electric motor drives thereby discontinuing the use of natural gas fueled engine drives.

The estimated cost of removing the facilities of Hurley TBS No. 2 is $5,100 which would be financed from cash on hand. It is stated that the estimated salvage value of the facilities being retired is $2,550.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 19, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any party wishing to become a party in any hearing therein, must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plum, Secretary.

[Federal Register Document CP77-443 Filed 7-7-77; 8:45 am]

MISSISSIPPI POWER CO.

Presiding Administrative Law Judge's Certification of Proposed Settlement to Commission


Take notice that on June 2, 1977, Presiding Administrative Law Judge Ernst Liebman certified to the Commission for consideration and disposition a Settlement Agreement which would resolve all outstanding issues in the case. Judge Liebman indicated that all parties, including Staff, concur in the settlement.

Any person desiring to do so may submit written a June 3, 1977, a proposed Settlement Agreement. All such comments will be considered by the Commission in determining the appropriate action to be taken. Comments should be addressed to the Federal Power Commission, 2223 Dodge Street, Omaha, Nebraska 68102, and should be filed on or before July 13, 1977. Copies of this notice are on file with the Commission and are available for public inspection.

Kenneth F. Plum, Secretary.

[Federal Register Document CP77-457 Filed 7-7-77; 8:45 am]

NORTHWEST PIPELINE CORP.

Application


Take notice that on June 22, 1977, Northwest Pipeline Company (Applicant), 315 East Second South, Salt Lake City, Utah 84111, filed in Docket No. CP77-457 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas on a new and open line to the facilities of Applicant at Saxon, Wisconsin.

Applicant requests authorization to transport up to 40,000 Mcf of natural gas per day on a best efforts basis for Natural pursuant to a gas transportation agreement dated June 16, 1977, between Applicant and Natural. Applicant indicates that Natural and Colorado Interstate Gas Company (CIG) have entered into an agreement dated June 16, 1977, which provides that CIG will sell to Natural up to 40,000 Mcf of natural gas per day for a term commencing on July 1, 1977, and continuing through October 31, 1977, and that the sale by CIG to Natural would be at the existing point of interconnection between the facilities of Applicant and CIG in the vicinity of Green River, Wyoming.

It is stated that in order to make such gas as it may purchase from CIG available to its transmission system, Natural has requested that Applicant transport such volumes of natural gas as Natural may purchase from CIG and deliver such volumes to El Paso Natural Gas Company (El Paso). It is indicated that El Paso and Transwestern Pipeline Company (Transwestern) would further...
transport and/or exchange such gas as may be necessary or desirable to make approximately equal volumes of gas available to Natural's transmission system.

Applicant states that pursuant to the terms of the transportation agreement dated June 15, 1977, between Applicant and Natural, it would transport up to 43 billion Btu's of natural gas per day on a best efforts basis for Natural. It is stated that Natural would cause CIG to deliver or otherwise make available to Applicant and Applicant would accept the proposed volumes of gas at an existing point of interconnection between the facilities of CIG and Applicant in the vicinity of Green River, Wyoming, and that Applicant would redeliver equivalent billion Btu's to El Paso at an existing point of interconnection between the facilities of Applicant and El Paso in the vicinity of Ignacio, Colorado.

It is stated that deliveries by CIG to Applicant for the account of Natural would be made pursuant to a proposed new reservation contract for up to 5,000 Mcf of natural gas per day. It is stated that any additional facilities to effectuate the proposal, it is said.

Applicant states that it would charge Natural 8 cents per million Btu's for the proposed transportation service, and that this 8 cent rate is based.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 29, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be further notice of such hearing will be duly given.

Kenneth F. Plumb, Secretary.

[Docket No. CP77-447]

NORTHWEST PIPELINE CORP.

Application


Take notice that on June 17, 1977, Northwest Pipeline Corporation (Applicant), P.O. Box 1528, Salt Lake City, Utah 84110, filed in Docket No. CP77-447 an application pursuant to Section 7(c) of the Natural Gas Act for public convenience and necessity authorizing the transportation of up to 5,000 Mcf of natural gas per day for IGC Production Company (IGC), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that IGC, a wholly owned subsidiary of Intermountain Gas Company (Intermountain), has developed or otherwise acquired natural gas reserves in the Rangely Field in Rio Blanco County, Colorado, and that IGC desires to make available the natural gas produced from the Rangely Field to Intermountain for use in Intermountain's distribution system. Consequently, IGC and Applicant have entered into a gas purchase, transportation and exchange agreement dated February 22, 1977, whereby IGC would deliver up to 5,000 Mcf of natural gas per day from the Rangely Field to Applicant at a point on Applicant's Pipeline at the western boundary of the Intermountain area located in Rio Blanco County, Colorado, and Applicant would receive for transportation, at an existing point of interconnection between the facilities of Applicant and Intermountain near Pocatello, Idaho. It is stated that no new facilities are required to effectuate the proposed transportation service.

It is stated that Applicant has the option to purchase up to 40 percent of the gas so delivered to it by IGC, and that Applicant would also deduct 2 percent of the gross heating value of the volumes actually delivered as compensation for fuel usage. It is stated that the base price to be paid by Applicant to IGC for each Mcf of gas purchased by Applicant would be:

(i) $1.44 for gas from a well or wells commenced on or after January 1, 1975, to be escalated by 1 cent at the end of each calendar quarter.

(ii) $1.222 for gas from a well or wells commenced on or after January 1, 1973, and prior to January 1, 1975, to be escalated by 1.3 cents at the end of each one-year period.

The price to be paid for the gas IGC proposes to sell to Applicant would be within the scope of Opinion 770-A or Opinion 742, it is said. Applicant would also pay a 1 cent per Mcf gathering charge for gas purchased from IGC. IGC would pay Applicant 16.03 cents per Mcf of natural gas delivered to Applicant for transportation, it is said.

It is stated that Applicant on April 14, 1977, commenced the purchase of all the volumes proposed herein to be transported and/or purchased by Applicant, and that Applicant constructed a meter station at the intersection of Applicant's and IGC facilities in Rio Blanco County, Colorado, for the receipt or the volumes purchased under the contract.

Applicant constructed such facilities pursuant to the agreements dated February 22, 1977, and October 19, 1976, at Docket No. CP76-459 authorizing Applicant to construct gas purchase facilities during the calendar year 1977, it is said. It is stated that the facilities would be available for utilization, pursuant to the proposed gas purchase, transportation and exchange agreement.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 19, 1977, file with the Federal Power Commission, Washington D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.
unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc.77-19443 Filed 7-7-77;8:45 am]

[Docket No. ER77-422]

PUBLIC SERVICE CO. OF OKLAHOMA

Order Accepting for Filing and Suspending Notices of Cancellation and Providing for Expedited Hearing


On June 3, 1977, Public Service Company of Oklahoma tendered for filing Notices of Cancellation of Rate Schedule FFC numbers 119-A, 119-B, 17-A as supplemented and 17-B, as supplemented for interconnected service between the Southwestern Power Administration (SWPA), Public Service Company of Oklahoma (PSOCO), and Oklahoma Gas and Electric Company (OG&E). PSOCO states that the rate schedules expire by their terms on June 30, 1977, and requests waiver of the Commission’s thirty day notice requirement to make July 1, 1977, the effective date of the cancellation.

Public notice of the filing was issued on June 10, 1977. On June 22, 1977, a petition to intervene and protest was timely filed by the Municipal Customer Group (Municipals), wholesale preference customers of the Southwestern Power Administration. Municipalites contend that their entire power supply is supplied by one of the rate schedules being sought to be cancelled herein, and that no new contractual arrangements have been finalized for service between PSOCO, OG&E, and SWPA. Municipalities therefore seek a Commission order continuing the terms of the present contract until a new contractual arrangement may be accepted by the Commission. Municipalities state that they are completely dependent on the power service provided under the present contract, and that a serious hazard to the safety, health, and welfare of their respective communities is posed by its threatened termination.

On June 27, 1977, PSOCO filed an answer to the petition to intervene and protest contending that Municipalities were not totally dependent upon SPA since two of the cities receive a portion of their power supply from OG&E, and that this Commission lacks authority to extend the terms of the present contract beyond the five month suspension period provided under Section 305(e) of the Federal Power Act.

Commission review of the proposed cancellations indicates that they have not been shown to be just and reasonable and may be unjust, unreasonable, unduly discriminatory, preferential, or otherwise unlawful. Accordingly, the Commission shall accept for filing the proposed notices of cancellation, suspend their effectiveness for five months and establish expedited hearing procedures to determine whether service may be terminated consistent with Sections 205 and 206 of the Federal Power Act.

The Commission finds: (1) Good cause exists to accept PSOCO’s notices of cancellation for filing and suspend their effectiveness for five months and establish hearing procedures.

(2) Good cause exists to grant intervention to the Municipalities in this proceeding.

The Commission orders: (A) Pursuant to the authority of the Federal Power Act, particularly Sections 205 and 206 thereof, and the Commission’s Rules and Regulations, an expedited public hearing shall be held concerning the justness and reasonableness of PSOCO’s service termination.

(B) Pending a hearing and final decision thereon, PSOCO’s submittals are hereby accepted for filing and suspended for five months, until December 31, 1977.

(C) Municipalities are hereby permitted to intervene in this proceeding, subject to the Rules and Regulations of the Commission; Provided, however, that participation of such intervenors shall be limited to matters set forth in the petition to intervene; and Provided, further, that the admission of such intervenors shall not be construed as recognition by the Commission that they might be aggrieved because of any order or orders of the Commission entered in this proceeding.

(D) The Secretary shall cause prompt publication of this order to be made in the Federal Register.

By the Commission.

Kenneth F. Plumb,
Secretary.

[FR Doc.77-19500 Filed 7-7-77;8:45 am]

[Docket No. ER77-87]

SIERRA PACIFIC POWER CO.

Order Approving Settlement


On March 7, 1977, the Presiding Administrative Law Judge in this proceeding certified to the Commission a proposed Settlement Agreement, together with a portion of the evidentiary record and a Statement of Evidence submitted by Sierra Pacific Power Company (Sierra) regarding the proposed fuel adjustment clause. The Commission finds that the Settlement Agreement is in the public interest and accepts and approves it as hereinafter ordered and conditioned.

Proceedings in this docket were initiated on August 22, 1975, when Sierra submitted for filing proposed changes in its Rate Schedule R and a revised fuel adjustment clause, which together would increase revenues from Sierra’s wholesale customers by approximately $716,152. Sierra’s filing also proposed to transfer Rate Schedule R service to one of its wholesale customers, Mt. Wheeler Power, Inc. (Mt. Wheeler), to reflect the fact that Mt. Wheeler has been integrated with Sierra’s system as of August 1975, when construction of a 230 kv transmission line was completed.

Certain deficiencies in Sierra’s August 22, 1975, filing were cured in its amended filing submitted October 29, 1975. By order issued November 26, 1975, the Commission permitted Sierra’s rate change to become effective as of December 29, 1975, subject to refund. Effective the same date, Sierra was allowed to place service to Mt. Wheeler under its Rate Schedule R. The order then set the entire filing for hearing. In addition, the order permitted the interventions of California-Pacific Utilities Company (Cal-Pac); Mt. Wheeler: Pacific Gas and Electric Company (PG&E); the City of Fallon, Nevada (Fallon); the Truckee-Donner Public Utility District (Truckee); and the Public Service Commission of Nevada (Nevada). The late intervention of the Secretary of the Navy was granted by order issued June 6, 1976.

As a result of informal settlement conferences among the parties, a proposed Settlement Agreement 1 was submitted and received into evidence at a hearing held December 22, 1976 (Tr. 4:108-110). The proposed Agreement would modify certain portions of the Company’s tariff and provide that Sierra would withdraw its rate increase application in this docket and make the requisite refunds. Service to Mt. Wheeler would remain under Rate Schedule R (Tr. 4:108-100) but, together with service to the Company’s other wholesale customers, would be priced at the Rate Schedule R rate previously approved in Docket No. E-8224.

The proposed Agreement does not resolve the issue of whether it is proper for Sierra to transfer to Mt. Wheeler its Rate Schedule R, the schedule under which Sierra’s other wholesale customers are served, and, if so, whether Mt. Wheeler is entitled to a high voltage discount. Although all parties concurred in certifying the proposed settlement to the Commission, Mt. Wheeler believes the reservation of issues as set forth in the Agreement is too narrowly drawn. Mt. Wheeler’s suggested wording of the reservation includes a series of alleged facts relating to the “right and/or reasonable-ness of Mt. Wheeler Power, Inc. (Mt. Wheeler) to charge a rate for its system...”

We find that, despite the shifts in emphasis attending the different descriptions of the reserved issues, there is no real difference in the nature of the issues they describe. However worded, the issue

1 The Agreement was executed by Sierra, Fallon, Truckee-Donner, Cal-Pac, PG&E, and the Navy, but not by Mt. Wheeler.

NOTICES

35205

is whether Sierra's proposed rates to Mt. Wheeler, filed under Section 205 of the Federal Power Act, are just and reasonable or whether they would unduly prejudice or disadvantage Mt. Wheeler. An investigation of this type was in fact the subject of a hearing in this docket, and the Initial Decision therein, issued March 26, 1977, is currently pending review by the Commission.

On the same day on which the proposed Settlement Agreement was submitted for inclusion in the record, Sierra circulated a modification to its fuel adjustment clause (Tr. 4:107-108). The modification was intended to bring the fuel clause into compliance with Order No. 517. In light of their inability to examine the changes prior to the hearing, some of the parties reserved the right to object to the modified fuel clause after sufficient time for review thereof (Tr. 4:109, 111).

The parties subsequently convened an informal settlement conference to resolve any objections to Sierra's amended fuel clause. On February 28, 1977, Sierra submitted a Statement of Position to which was attached a revised fuel adjustment clause (Tr. 4:107-108). The modification was intended to bring the fuel clause into compliance with Order No. 517. In light of their inability to examine the changes prior to the hearing, some of the parties reserved the right to object to the modified fuel clause after sufficient time for review thereof (Tr. 4:109, 111).

The parties subsequently convened an informal settlement conference to resolve any objections to Sierra's amended fuel clause. On February 28, 1977, Sierra submitted a Statement of Position to which was attached a revised fuel adjustment clause reflecting the pricing of generation and interchange fuel costs based on a one-month operating period and reflecting average actual costs in the period. Also attached to Sierra's Statement were the parties' responses to Sierra's earlier proposing of alternate proposals for pricing fuel costs: (1) a price based on the one month operating period and reflecting average costs experienced during the last month of the operating period; (2) the one month operating period alternative which Sierra subsequently submitted as it settlement offer.

Comments in support of the first alternative were filed by PG&E. Comments in favor of the second alternative were received from the Commission Staff, the Department of the Navy, Truckee Donner, and Fallon. Mt. Wheeler submitted a statement that, while it believed that for some wholesale customers the second alternative was proper as written, it had no objection to any number of amendments to the clause which would have to be made before Mt. Wheeler could agree to it.

Mt. Wheeler posits three objections to the application to it of the second (alternative) fuel clause. First, Mt. Wheeler argues that the base energy cost of Sierra's clause would be equivalent to the energy cost contained in the effective Schedule R rate. But Mt. Wheeler's position is that it should be billed under the separate Schedule R-2 and that therefore any fuel clause applied to Mt. Wheeler as a base cost was a loss factor equivalent to the energy cost of the R-2 rate.

Mt. Wheeler's second objection is that there would be a different loss factor attributable to it than to the other wholesale customers, because Mt. Wheeler takes its service at 230 kv while the other wholesale customers receive service at 69 kv or lower. Consequently, service to the other customers has different loss factor characteristics than service to Mt. Wheeler.

Finally, Mt. Wheeler argues that, to the extent its purchases from Sierra are intermittent, under the Company's fuel clause there will be a lack of synchronization between the fuel costs which Mt. Wheeler incurs and the fuel costs for which it would be billed. This is because the clause bills fuel costs for one month using the actual average cost experienced in the previous month. To alleviate the synchronization problem Mt. Wheeler recommends using a "self-correcting" fuel clause which retroactively accounts for and bills the actual fuel costs each customer causes Sierra to incur.

The pertinence of Mt. Wheeler's first objection, regarding the proper base energy cost, rests on the resolution of which, if any, clause would be applicable to Mt. Wheeler. According to the Agreement this question was a reserved issue, and the Initial Decision therein is currently pending review by the Commission.

Mt. Wheeler's second objection is geared to its objection to the proposed Settlement Agreement. If the fuel clause is to be applied to Mt. Wheeler, the revision of the fuel clause to reflect average actual costs in the period is necessary. Also, in the period where Sierra receives from Mt. Wheeler, the Commission suspended the proration formula and directed Sierra to billing as if Mt. Wheeler was not a customer during the period.

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Mt. Wheeler's second objection is geared to its objection to the proposed Settlement Agreement. If the fuel clause is to be applied to Mt. Wheeler, the revision of the fuel clause to reflect average actual costs in the period is necessary. Also, in the period where Sierra receives from Mt. Wheeler, the Commission suspended the proration formula and directed Sierra to billing as if Mt. Wheeler was not a customer during the period.
NOTICES

On May 16, 1977, Tennessee Gas Pipeline Company (Tennessee), a division of Tenneco, Inc., tendered for filing proposed tariff sheets reflecting rate adjustments under the "purchased gas (PGA), curtailment demand charge, credit, and research and development (R&D) credit, surcharge, and adjusting rate" for Tennessee's FPC Gas Tariff. The proposed effective date is July 1, 1977. Notice of the filing was issued on June 6, 1977, providing for protests and petitions to intervene to be filed on or before June 22, 1977. None has been received. The Commission shall accept the filing and permit it to become effective on July 1, 1977. However, the portion of the filing reflecting increased R&D expenditures will be considered subject to refund, as provided in Tennessee’s tariff, and subject to the outcome of the proceedings in Docket Nos. RT73-16, RT76-113, and RT77-02.

The proposed rate filings include three separate tracking adjustments: (1) a PGA rate increase of 6.44 cents per Mcf to track both increased gas costs of 5.71 cents per Mcf or $63.05 million per year and an increase of 0.73 cents recouping the balance in Tennessee’s Unrecovered Purchase Gas Cost Account; (2) curtailment credit rate decreases of 0.79 cents per Mcf to 2.14 cents per Mcf; and (3) a rate increase of 0.08 cents per Mcf or $921,000 to update R&D expenditures through March 31, 1977.

Included in Tennessee’s PGA surcharge is 0.14 cents per Mcf to recoup $741,229 in its deferred account that is the amount by which the costs of Tennessee’s purchases under the Emergency Natural Gas Act of 1977A (Pub. L. 95–2) 91 Stat. 4 (1977) exceed its average system gas costs. Under Order No. 7 of the Administrator in Docket No. E77-92, Tennessee is authorized to seek Commission approval to recover these additional costs through its PGA provision, as its purchases under the Emergency Act are less than two percent of its total purchases, 18 CFR 1000.9(e) (1). The Commission will grant this request and permit recovery in the PGA surcharge accepted here.

The Commission finds that the proposed rate adjustments, with the exception of the 0.08 cents per Mcf R&D rate increase, have been shown to be just and reasonable. The proposed R&D rate adjustment has not been shown to be just and reasonable and may be unjust, unreasonable and discriminatory. However,
the R&D provision in Tennessee's tariff provides that adjustments are not subject to suspension but become effective subject to refund of any portion found unjustified after hearing and final decision. Tennessee's R&D projects and expenditures are subject to refund of any portion found unjustified after hearing and final decision. Therefore, the proposed rates will be accepted for filing and permitted to become effective on July 1, 1977, as proposed.

The Commission orders: (A) Substitute Seventeenth Revised Sheet Nos. 12A and 12B to Ninth Revised Volume No. 1 of Tennessee's FPC Gas Tariff, as tendered by Tennessee on May 16, 1977, are hereby accepted for filing and permitted to become effective on July 1, 1977. (B) To the extent that the rates accepted here reflect charges attributable to R&D expenditures by Tennessee, these rates shall be subject to refund, with interest, upon conclusion of the proceedings in Docket Nos. RP75-13, RP75-113 and RP77-62. Refunds of the amounts collected to recoup those expenditures may be ordered at the conclusion of those proceedings. Therefore, the proposed rates will be accepted for filing and permitted to become effective on July 1, 1977, as proposed.

The Secretary shall cause prompt publication of this order to be made in the Federal Register.

By the Commission.

KENNETH F. PLUMB, Secretary.

[FR Doc. 77-10461 Filed 7-7-77; 8:45 am]

[Docket No. CP77-451]

TEXAS GAS TRANSMISSION CORP.

Application


Take notice that on June 29, 1977, Texas Gas Transmission Corporation (Applicant), P.O. Box 1160, Owensboro, Kentucky 42301, filed in Docket No. CP77-451 an application pursuant to Section 7(b) of the Natural Gas Act and Section 5 of the Commission's General Policy and Interpretations (18 CFR 2.70) for a certificate of public convenience and necessity authorizing the transportation of up to 2,304 Mcf per day of natural gas per day, on an interruptible basis, for Martin-Marietta Aluminum, Inc. (Martin-Marietta), an existing industrial customer of Western Kentucky Gas Company (Western Kentucky), one of the Applicant's resale customers, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant seeks authorization to transport for 2 years up to 2,304 Mcf of natural gas per day, on an interruptible basis, for Martin-Marietta pursuant to a transportation agreement dated May 27, 1977, between Applicant and Martin-Marietta.

It is stated that Martin-Marietta has entered into a contract with Equitable Petroleum Corporation (Equitable), for the purchase of volumes of natural gas to be produced or allocated to Martin-Marietta by Enron Texas, Inc., and that Martin-Marietta would pay Equitable commencing with the first day of delivery of natural gas, a price of $2.18 per Mcf, and that the price would continue for the next 365 days at a price in effect would be $2.33 per Mcf.

Applicant states that such gas would be delivered to it by Tennessee Gas Pipeline Company, a Division of Tenneco, Inc. (Tennessee), through a dispatching arrangement at the tailgate of the Champin Gasoline Plant, Panola County, Texas, and that applicant would supply the gas for the delivery of natural gas up to 2,304 Mcf per day at 14.73 psia to an existing point of delivery with Western Kentucky for the account of Martin-Marietta.

In no event would Applicant be obligated to deliver on any day an aggregate amount of more than 2,304 Mcf of natural gas at 14.73 psia through all points of delivery to Applicant in Tennessee. Applicant's Certificate of Public Convenience and Necessity authorizing the transport of volumes of gas to be transported and delivered by Applicant to Western Kentucky.

Applicant states that it would retain 5.27 percent above the delivered values as make-up for protest fuel and line loss, which percentage was calculated on an incremental basis for pipeline throughput to and within the rate zone in which the delivery by Applicant would be made. This certificate also contains an application for an initial charge of 17.81 cents per Mcf (at 14.73 psia) for all quantities of gas transported and delivered to Western Kentucky for the account of Martin-Marietta.

It is indicated that all of the volumes of gas proposed to be transported to Western Kentucky for delivery to Martin-Marietta at its Lewisport, Kentucky plant would be used for plant protection and process needs, which would be classified as Priority 2 uses.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 11, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity, and if the application 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
unecessary for Applicant to appear or be represented at the hearings.

KENNETH F. PLUMB
Secretary.

[FR Doc.77-10438 Filed 7-7-77:8:45 am]

[Docket No. CP77-452]

TRANCONTINENTAL GAS PIPE LINE CORP.
Application


Take notice that on June 28, 1977, Transcontinental Gas Pipe Line Corporation (Applicant), P.O. Box 1396, Houston, Texas 77001, filed in Docket No. CP77-452 an application pursuant to Section 7 of the Natural Gas Act and Section 2.79 of the Commission’s General Policy and Interpretations (18 C.F.R. 2.79) for a certificate of public convenience and necessity authorizing the transportation of up to 750 Mcf of natural gas per day on an interruptible basis for Collins & Aikman Corporation (Collins), Crown Aluminum, Division of Hunter-Douglas, Inc. and Davsco, Inc. (Davsco), industrial customers of Public Service Company of North Carolina, Inc. (PSNC), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant seeks authorization to transport the proposed volumes of natural gas for Collins, Davsco, and Crown on an interruptible basis pursuant to transportation agreements each dated April 15, 1977 between Applicant and Collins, and Davsco, severally, for a period of two years.

It is stated that Collins, Crown and Davsco have purchased from Samedan Oil Corporation (Samedan) up to 750 Mcf of natural gas per day (at 15.65 psia) of gas to be produced from the Carlin Unit No. 1, Bee County, Texas. It is indicated that Collins, Crown and Davsco would pay Samedan for all gas delivered $2.26 per million Btu’s (at 14.65 psia), and would also pay Samedan 8.4 cents per Mcf for gathering and transporting gas to delivery point.

Applicant states that Collins, Crown and Davsco would arrange to have such quantities delivered to United Gas Pipe Line Company (United) and United would deliver the gas to Applicant at mutually agreeable authorized exchange points between Applicant and United.

Applicant further states that it would deliver the transportation volumes existing points of delivery to PSNC for the accounts of Collins, Crown and Davsco, and that PSNC would transport the subject gas to Collins’ and Crown’s Roxboro, North Carolina plants and to Davsco’s Gastonia, North Carolina plant.

It is indicated that the volumes of gas proposed to be transported and delivered to Collins, Crown and Davsco would be used for Priority 2 use and that there is no alternate fuel for use at these plants.

Applicant states that it would charge Collins, Crown and Davsco 29.8 cents per Dekatherm (d) for all quantities delivered pursuant to their respective transportation agreements, and that this rate is applicable to similar transportation services providing for deliveries in its Rate Zone 2. Applicant further states that it would retain, initially, 3.9 percent of the quantities received for transportation as make-up for compressor fuel and line loss, and that this percentage is based on Applicant’s "optimum use" factor for pipeline throughput to and within its Rate Zone 2 in which the proposed transportation deliveries would be made.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 11, 1977, file a protest with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 C.F.R. 7.1 or 1.10) and the regulations under the Natural Gas Act (18 C.F.R. 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission’s Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by Sections 7 and 15 of the Natural Gas Act and the Commission’s Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is timely filed, or if the Commission, on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission, on its own motion, believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB
Secretary.

[FR Doc.77-10438 Filed 7-7-77:8:45 am]

[Docket No. RM77-20]

ASSOCIATED GAS DISTRIBUTORS
Petition for Notice of Proposed Rulemaking Concerning Pipeline Transportation


Take notice that on May 12, 1977, Associated Gas Distributors (Petitioners or AGD) filed in Docket No. RM77-20 a petition pursuant to Section 1.7 of the Commission’s Rules of Practice and Procedure (18 C.F.R. §1.7) and Section 5, 7 and 16 of the Natural Gas Act, requesting the Commission to issue a notice of proposed rulemaking concerning the transportation by interstate pipelines of gas not owned by the transporting pipeline (non-system gas).

AGD’s petition identifies several issues on which it seeks FPC rulemaking action. These include the following:

1. The need for a uniform approach to transportation rates applicable to non-system gas.

2. The need to take into account, in fashioning a uniform transportation rate policy, the important differences between transactions involving transportation service for a pipeline’s existing customers, on the one hand, and those involving transportation service for other "off-system" customers, on the other.

3. The need to consider, in any uniform transportation rate policy, the question of whether and how to distinguish between usual transportation service and so-called back-haul service, where transportation service is effectuated by displacement.

4. The need to consider, in any uniform transportation policy, the circumstances under which a pipeline may be obligated to provide transportation service.

Petitioners point out that the need for a uniform policy on pipeline transportation service for non-system gas has become more prevalent in recent years as more gas distributors and industrial users have engaged in self-help measures to offset increasing pipeline curtailments. They further allege that there are wide variations among interstate pipelines’ charges for non-system transportation service, making it difficult for parties seeking transportation service to plan transactions effectively and discouraging pipeline customers from undertaking efforts to reduce some of these shortages. By establishing uniform rules governing pipeline transportation service of non-system gas, it is alleged that pipeline customers will be encouraged to look out supplemental sources of gas, thereby increasing the general intertate supply.

The petition includes a draft statement of the general guidelines recommended by AGD with regard to transportation service for non-system gas. AGD states that it is prepared to offer more detailed comments and suggestions if and when the Commission decides to initiate the proposed rulemaking proceeding.

The purpose of this notice is to invite responses from interested parties and the public concerning whether the request for a rulemaking should be granted, i.e., whether or not the Commission should institute a formal rulemaking proceeding to resolve any or all of the issues identified in the petition and outlined above.

Any person desiring to be heard or to make any protest with reference to said
petition should on or before July 15, 1977, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene in a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 C.F.R. 1.8 or 1.110). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[APPENDIX A]

ASSOCIATED GAS DISTRIBUTORS
Atlanta Gas Light Co.
Baltimore Gas and Electric Co.
The Brooklyn Union Gas Co.
Central Hudson Gas & Electric Corp.
Chesapeake Utilities Corp.
Consolidated Edison Company of New York, Inc.
Delmarva Power & Light Co.
Elizabethtown Gas Co.
Long Island Lighting Co.
Lynnhurst Gas Co.
New Jersey Natural Gas Co.
New York State Electric & Gas Corp.
Philadelphia Electric Co.
Pennsylvania Gas Works
Public Service Company of North Carolina, Inc.
Public Service Electric & Gas Co.
South Jersey Gas Co.
UGI Corporation
Washington Gas Light Co.

[FEDERAL REGISTER No. RP75-102] PANHANDLE EASTERN PIPE LINE CO.
Order Accepting for Filing and Approving Tariff Revisions, Accepting for Filing and Suspending Proposed Advance Payment Tracking Increase, Establishing Procedures, and Requiring Submission of Revised Settlement Rates


On May 9, 1977, as modified on May 31, 1977, Panhandle Eastern Pipe Line Company (Panhandle) tendered for filing tariff sheets which are allegedly in compliance with the Commission's order of April 25, 1977, approving Panhandle's rate settlement in the capitated proceeding. These tariff sheets are proposed to be effective as of December 1, 1976. The tariff sheets incorporate certain changes in the purchased gas adjustment provision (FGA) of Panhandle's rates, and as such are contained in the DCA Rate Schedules TT-1, TSTE-1 and TSE-1. The proposed changes in Panhandle's FGA relate to the determination of the base cost of gas from suppliers, the allocation of gas from pipeline suppliers, and the removal of off-system sales to Colorado Interstate Gas Company and Kansas Nebraska Natural Gas Company from the calculation of the average cost of purchased gas. The FGA revisions and the revisions to Panhandle's Rate Schedules comply with the terms of the settlement agreement in this docket and, therefore, will be approved.

Panhandle included as part of its filing First Substitute Nineteenth Revised Sheet No. 3-A, proposed to become effective April 1, 1977. This sheet increases the FGA part of the rate to current levels, excludes amounts applicable to Gas Arctic Northwest Project and Northern Border Pipeline Project, and includes an increase in advance payment surcharge. This sheet reflects rate level approval in various PGA filings by Panhandle during the pendency of the settlement approval by the Commission on April 25, 1977. Under the settlement agreement, First Substitute Nineteenth Revised Sheet No. 3-A could not become effective prior to approval of the settlement. (Article II, Section 2 and Article VIII.) April 25, 1977, was the earliest date on which a tariff sheet filed in accordance with the terms of the settlement could become effective.

The Commission finds that the proposed advance payment increase included in First Substitute Nineteenth Revised Sheet No. 3-A has not been shown to be just and reasonable. Accordingly, the Commission shall suspend operation of this sheet for one day from the earliest possible effective date, or until April 26, 1977, at which time it shall be permitted to become effective, subject to refund. Hearing procedures shall be instituted to determine the lawfulness of the proposed increase.

Panhandle's tendered settlement rates in Docket No. RP75-102 have been adjudged for approved 1976-1977 PGA rate increases, a .1 cent per Mcf advance payment increase, and then subject to refund to Artic Northwest Project and the Northern Border Pipeline Project. The adjusted rates form the basis for refunds to be made by Panhandle in this docket. In its calculation of the adjusted rates, Panhandle included the .1 cent per Mcf advance payment increase as if it had become effective August 1, 1976. Panhandle did not have advance payment tracking authority from August 1, 1976 to Panhandle's order. Any person required to file revised settlement rates excluding the unauthorized .1 cent per Mcf advance payment charge for the period August 1, 1976, through April 25, 1977.

The Commission orders: (A) The proposed tariff sheets listed in Appendix A are accepted for filing as of December 1, 1976, and are approved.

(B) Pursuant to the authority of the Natural Gas Act, particularly sections 4, 5, 8, and 15 thereof, and the Commission's rules and regulations, a public hearing shall be held concerning the lawfulness of the increased advance payment rates proposed herein by Panhandle.

(C) Pending hearing and decision, Panhandle's proposed First Substitute Nineteenth Revised Sheet No. 3-A, rate increase is accepted for filing and suspended for one day or until April 26, 1977, when it shall be permitted to become effective subject to refund. Panhandle may file a revised tariff sheet, eliminating the proposed advance payment increase to be effective on April 25, 1977.

(D) An informal conference shall be convened by the Commission staff within 30 days from the date of this order for the purpose of resolving the issues in this proceeding. Further procedures, if any, as may be required following conclusion of the conference shall be prescribed by the Presiding Law Judge upon motion by the parties to the proceeding, including the staff.

(E) A Presiding Administrative Law Judge, to be designated by the Chief Administrative Law Judge pursuant to 18 C.F.R. 5.5(D), shall be assigned to this proceeding for the purposes set forth in this order and to preside over any hearings which ultimately may be required.

(F) Panhandle shall file within fifteen (15) days of issuance of this order revised settlement rates excluding the unauthorized .1 cent per Mcf advance payment charge for the period August 1, 1976, through April 25, 1977.

(G) Panhandle's refund shall be submitted in the settlement in this docket based on the revised rates filed pursuant to (F) above.

(H) The Secretary shall cause prompt publication of this order to be made in the Federal Register.

By the Commission.

KENNETH F. PLUMB,
Secretary.

MICHIGAN WISCONSIN PIPE LINE CO.,
ET AL
Settlement Proposal

JULY 1, 1977.

Take notice that on March 8, 1977, Michigan Consolidated Gas Company (MCC) filed with the Commission in Docket No. CP76-253, one of the above-captioned dockets in this consolidated proceeding, a settlement proposal, which purports to resolve MCC's rates in this proceeding.

The settlement was certified to the Commission by the President Administrative Law Judge on March 22, 1977. Any person wishing to file a protest concerning MCC's settlement proposal. All comments should be addressed to the Federal Power Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, and should be mailed or filed on or before July 12, 1977. Reply comments should be mailed or filed on or before July 26, 1977. MCC's settlement proposal is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FEDERAL REGISTER No. CP76-253]
NOTICES

NATURAL GAS PIPELINE CO. OF AMERICA

Order Accepting for Filing and Suspending Proposed Rate Increase, Granting in Part and Denying in Part Requests for Waiver of Regulations, Initiating Hearings and Establishing Procedures


On May 31, 1977, Natural Gas Pipeline Company of America (Natural) tendered for filing in the captioned docket proposed changes to its FPC Gas Tariff which would increase its revenues for jurisdictional gas sales and services by $50.8 million annually above rates currently in effect subject to refund, and onshore transmission property and transmission for production, gathering, storage and transportation of gas, and any derivative revenues. The increased revenues would result from the following:

- A 10.69 percent overall rate increase for all offshore property.
- A 4.5 percent overall rate increase for onshore transmission property and transmission for production, gathering, storage, and transportation of gas.
- A 12.4 percent overall rate increase for the North Lansing field storage project; and
- A 14.9 percent overall rate increase for the proposed expansion of the Natural states that the principal reasons for its proposed rate increase are a need for a 10.69 percent overall rate of return reflecting a 15.5 percent return on common equity; the costs associated with certain offshore transmission facilities and the proposed expansion of the North Lansing field storage project; a need for depreciation rates of 5.75 percent for production, gathering, storage, and offshore transmission property; and the increased cost of transportation of gas by others; and the costs associated with Natural's proposed exploration and development program in the Rocky Mountain area.

Based upon a review of Natural's filing, the Commission finds that the increased rates which Natural proposes to become effective July 1, 1977, have not been shown to be just and reasonable, and may be unjust, unreasonable, unduly discriminatory or otherwise unlawful. Accordingly, the Commission accepts for filing those rates proposed to become effective on July 1, 1977, but shall suspend their use for five months or until December 1, 1977, when shall be subject to refund, and shall set the matter for hearing.

Natural requests waiver of the Commission's regulations to permit it to file the tariff sheets dated January 1, 1978, more than 60 days prior to the proposed effective date of the sheets. Natural states that certain tariff provisions and contract protest provisions which would prevent the rates changes set forth on such sheets until January 1, 1978. Good cause for granting waiver of the Regulations has not been shown. Accordingly, Natural's request shall be denied, and the tariff sheets dated January 1, 1978 shall be rejected. Rejection is without prejudice, however, to Natural reffiling such sheets at least 50 days but no more than 60 days prior to the proposed effective date in accordance with Section 154.22 of the Commission's Regulations.

Natural has included in its claimed rate base costs related to certain facilities which have not been certified as of the date of filing in this docket. Natural requests waiver of Section 154.63(e) (2) (ii) (D) of the Commission's Regulations to permit such inclusion and in support of its request states that it anticipates receiving all necessary certifications prior to the time its proposed rates become effective. The Commission shall grant the requested waiver of its Regulations provided, however, that if such facilities are not certified and placed in service on the date the proposed rates take effect subject to refund, Natural shall file revised tariff sheets which reflect exclusion of the costs associated with those facilities which have not been certified and placed in service as of that date. Natural shall, also, submit supplemental cost and revenue data which reflect the elimination of such costs from its cost of service.

Natural has restated its depreciation reserve to reflect depreciation rates of 5 percent for production, gathering, storage and offshore plant and 4.5 percent for transmission plant. These are the actual depreciation rates approved by the Commission. Since December 1, 1976, in Docket No. RP76-106, however, Natural has collected, subject to refund, rates which reflect 5.75 percent for property other than offshore transmission and 8.0 percent for offshore transmission other than Stingray property.

The effect of Natural's restatement of its depreciation reserve is to allow the company to calculate its rate base as if it had not filed to change its depreciation rates in its last rate increase filing, with the result that the return and income taxes associated with included in Natural's cost of service are not synchronized with the depreciation expense included in its cost of service and, more importantly, in its rates. This restatement of the accumulated reserve for depreciation results in a base, and consequent allowance for return and associated income taxes, in excess of the rate base, return and income taxes which would result if the proposed rates and tax rates were made consistent with the proposed effective date.

Public notice of Natural's filing was issued on June 10, 1977, with comments and petitions to intervene due on or before June 22, 1977. Timely petitions to intervene were filed in Appendix B. The Commission believes that intervention of such petitioners may be in the public interest, and, accordingly, they will be permitted to intervene in the proceedings hereinafter ordered.

(2) Good cause exists to deny Natural's request for waiver of Section 154.22 of the Regulations requiring that proposed tariff sheets shall be filed more than 60 days prior to the proposed effective date thereof.

(3) Good cause exists to grant waiver of Section 154.63(e) (2) (ii) (D) of the Regulations, subject to the condition hereinabove ordered.

(4) Good cause exists to order Natural to file revised tariff sheets and supplemental cost and revenue data reflecting the accumulated reserve for depreciation resulting from Natural's claimed depreciation rates for the period following December 1, 1976, with appropriate changes in the allowance for return and taxes and reflecting the actual advance payment balance in Account No. 168 as of November 30, 1977.

(5) Good cause exists to permit the intervention of the petitioners listed in Appendix B.

See: Appendix A.

See: Appendix B.
The Commission orders: (A) Pursuant to the authority of the Natural Gas Act, particularly sections 4, 5, 8, and 15 thereof, and the Commission's rules and regulations, a public hearing shall be held concerning the lawfulness of these rates which Natural proposes to become effective on July 1, 1977. (B) Pending hearing and decision, the rates which Natural proposes to become effective on July 1, 1977, are accepted for filing and suspended for five months or until December 1, 1977, when they shall be permitted to become effective, subject to refund, upon motion filed by Natural in accordance with the provisions of the Natural Gas Act. (C) Natural's request for waiver of Section 154.22 of the Commission's Regulations requiring that proposed tariff sheets shall not be filed more than 60 days prior to the proposed effective date is hereby denied, and, accordingly, those tariff sheets dated January 1, 1978 are hereby rejected. Such rejection is without prejudice to the filing of such tariff sheets at such a time as is in accordance with the Commission's Regulations. (D) Natural's request for waiver of Section 154.24 of the Commission's Regulations is hereby granted: Provided, however, That Natural file revised tariff sheets and supplemental cost and revenue data reflecting the actual accumulated reserve for depreciation resulting from Natural's claimed depreciation rates for the period following December 1, 1976, with appropriate changes in the allowance for return and taxes and reflecting the actual advance payment balance in Account No. 168 as of November 30, 1977. (E) Natural shall file revised tariff sheets to become effective December 1, 1977 and suplemental cost and revenue data reflecting the accumulated reserve for depreciation resulting from Natural's claimed depreciation rates for the period following December 1, 1976, with appropriate changes in the allowance for return and taxes and reflecting the actual advance payment balance in Account No. 168 as of November 30, 1977. (F) The petitioners listed in Appendix B are hereby permitted to intervene in this proceeding, subject to the rules and regulations of the Commission; provided, however, that participation of such intervenors shall be limited to matters affecting asserted rights and interests as specifically set forth in their petitions to intervene; and provided, further, That the admission of such intervenors shall not be construed as recognition by the Commission that they might be aggrieved because of any order or orders of the Commission entered in this proceeding. (G) The Staff shall prepare and serve top sheets on all parties for settlement purposes on or before November 1, 1977. See Administrative Order No. 153. (H) A Presiding Administrative Law Judge to be designated by the Chief Administrative Law Judge for that purpose, (Gas Delegation of Authority, 18 CFR 3.50(a)) shall convene a settlement conference in this proceeding on a date certain within 10 days after the service of top sheets by the Staff, in a hearing or conference room of the Federal Power Commission, 825 North Capital Street, N.E., Washington, D.C. 20426. Said Presiding Administrative Law Judge is hereby authorized to establish such further procedural dates as may be necessary and to rule upon all motions (except motions to consolidate, sever, or dismiss), as provided for in the rules of practice and procedure. (I) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. PLUMB, Secretary.

APPENDIX A

TARIFF SHEETS PROPOSED TO BE EFFECTIVE JULY 1, 1977

Third Revised Volume No. 1—Thirty-second Revised Sheet No. 5, Eighth Revised Sheet No. 6A, Fifth Revised Sheet No. 9, First Revised Sheet No. 3A, Fifth Revised Sheet No. 14, First Revised Sheet No. 108, Eighth Revised Sheet No. 119, Sixth Revised Sheet No. 122, Second Revised Sheet No. 131, First Revised Sheet No. 191, Second Revised Sheet No. 220 (R/S X-30), Fifth Revised Sheet No. 270 (R/S X-35), First Revised Sheet No. 293 (R/S X-40), Second Revised Sheet No. 407 (R/S X-45), Second Revised Sheet No. 423 (R/S X-49), First Revised Sheet No. 710 (R/S X-50), First Revised Sheet No. 744 (R/S X-55), First Revised Sheet No. 1000 (R/S X-64).

TARIFF SHEETS PROPOSED TO BE EFFECTIVE JANUARY 1, 1978

Second Revised Volume No. 2—First Revised Sheet No. 467 (R/S X-50), First Revised Sheet No. 653 (R/S X-65), First Revised Sheet No. 654 (R/S X-62), First Revised Sheet No. 668 (R/S X-63), First Revised Sheet No. 685 (R/S X-67).

APPENDIX B

TIMELY PETITIONS TO INTERVENE FILED BY:

Interstate Power Company
Illinois Power Company
United Cities Gas Company
Wisconsin Southern Gas Company, Inc.
Iowa Power and Light Company
Northern Illinois Gas Company
Northern Indiana Public Service Company
North Central Public Service Co. Division of Donovan Companies, Inc.
Central Illinois Public Service Company
Iowa-Illinois Gas and Electric Company
Columbia Gas Transmission Corporation
[FR Doc. 77-19459 Filed 7-7-77; 3:45 am] 1

[Opinion No. 156-2; Docket No. CF74-138, CF74-139, CP74-140]

TRUNKLINE GAS CO. AND TRUNKLINE GAS CO.

Opinion and Order on Rehearing Modifying Prior Opinion and Granting Late Petitions to Intervene


Applications for rehearing of Opinion No. 155 issued the 23rd, 1977, in the proceeding were filed by Algonquin LNG Company, et al. (Algonquin), Battle Creek Gas Company (Battle Creek), Columbia Gas Transmission Corporation (Columbia LNG Corporation (Columbia LNG), Consumers Power Company (Consumers Power), Esocgas LNG, Inc. (Esocgas), East Ohio Gas Company (East Ohio), El Paso Corporation (El Paso Algeria), General Motors Corporation (General Motors), Indiana Gas Company, Inc. (Indiana Gas), Interstate Natural Gas Association of America (INGAA), Mississippi River Transmission Corporation (MRTCO), Public Service Electric & Gas Company (PSE&G), Southern Natural Gas Company, et al. (Southern), Southern California Gas Company (So-Cal), and Tennessee Gas Pipeline Company (Tennessee). Motions for reconsideration 1 were filed on June 1, 1977, by Michigan Consolidated Gas Company (Michigan Consolidated), and by the City of Indianapolis D/B/A Citizens Gas & Coke Utility (Indianapolis); on June 3, 1977, by Northern Indiana Public Service Company (NIPSCO); and on June 9, 1977, by Southeastern Michigan Gas Company (Southeastern). In response to the Commission's "Order Setting Oral Argument* * *", FFC-1, issued June 2, 1977, in this proceeding, comments were filed by Algonquin; jointly by Distrigas Corporation and DistriGas of Massachusetts Corporation (DistriGas); jointly by the Environmental Defense Fund, the Consumer Federation of America, and the Public Interest Economics Center (EDF, et al.); Pertamina;

1 Although these pleadings were styled as "applications for rehearing," they are being treated as motions for reconsideration because they were not filed within the time prescribed by Section 2 of the Commission's Rules of Practice and Procedure.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
Michigan Gas Utilities Company (Michigan Gas); the Federal Energy Administration on behalf of the Energy Resources Council (ERC); the Commission Staff; the National Association of Regulatory Commissioners (NARUC); and by the State Regulatory Commissions of Ohio, Michigan, Missouri, Indiana, Kansas and Illinois. On June 13, 1977, the Commission set forth a number of oral arguments concerning issues raised in the applications for rehearing and in other pleadings filed with the Commission. Participants in the oral argument included Trunkline, EDF, et al., Indiana Gas, Michigan Consolidated, INGAA, Tennessee, So-Cal, Columbia Gas, Columbia LNG, Eascomas, PS&E&G, Southern MRTC and the Commission Staff. For the reasons set forth below, the Commission shall modify Opinion No. 796. On June 24, 1977, the Commission granted rehearing of Opinion No. 796 for purposes of further consideration.

INCREMENTAL VERSUS ROLLED-IN PRICING

Most of the parties addressed this issue and, on behalf of the Commission Staff and EDF, et al. opposed incremental pricing and supported the use of rolled-in pricing. The Energy Resources Council filed a statement calling the Commission's attention to Section 414 of the proposed National Energy Act transmitted by the President to the Congress on April 28, 1977. According to the positions and positions considered in drafting Section 414, which is entitled "Incremental Pricing of Natural Gas," are similar to those considered by the Commission in Opinion No. 796. The ERC explains that, however, that whereas Opinion No. 796 provides for full marginal cost pricing of a specific source, Section 414 provides that the costs of all above-average-cost gas supplies will be allocated to low priority users until the burner-tip prices for such users reach the prices of substitute fuels.

Those opposed to incremental pricing contend, inter alia, (1) incremental pricing denies the financeability of the LNG project, (2) only allows those customers with the ability and foresight to sign up to purchase LNG in 1977 for delivery in 1980, (3) is inconsistent with Opinion No. 786 (Columbia LNG) wherein the FPC approved rolled-in pricing for imported LNG), and with the Commission's Alaska pipeline report to the President (wherein in rolled-in pricing was also recommended), (4) is improper where LNG is used for base load, high priority uses, (5) is inconsistent with the goal of encouraging all forms of supplemental supplies in times of energy shortfalls, (6) is difficult to administer and impedes the flexibility and reliability of a pipeline's system, and (7) discriminates against high priority customers of low base load customers of Trunkline, Panhandle and MRT who won't be able to contract to purchase the LNG because such purchases will have to be at 100 percent load factor or made only by the take-or-pay arrangements of the import contract. As an example, Tennessee's oral argument cited page 8 of Columbia LNG, et al., Opinion No. 786 wherein the Commission noted that under Opinion No. 622-A, which required incremental pricing, 44 of Columbia's 129 resale customers elected to purchase LNG on an incremental basis. The Commission stated:

"Nine large relatively high load factor customers purchased over 92 percent of the LNG, and the remaining LNG was sold to two small load factor customers, primarily municipally-registered systems, did not participate in the purchase of the LNG. To oblige themselves to purchase LNG incrementally now. These customers represent small cities and towns throughout the southeastern part of the United States."

Tennessee Gas argues that the "market test," envisioned by Opinion No. 796 won't work because new, high priced supplies of coal, oil and electricity are usually rolled-in. Tennessee Gas and other parties also argue that Opinion No. 796 adopted incremental pricing without substantial evidence as required by Columbia LNG, et al. v. FPC, 491 F.2d 651 (5th Cir., 1974) on such issues as: (1) the incremental problems of the Commission, (2) the cost of implementation, and (3) the degree to which the public interest would be served by incremental pricing. It is also argued that a future Commission almost assuredly will not observe the "non-curtailable" provision, a fact which, it is alleged, would adversely affect investors' confidence in the project.

While not directly opposing the FPC's incremental pricing decision, the Ohio Commission sets forth its policy, used at the state level, and belief that only short term supplies of gas should be incrementally priced, whereas long term supplies of gas, which require long term capital commitments (such as the Trunkline LNG project) should be rolled in. The Missouri Commission questions the financeability and the general wisdom of using incremental pricing and recommends use of the rolled-in method. The Indiana, Illinois, Kansas and Michigan Commissions, as well as NARUC, also support use of the rolled-in method. The Commission also notes the reasons set forth, in Opinion No. 796 to account for higher winter peaks, stating that if the "price comparability" test used by the Commission to distinguish Columbia LNG, Opinion No. 786 from Opinion No. 796 against attacks that the Commission should have adjusted the price of LNG in Opinion No. 786 of Section No. 129 for winter peak higher winter costs. Staff rejects this argument as "bootstrapping," stating that if the estimated price in Columbia LNG were $3.37 per Mcf, the Commission would also have required incremental pricing in that case.

EDF, et al. supports the Staff position and argues, inter alia, that the Commission should price LNG incrementally, to encourage all state regulatory authorities to do the same rather than discourage efforts to use

NOTICES

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
of rolled-in pricing. Because of national defense and balance of payments considerations, the need for incremental pricing of foreign LNG is particularly compelling, even though EDF, et al., would recommend incremental pricing of all new supplemental supplies of high cost gas.

Upon consideration of the arguments raised by the parties on rehearing, in the comments, and at oral argument, as well as a reconsideration of the record in this case and of Opinion No. 786, the Commission is convinced that the incremental pricing method should not be used herein and that the rolled-in method should be used in its stead. One of the Commission's primary concerns is in the financeability of the project. Trunkline has stated that the incremental pricing provisions, if upheld on rehearing, would probably render the project unfinanceable. Trunkline has further stated that with incremental pricing, there is not enough present firmness of demand to warrant going forward with the project on an incremental basis. The response of Staff, to this statement is that if the demand on the Trunkline system does not exist for LNG at its "true market cost", then the gas should not be imported and the project should be allowed to fail because there is not enough market demand for the LNG to justify the project. The evidence in this proceeding indicates that the true issue facing the Commission is not whether this project would require incremental or rolled-in pricing, but rather whether to certify this project with rolled-in pricing or to, in effect, kill the project by using incremental pricing, an action tantamount to denying Trunkline's request for certification of the project. Given the record in the proceeding, and considering all factors, the Commission finds that certification of this project is in the public interest.

One of the primary factors leading us to this conclusion is that this gas should be made available on the Trunkline system as insurance to protect Priority 1 loads and Priority 2 plant protection requirements. To ensure that this supply is made available to the Trunkline system, gas should be offered at the rolled-in pricing method as a necessary ingredient to the project's financeability and therefore its ultimate viability. The availability of such gas to these customers, particularly when they are customers of low load factor distributors, should not hinge on the distributor's present ability and willingness for lack thereof to sign up for LNG for use in 1980 and thereafter under separate incremental rate schedules, which, in all probability, will contain take-or-pay provisions which require the LNG to be taken at 100 percent load factor. The record indicates that one-half of Trunkline Gas' base load is projected to be LNG by the end of 1980. Thus, Trunkline Gas will be meeting 75 percent of its Priority 1 requirements, even with imported LNG, with no gas left over for lower priorities (L.D., p. 37). As the Commission stated in Columbia LNG, Opinion No. 786 where the gas will be used as base load to serve high priority users in Priorities 1 and 2, rather than as an "exotic" supplemental supply for use by a market that is uncertain, reliability pricing should be used. Thus, with rolled-in pricing, the LNG will be available on the Trunkline Gas system as a part of Trunkline Gas' general system supply. Thus, it is only proper that all customers pay their proportionate share of the costs of the LNG since all customers would benefit therefrom.

With respect to the availability of alternate fuels, the Commission agrees with and adopts the Presiding Judge's finding (L.D., p. 53):

--- that alternate fuels are not available in a sufficient quantity or within a comparable price range to offset the need for imported LNG, for the reasons set forth in his Initial Decision.

In related matters, the Commission agrees that it cannot in this proceeding, ensuring that future commissions or successor regulatory authorities, would never curtail the gas sold under separate incremental rate schedules. We also agree that the requirement of this LNG supply, under purportedly "non-curtailable" rate schedules, has been a major factor in the apparent reluctance of parties to sign 20-year contracts with take-or-pay provisions for the purchase of LNG. Accordingly, consistent with our decision to use rolled-in pricing, the LNG from the project shall be curtailed pursuant to Trunkline Gas' end-use curtailment plan.

We further agree with certain of the applicants that use of the rolled-in pricing method is consistent with our decision in the Alaska Pipeline renegotiation and with our decision in Columbia LNG, Opinion No. 786 to use rolled-in pricing. Once we have determined that a supplemental gas supply project is in the public interest, the Commission should take reasonable steps, consistent with its consumer protection responsibility under Sections 4 and 5 of the Natural Gas Act, to ensure the financial viability of the project.

We note that the certified initial rate of $3.37 per MMBtu is based upon calculations using a 15 percent rate of return on common equity. Although the instant opinion reduces the risk to Trunkline LNG by using rolled-in, as opposed to incremental pricing, we find the initial rate of $3.37 to be within the zone of reasonableness. Furthermore, the rate of return issue shall be reviewed in Trunkline LNG's first Section 4 or 5 rate proceeding before the Commission, or its successor agency.

**Fixed Rate Provision**

Trunkline and others argue that the so-called "fixed rate" provision of Opinion No. 936, which permits no change in the straight volumetric rate of $3.37 per MMBtu except for changes due to currency adjustments or the operation of the minimum bill provisions, unless a proceeding is instituted under Section 4 or 5 of the Natural Gas Act, seriously jeopardizes the financeability of the project. Specifically, the Commission is asked to approve the Panhandle-Sonatrach contract; particularly the escalator which ties the price of the LNG to the price of $2 and $6 oil. Furthermore, the Commission is urged to approve the shipper contracts, particularly the (1) those permitting increased rates for cost overruns in the LNG tankers themselves, (2) the escalator which tracks interest charges applicable to Title XI bonds, and (3) certain other unavoidable costs as set out in the shipping contracts. In addition, the Commission is asked to approve a cost-of-service tariff to track costs of the Trunkline LNG terminal facilities.

The parties in support of these modifications recommend use of the Presiding Judge's requirement that these adjustments be justified, after they have taken effect, by yearly fillings. With respect to the Panhandle-Sonatrach supply contract, the parties argue that the Pacific Gas Transmission case is inapplicable because that was a case of unilateral price increases, whereas the instant case involves a set index related to the price of $2 and $6 oil. With respect to the shipping costs, Trunkline at the oral argument conceded that a portion of the costs are to be financed by subsidies from the Maritime Administration and that this agency will monitor the costs of the shipbuilding. (Tr. 2901) Tennessee argues that the record is sufficient to approve the shipping contract, and the cost escalators provided therein. Tennessee and others also argue that cost-of-service tariffs to cover, inter alia, Trunkline's LNG terminal costs are not proscribed by the Pacific Gas Transmission case. Furthermore, Tennessee also argues that the decision not to approve a cost-of-service tariff but to rely instead.

--- This is the price for gas delivered at Trunkline Gas' now existing pipeline system.

--- Trunkline's Counsel indicated at oral argument that Trunkline supported the requirement of a Section 4 proceeding with respect to the contract renegotiation provision which requires approval by the Algerian authorities and the Federal Power Commission, or its successor agency, of any contract renegotiation not approved in the supply contract. (Tr. 2909-2900)
on Section 4 procedures for rate changes was not supported by substantial evidence.

Staff generally supported the decision in Opinion No. 796 on this issue, noting that the gas shipped under the supply contract was analogous to the *Pacific Gas* situation because there the Canadian Government was basing the price of exported gas on the price of alternate fuels (oil). With respect to the requested approval of the shipping contracts and the requested cost-of-service tariff to track exceed terminal costs, Staff argues that despite the track exceed record in this case, these costs are unknown or unpredictable. Furthermore, Staff notes that the Commission's initial certification rate reflects a 15% rate of return on common equity which offsets any increased risk in recovery or terminal or other costs through a fixed rate.

With respect to the index in the Panhandle-Sonatrach contract relating to base price of #2 and #6 oil, the Commission finds that Trunkline LNG should be able to track such amounts in its tariff pursuant to a rate adjustment provision which provides for 30 days' notice of such a filing to Trunkline Gas, to the customers of Trunkline Gas and to the affected state commissions, accompanied by appropriate calculations showing that the new rate correctly reflects the application of the escalation provision in the Panhandle-Sonatrach supply contract and that Trunkline LNG has used the correct figures for #2 and #6 oil as required by the supply contract. We find that this is substantially consistent with our treatment of similar provisions in Opinion No. 622-A and will enable Trunkline LNG to recover such costs in a rapid manner. Because of the fact that the formula is reasonably well defined and predictable as to timing, with escalations (i.e., loss of return on or return of equity) if at least 90 percent of the annual volumes were delivered; and (3) credit the purchasers for supply and transportation costs to the extent the Province is able to avoid such costs under its supply and shipping contracts. Upon review, the Commission finds these recommended changes reasonable and shall modify the minimum bill to so provide.

Other parties argue that the minimum bill should permit recovery of return of and return on equity in the event of service interruption and further that Trunkline should not be penalized for loss of equity in cases where the interruption is not the fault of Trunkline. As stated on Opinion No. 796, the provision for a pro rata reduction of both return of and return on equity during periods of service interruptions represents a balancing of the risk between consumers and stockholders. Accordingly, the Commission reaffirms its position herein.

In response to a request for clarification by So-Cal, the Commission notes that Trunkline LNG will be permitted to recover costs actually incurred during the locked-in period, except that capital costs (i.e., debt costs, return on equity, etc.) and the depreciation expense shall be calculated based upon the rates approved by the Commission for Trunkline LNG in the rate case covering the period of interruption.

As discussed above, we find the principles of Trunkline LNG's proposals to modify the minimum bill provisions reasonable. However, Trunkline LNG has proposed a minimum bill based upon a cost-of-service tariff such that all costs incurred over the year would be collected from Trunkline Gas and the appropriate refunds made at the end of the year. However, because the Commission has rejected Trunkline's request for a cost of service tariff set forth in paragraph 4 of Opinion No. 796, a different type of minimum bill is required, as set forth below:

"In the event that Seller is unable to deliver 100 percent of the gas contracted for by Buyer during a monthly billing period, Buyer shall reimburse Seller not only for volumes delivered, but also for contract volumes not delivered, such that Seller will recover on the nondelivered volumes an apportioned share of Seller's non-utility-related fixed expenses incurred during such period, limited to the following:

(a) Operating and maintenance expenses.
(b) Taxes payable.
(c) Interest expense based on that portion of Seller's then existing debt which was incurred for the construction of the LNG and related facilities.
(d) The requirements for repayment of such debt.
(e) Amounts, if any, shall be obligated by penalty for LNG supplies and for ocean transportation under the LNG supply and shipping contract.
(f) All of return on and return in equity on equity in cases where the interruption is not the fault of Trunkline.

Provided, however, that Buyer's obligation to pay for nondelivered amounts shall not extend beyond the time at which Seller, if it is the party claiming force majeure, could have remedied the cause in an adequate manner with all reasonable dispatch in order to resume deliveries to Buyer."

As set forth above, the minimum bill would permit a "swing" of 10% in delivery of volumes without any loss of return of or return on equity. However, should such deliveries fall below the contractual volumes, then Trunkline LNG would be subject to a proportional loss of return of and return on equity. Thus, delivery of 50% of contractual volumes during a given period would entitle Trunkline LNG to recover 50% of its return of and return on equity from all non-equity-related fixed expenses as set forth in subparagraphs (a) through (e) of the minimum bill formula. We view the 10% "swing" provision not as a "guarantee" of return of and return on equity as such, but as a recognition of the need for an allowance: (1) for "down time" on the LNG facilities for maintenance, and (2) for time for short delays in deliveries.

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With regard to the shipping contracts, we are not persuaded that the *Pacific Gas* case is applicable to the instant case based upon the record in this proceeding. With regard to the renegotiation of the contract, the Commission concurs with the statement of Trunkline's Counsel that Section 4 is applicable. As Staff correctly notes, the costs for this portion of the contract are not known and are subject to overruns due to increases in, inter alia, ship construction costs, any change in the $3.37 per MBtu rate necessitated by changes in the shipping arrangements should continue to be subject to review in a Section 4 proceeding for prudence. The Commission wishes to emphasize, however, that the review of shipping costs will not be done on a "cost-plus-fair-return" basis, but rather on a prudent cost incurrence basis. To give up even this limited right of review of such costs would be inconsistent with the responsibility to assure just and reasonable rates for the nation's gas consumers.

The Commission shall similarly reject the request for a cost-of-service tariff to track Trunkline LNG's terminal costs. The terminal is a jurisdictional facility and, as such, the costs related thereto must be reviewed to establish if they are just and reasonable. In reviewing Trunkline LNG's Section 4 application to determine whether or not suspension is appropriate, and if so, the length of suspension required, the Commission shall, of course, consider the necessity of Trunkline LNG, like other jurisdictional facilities to recover their costs of doing business.

**MINIMUM BILL PROVISIONS**

Trunkline has said that if is willing to accept the general outline of the minimum bill if modifications were made that: (1) permit calculation related to the minimum bill on an annual (rather than daily) basis; (2) impositive no penalty (i.e., loss of return on or return of equity) if at least 90 percent of the annual volumes were delivered; and (3) credit the purchasers for supply and transportation costs to the extent Trunkline LNG is able to avoid such costs under its supply and shipping contracts. Upon review, the Commission finds these recommended changes reasonable and shall modify the minimum bill to so provide.

Other parties argue that the minimum bill should permit recovery of return of and return on equity in the event of service interruption and further that Trunkline should not be penalized for loss of equity in cases where the interruption is not the fault of Trunkline. As stated on Opinion No. 796, the provision for a pro rata reduction of both return of and return on equity during periods of service interruptions represents a balancing of the risk between consumers and stockholders. Accordingly, the Commission reaffirms its position herein.

In response to a request for clarification by So-Cal, the Commission notes that Trunkline LNG will be permitted to recover costs actually incurred during the locked-in period, except that capital costs (i.e., debt costs, return on equity, etc.) and the depreciation expense shall be calculated based upon the rates approved by the Commission for Trunkline LNG in the rate case covering the period of interruption.

As discussed above, we find the principles of Trunkline LNG's proposals to modify the minimum bill provisions reasonable. However, Trunkline LNG has proposed a minimum bill based upon a cost-of-service tariff such that all costs

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NOTICES

The reason for the monthly formula, which is eventually adjusted to reflect the calculation of the minimum bill on an annual basis, is that monthly billing under the rate formula prescribed herein, with adjustments at the end of the year, to prevent undue delays in the recovery of Trunkline LNG's costs, would result in the minimum bill which might occur if recovery were delayed until the end of the year.

MISCELLANEOUS

Algonquin, Escagas and Public Service Electric & Gas urge deletion of Ordering Paragraph (L) of Opinion No. 796 because, inter alia, it conditions the Commission's approval of this project under sections 3 and 7 of the Natural Gas Act to the obtaining by Trunkline LNG of all requisite permits, certificates, etc. from applicable state, local and other federal agencies. This, it is argued, subjects the Commission's authority to that of these other affected governmental units and, in effect, gives them the power to veto the Commission's certificates granted herein. Trunkline LNG is already obligated to comply with applicable laws and regulations so that compliance with such provisions is not threatened by deletion of Ordering Paragraph (L). Trunkline LNG does not specifically object to the provision of right to request modification of that condition in the future should it become necessary.

We note that similar conditions have been imposed in previous Commission certificate orders including Transwestern Coald, et al. Opinion No. 728, FPC—issued April 21, 1975 (mimeo, p. 3). Ordering Paragraph (C) and in Columbia LNG, et al. Opinion No. 622, 47 FPC at 1849. We find they are necessary to assure that this project is in the public convenience and necessity. Should a severe problem arise as to this condition, Trunkline LNG may, of course, seek amendment of the certificate in an application under section 3 of the Natural Gas Act stating the reasons therefor.

Tennessee argues for a guaranty of recovery of all costs in the event of project failure. Trunkline LNG states that it will assume the risks associated with project failure and the possibility of not being able to recover its costs. The Commission reaffirms its finding in Opinion No. 796 that such determination should be made at such time as project failure occurs so as to judge the circumstances as they then exist. It is premature at this time to make a determination. Late petitions to intervene were subject to the conditions set forth below.

The Commission finds: (1) Good cause exists to modify Opinion No. 796 as described in the body of this Opinion.

(2) Participation of the above-named petitioners in this proceeding may be in the public interest.

The Commission orders: (A) Opinion No. 796 is hereby modified as set forth in the body of this opinion and order.

(B) To the extent not granted above, the applications for rehearing and motions for reconsideration of Opinion No. 796 are denied.

(C) The above-named petitioners are permitted to intervene in this proceeding as heretofore discussed, subject to the Rules and Regulations of the Commission; Provided, however, that the participation of such intervenors shall be limited to making findings as to their rights and interests specifically set forth in their petitions to intervene; Provided, further, that the granting of such petitions shall not be grounds for delay in this proceeding, and that such intervenors shall take the record as they find it.

(D) The Secretary shall cause prompt publication of this order to be made in the FEDERAL REGISTER.

By the Commission.

KENNETH F. PLUM, Secretary.

[FB Doc. 77-19485 Filed 7-7-77:45 AM]

FEDERAL RESERVE SYSTEM

[FR 2.1977 No. 25]

ACTIONS OF THE BOARD; APPLICATIONS AND REPORTS RECEIVED DURING THE WEEK ENDING JUNE 18, 1977

ACTIONS OF THE BOARD

Regulation J amendment, by adding a new section concerning the wire transfer of funds between member banks (Docket No. R-9013).

The Board of Governors noted that five new Standard Metropolitan Statistical Areas (SMSAs) have been designated and that this affects banks and thrift institutions subject to the Home Mortgage Disclosure Act in those areas.

Pamphlet explaining provisions of the Equal Credit Opportunity Act as it applies to doctors, lawyers and small businessmen is now available for public distribution.

Staff study of private placement activities of commercial banks, letter to Chairman Henry S. Reuss with enclosure of report.

Bank of the Commonwealth, Detroit, Michigan, to make an additional investment in bank premises.

Bank of New Jersey, Camden, New Jersey, to make an investment in bank premises.

English State Bank, English, Indiana, to make an additional investment in bank premises.

Termination of registration for Atlas Credit Union, Wood River, Illinois.

Barnett Bank of Lake Placid, Lake Placid, Florida, proposed merger with Barnett Bank at Sebring, Sebring, Florida, report to the Federal Deposit Insurance Corporation on competitive factors.

Application processed on behalf of the Board of Governors under delegated authority.


Century National Bank of Fort Lauderdale, Fort Lauderdale, Florida, proposed merger with Century National Bank of Broward, Fort Lauderdale, Florida, report to the Comptroller of the Currency on competitive factors.


Merchants and Farmers Bank, Portsmouth, Virginia, proposed merger with First National Bank of Tidewater, Norfolk, Virginia, report to the Comptroller of the Currency on competitive factors.

Plantein Banks and Trust Company, Staunton, Virginia, proposed merger with Augusta Bank & Trust Company, Augusta County, Virginia, report to the Federal Deposit Insurance Corporation on competitive factors.

Second American State Bank, Lubbock, Texas, proposed merger with American State Bank, Lubbock, Texas, report to the Federal Deposit Insurance Corporation on competitive factors.

Correction: On JZ 29, 24.

Statement by Governor J. Charles Partee before the Senate Committee on Banking, Housing and Urban Affairs on H.R. 3675, which permits the payment of interest on Treasury accounts.

Letter to Chairman William Proxmire, Senate Committee on Banking, Housing and Urban Affairs, answering questions regarding monetary velocity—the intensity with which money is being used.

To Establish a Domestic Branch Pursuant to Section 9 of the Federal Reserve Act.

APPROVED

Lake View Trust and Savings Bank, Chicago, Illinois. Branch to be established at 538 West Diversey, Chicago.

Central Bank and Trust Company, Portland, Oregon, Branch to be established in the Portland, Oregon, Branch of First National Bank of Portland, Oregon, to be opened as a Branch of Portland, Oregon, Branch.

English State Bank, English, Indiana, Branch to be established in the Jay-G Plaza Shopping Center at the intersection of U.S. Highway 44 and State Road 37, I., English, Crawford County, Indiana.

Central Bank of Denver, Denver, Colorado, Branch to be established at the intersection of 10th and Larimer Streets, Denver.

To Establish an Overseas Branch of a Member Bank Pursuant to Section 25 of the Federal Reserve Act.

APPROVED

Chase Manhattan Bank, N.A.: Branch—Manila, Philippines.

Croker National Bank: Branch—Manila, Philippines.

Security Pacific National Bank: Branch—Manama, Bahrain.


International Investments and Other Actions Pursuant to Sections 25 and 28(a) of the Federal Reserve Act and Sections 4(e) (9) and 4(e)(13) of the Bank Holding Company Act of 1956, as amended

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES


Bamercan International Financial Corporation: For MBIC International Limited, Australia. To engage in the business of underwriting or dealing in Equity Securities.

To Expand a Bank Holding Company Pursuant to Section 3(a) (3) of the Bank Holding Company Act of 1956.

Hawkeye Bancorporation, Des Moines, Iowa, for approval to acquire 60 per cent or more of the voting shares of Commercial State Bank, Marshalltown, Iowa.

First City Bancorporation of Texas, Inc., Houston, Texas, for approval to acquire 100 per cent (less directors' qualifying shares) of the voting shares of City National Bank of Austin, Austin, Texas.

First International Bancshares, Inc., Dallas, Texas, for approval to acquire 100 per cent of the voting shares (less directors' qualifying shares) of the successor by merger to People State Bank of Baytown, Baytown, Texas.

Denied

D. H. Baldwin Company, Cincinnati, Ohio, for approval to directly acquire 100 per cent of the voting shares of Rifle Bank Agency, Inc., Rifle, Colorado and to indirectly acquire 89.6 per cent or more of the voting shares of The First National Bank of Rifle, Rifle, Colorado.

To Expand a Bank Holding Company Pursuant to Section 4(c) (8) of the Bank Holding Company Act of 1956.

Union Trust Bancorp, Baltimore, Maryland, notification of intent to engage in de novo activities (acting as agent in the sale of insurance collateral and against its extensions of credit) at 119 East Innes Street, Salisbury, North Carolina, through its subsidiaries, Landmark Financial Corporation, North Carolina, and Landmark Mortgage Corporation (wholly-owned subsidiaries of Landmark Financial Services, Inc.).

Reactivated

Industrial National Corporation, Providence, Rhode Island, notification of Intent to engage in de novo activities (the sale of credit life and credit accident and health insurance) at 13 East Schuamberg Road, Schaumberg, Illinois, through a subsidiary, Mortgage Associates, Inc. (6-17-77).

Permitted

Northeast Bankshares Association, Lewiston, Maine, notification of intent to engage in de novo activities (preparing and originating loans and other extensions of credit related to credit card issuance by banks and merchants primarily providing credit card administration, processing and customer service

including distribution of newly approved and renewed credit cards; the calculation and distribution of monthly customer billing; the resolution of customer complaints and billing errors; the receipt of customer payment; and the disbursement of funds to the merchant (the bank customer) at 178 Court Street, Auburn, Maine, through its subsidiary, Northeast Consumer Services Corporation (6-17-77).

Chemical New York Corporation, New York, New York, notification of intent to engage in de novo activities (the origination and sale of mortgage loans collateralized, commercial and industrial real estate; the servicing of mortgage loans owned by The Galeman Mortgage Company and owned by others) in the vicinity of Briley Parkway and Murfreesboro Pike, Nashville, Tennessee and in the vicinity of the Garden area on Westheller Street, Houston, Texas, through its subsidiary, The Galman Mortgage Company (6-16-77).

Citicorp, New York, New York, notification of intent to relocate de novo activities (making of consumer installment personal loans, purchasing consumer installment sales finance contracts; sale of credit related life/accident and health insurance; sale by a financial institution the purchase of which protects personal property) and to engage in de novo in the following additional activity: making loans for the account of others such as one-to-four-family unit mortgage loans) from 3845 Florida Street, Baton Rouge, Louisiana to Cortana Mall, Baton Rouge, Louisiana; through its subsidiary, Citicorp Personal-to-Person Financial Services, Inc.

Philadelphia National Corporation, Philadelphia, Pennsylvania, notification of intent to engage in de novo activities (leasing of real and personal property and providing that at the inception of the initial lease the effect of the transaction will be to yield a return that will not be less than the lessor's full investment in the property over the term of the lease and that the transaction is otherwise in conformity with Section 235.4(a) (9) of Regulation Y) at Broad and Chestnut Streets, Philadelphia, Pennsylvania and 1123 Avenue of the Americas, New York, New York, through its direct and indirect subsidiary, Congress Factors Corporation, at 1155 Avenue of the Americas, New York, New York, through its direct and indirect subsidiary, Congress Financial Corporation and 1401 Brickell Avenue, Miami, Florida, through its direct and indirect subsidiary, Congress Financial Corporation, Florida (6-18-77).

Bank of Virginia Company, Richmond, Virginia, notification of intent to relocate de novo activities (making loans or extensions of credit such as would be made by a finance company; and acting as agent for credit life/accident and health insurance written to protect collateral held by a finance company; and acting as agent or broker for the sale of credit related life and credit related accident and disability insurance in connection with extensions of credit made or bought by customers of finance companies) at 1801 East 47th Street, Denver, Colorado, through its subsidiary, Security Pacific Mortgage Corporation (6-12-77).

To Expand a Bank Holding Company Pursuant to Section 4(c) (12) of the Bank Holding Company Act of 1956.

Warner Communications Inc., New York, New York, notification of intent to merge with or acquire the common stock of Knickerbocker Toy Co., Inc., Middlesex, New Jersey (6-12-77).

Permitted

First Missouri Banks, Inc., Crevoisier, Missouri, prior certification pursuant to § 4168 (a) of the Internal Revenue Code, that the sale by First Properties, Inc., a subsidiary of First Missouri, of 7.3 acres of real property to Gilbert Buck, Inc., St. Louis, Missouri, was necessary or appropriate, to effectuate § 4 of the Bank Holding Company Act. (Legal Division Docket TUR 70-106).

Certificates Issued Pursuant to the Bank Holding Company Act of 1970.

First Missouri Banks, Inc., Crevoisier, Missouri, prior certification pursuant to § 4168 (a) of the Internal Revenue Code, that the sale by First Properties, Inc., a subsidiary of First Missouri, of 7.3 acres of real property to Gilbert Buck, Inc., St. Louis, Missouri, was necessary or appropriate, to effectuate § 4 of the Bank Holding Company Act. (Legal Division Docket TUR 70-106).
NOTICES

APPLICATIONS RECEIVED

To Establish a Domestic Branch Pursuant to Section 9 of the Federal Reserve Act.

Lake View Trust and Savings Bank, Chicago, Illinois. Branch to be established at 535 West Diversey, Chicago.

To Establish an Overseas Branch of a Member Bank Pursuant to Section 25 of the Federal Reserve Act.


To Form a Bank Holding Company Pursuant to Section 3(a) (1) of the Bank Holding Company Act of 1956.

Citicorp, New York, New York, notification of intent to relocate de novo activities (making and acquiring, for its own account, loans and other extensions of credit such as would be made or acquired by a finance company; such activities would include, but not be limited to, making loans and other extensions of credit to small businesses; purchasing installment sales finance contracts; and making loans secured by real property; acting as agent or broker for the sale of credit related life and credit related accident and disability insurance; and credit related property insurance in connection with extensions of credit made or acquired by FinanceAmerica Mortgage Services, Inc.) from 490 Valley Street to 35217 West Phillips Avenue, Seminole, Oklahoma, through its wholly owned subsidiary, Southland Mortgage Corporation, Dallas, Texas.

Security Pacific Corporation, Los Angeles, California, notification of intent to engage in de novo activities (making and acquiring, for its own account, loans and other extensions of credit such as would be made or acquired by a finance company; such activities would include, but not be limited to, making loans and other extensions of credit to small businesses; purchasing installment sales finance contracts; and making loans secured by real property; acting as agent or broker for the sale of credit related life and credit related accident and disability insurance; and credit related property insurance in connection with extensions of credit made or acquired by FinanceAmerica Mortgage Services, Inc.) from 490 Valley Street to 35217 West Phillips Avenue, Seminole, Oklahoma, through its wholly owned subsidiary, Southland Mortgage Corporation, Dallas, Texas.

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First National Bank of California, San Francisco, notification of intent to engage in de novo activities (making and acquiring, for its own account, loans and other extensions of credit such as would be made or acquired by a finance company; such activities would include, but not be limited to, making loans and other extensions of credit to small businesses; purchasing installment sales finance contracts; and making loans secured by real property; acting as agent or broker for the sale of credit related life and credit related accident and disability insurance; and credit related property insurance in connection with extensions of credit made or acquired by FinanceAmerica Mortgage Services, Inc.) from 490 Valley Street to 35217 West Phillips Avenue, Seminole, Oklahoma, through its wholly owned subsidiary, Southland Mortgage Corporation, Dallas, Texas.

West Diversey, Chicago, Illinois. Branch to be established at 4110 North Lincoln Avenue, North, Park Plaza, Tulsa, Oklahoma, through its wholly owned subsidiary, Southland Mortgage Corporation, Dallas, Texas.

Ohio and Southroads Shopping Center, 4945 E. 41st Street, Tulsa, Oklahoma, through its wholly owned subsidiary, Person to Person Financial Center (6-13-77).

Citicorp, New York, New York, notification of intent to relocate de novo activities (making and acquiring, for its own account, loans and other extensions of credit such as would be made or acquired by a finance company; such activities would include, but not be limited to, making loans and other extensions of credit to small businesses; purchasing installment sales finance contracts; and making loans secured by real property; acting as agent or broker for the sale of credit related life and credit related accident and disability insurance; and credit related property insurance in connection with extensions of credit made or acquired by FinanceAmerica Mortgage Services, Inc.) from 490 Valley Street to 35217 West Phillips Avenue, Seminole, Oklahoma, through its wholly owned subsidiary, Southland Mortgage Corporation, Dallas, Texas.

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Southwest Florida Banks, Inc., Fort Myers, Florida, notification of intent to engage in de novo activities (making and acquiring, for its own account, loans and other extensions of credit such as would be made or acquired by a finance company; such activities would include, but not be limited to, making loans and other extensions of credit to small businesses; purchasing installment sales finance contracts; and making loans secured by real property; acting as agent or broker for the sale of credit related life and credit related accident and disability insurance; and credit related property insurance in connection with extensions of credit made or acquired by FinanceAmerica Mortgage Services, Inc.) from 490 Valley Street to 35217 West Phillips Avenue, Seminole, Oklahoma, through its wholly owned subsidiary, Southland Mortgage Corporation, Dallas, Texas.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

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under § 3(a) (3) of the Bank Holding Company Act (12 U.S.C. § 1842 (a) (3)) to acquire 24.9 per cent of the voting shares of Twin Lakes Financial Corporation, Wichita, Kansas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842 (c)). The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than July 26, 1977.


GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

LAKE VIEW BANCORP, INC.
Formation of Bank Holding Company

Lake View Bancorp, Inc., Northbrook, Illinois, has applied for the Board's approval under § 3(a) (1) of the Bank Holding Company Act (12 U.S.C. § 1842 (a) (1)) to become a bank holding company through acquisition of 99.9 per cent of the voting shares of Lake View Trust and Savings Bank, Chicago, Illinois. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842 (c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than July 26, 1977.


GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

MIDLAND CAPITAL CO.
Order Approving Formation of Bank Holding Company and Acquisition of Midland Mortgage Co.

Midland Capital Co., Oklahoma City, Oklahoma, has applied for the Board's approval under § 3(a) (1) of the Bank Holding Company Act (12 U.S.C. § 1842 (a) (1)) of a bank holding company through acquisition of 100 per cent of the voting shares of Midland Bank (Bank), of which Midland is the holding company. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842 (c)).

Applicant has also applied pursuant to § 4(a) (8) of the Act (12 U.S.C. § 1843 (c) (8)) and § 225.4(a) (2) of the Board's Regulation Y, for the Bank's approval to acquire 76 per cent of the voting shares of Midland Mortgage Co., Oklahoma City, Oklahoma ("Mortgage"), a company principally engaged directly and through a wholly owned subsidiary, Johnston-Records Co., in the general business of mortgage banking, including the origination and servicing of conventional, FHA and VA, and savings and loan mortgage loans. The mortgage banking activities of Applicant proposes to engage in have been determined by the Board to be closely related to banking (12 C.F.R. § 225.4(a) (1)).

Notice of the applications, affording opportunity for interested persons to submit comments and views, has been given in accordance with §§ 3 and 4 of the Act (12 U.S.C. § 1842). The time for filing comments and views has expired, and the Board has considered the applications and all comments received in light of the factors set forth in § 3(c) of the Act and the considerations specified in § 4(a) (8) of the Act.

Applicant is a non-operating corporation organized for the purpose of becoming a bank holding company through the acquisition of Bank and of engaging in the general business of mortgage banking through the acquisition of Mortgage. Bank, with deposits of approximately $24.5 million, has capital approximately 0.2 per cent of total commercial bank deposits in the State and is the 36th largest banking organization in the Oklahoma City market.7 The time for filing comments and views has expired, and the Board has considered the applications and all comments received in light of the factors set forth in § 3(c) of the Act and the considerations specified in § 4(a) (8) of the Act.

The financial and managerial resources and future prospects of Applicant, which are dependent upon those of Bank and Mortgage, are considered satisfactory, which are dependent upon those of Bank and Mortgage, are considered satisfactory, which are dependent upon those of Bank and Mortgage, are considered satisfactory, which are dependent upon those of Bank and Mortgage, are considered satisfactory.
to other considerations, the Board finds Mortgage both compete in the Oklahoma mortgage loan servicing portfolio of the Bank and Mortgage as described above, at four locations in the Oklahoma City area and in Lawton, Tulsa, and Broken Arrow, Oklahoma; Tucson, Phoenix, and Prescott, Arizona; Houston and San Antonio, Texas; Denver, Colorado Springs, Pueblo, and Canon City, Colorado; and Tustin, California. As of July 31, 1976, Mortgage ranked as the 56th largest mortgage servicer in the United States, with a mortgage loan servicing portfolio of $575.5 million. During 1976, it originated in excess of $121 million in residential and commercial loans.

Bank and Mortgage are presently under common ownership. Bank, having been acquired by a principal of Mortgage during the latter half of 1976, Bank and Mortgage both compete in the Oklahoma City market in the origination of mortgage loans in family residential properties. During 1976, Mortgage originated $19.5 million of such mortgages while Bank originated $9.4 million. Approval of Applicant's proposal would have some adverse effects on competition in the origination of loans on 1-4 family residential properties in the relevant market, but the Board does not regard such effects as being particularly significant in view of the relatively small market shares (Bank and Mortgage accounted for about three percent of the 1-4 family mortgage origination) and the large number and variety of mortgage lenders with respect to the market. On the other hand, consummation of the proposal whereby Applicant will acquire Bank and Mortgage will result in a well-capitalized and financially strong organization capable of providing an increased variety of banking and mortgage activities to the public. The Board regards such results as positive factors in its consideration of the proposal. In addition, with respect to other considerations, the Board finds no evidence in the record that consummation of the proposal would result in an undue concentration of resources, conflicts of interests, unsound banking practices or other adverse effects upon the public interest.

In connection with the application to acquire Mortgage, the Board has also considered Mortgage's ownership of 100 percent of the shares of Midland Property Management Co. and Midland Center Co., both of which are essentially inactive corporations that exist for the sole purpose of owning Midland Realty Co., a general partnership that holds title to and operates Midland Center, an office building in downtown Oklahoma City, Oklahoma, that serves as the head office for Mortgage's operation. Mortgage currently has approximately 18.9 percent of the total available space in Midland Center with the remainder leased to third parties with an annual rental of approximately $19.5 million. Although Applicant has indicated that it and its subsidiaries ultimately plan to occupy all of the space in Midland Center and that it expects to occupy up to 25 percent of the building at an initial stage of development of a data processing system for Mortgage's operation, it is estimated that it will be nine years before the building is at least 50 percent occupied by Applicant.

Based on Applicant's projections for the future utilization of Midland Center, the Board is unable to conclude that Applicant's interest in Midland Center is insignificant or that it should be regarded as "functional activities ... necessary to carry on the activities" of Mortgage, within the meaning of § 225.4(a) of Regulation Y. Accordingly, under § 225.4(a) of the Act, Applicant's application is required to dispose of its direct or indirect ownership or control of Midland Center within two years from the date it becomes a bank holding company.

Based on the foregoing and other considerations reflected in the record, the Board has determined that the considerations affecting the competitive factors under § 3(c) of the Act and the balance of the public interest factors set forth in § 4(d) (b) of the Act both favor approval of Applicant's proposed transaction, and that these applications should be approved.

The acquisition of Bank shall not be made before the thirtieth calendar day following the effective date of this Order; and neither the acquisition of Bank nor the commencement of the above-described mortgage business activities shall be accomplished later than three months after the effective date of this Order, unless such period is extended for good cause by the Board of Governors of the Federal Reserve System or by the Federal Reserve Bank of Richmond pursuant to delegated authority.


ROBERT P. BLACK, President.
NOTICES

PIEDMONT BANKGROUP INC.
Order Approving Formation of Bank Holding Company

Piedmont Bankgroup Incorporated, Martinsville, Virginia (Applicant), has applied for prior approval under Section 3(a) (1) of the Bank Holding Company Act (12 U.S.C. § 1842(a) (1)) to become a bank holding company through the acquisition of 100 percent of the voting shares of the successors by merger to the Piedmont Trust Bank (Piedmont), Collinsville, Virginia, a State member bank and the Bank of Carroll (Carroll), Hillsville, Virginia, a State nonmember bank. The banks into which Piedmont and Carroll are to be merged have no significant interstate branches and the proposed acquisition of the shares of the two banks. Accordingly, the proposed acquisition of the success or organizations are treated herein as the proposed acquisition of the shares of the banks. The application is to be acted upon by the Federal Reserve Bank of Richmond (Reserve Bank) under authority delegated by the Board of Governors (12 C.F.R. 265).

Notice of the receipt of the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with Section 3(b) of the Act, and the time for filing comments and views has expired. The Reserve Bank has considered the application and all comments received in light of the factors set forth in Section 3(c) of the Act (12 U.S.C. § 1842 (c)).

Applicant has no present operations and the two banks to be acquired are located in distinctly separate commercial banking markets. Piedmont ranks second with 35.8 percent of deposits in Carroll County and the City of Martinsville while Carroll ranks fourth with 6.9 percent of deposits in Carroll County and the City of Galax. These relative positions will not be influenced by holding company affiliation and, under State law, neither bank will establish de novo branches in the market of the other. Consummation of the proposal, therefore, would eliminate neither existing nor potential competition and would not appear to have adverse effects on other banks in the respective areas. Consequently, the factors related to competition are consistent with approval.

The banking factors, including future prospects and managerial resources of Applicant, are considered satisfactory. Therefore, convenience and needs of community could be served and are consistent with approval. In particular, it appears that the acquisition of Carroll would enable the latter to offer a full line of banking services and become more responsive to the banking needs within its market. Accordingly, it is the Reserve Bank's judgment that the proposed transaction would be in the public interest and that the application may be approved.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be consummated (a) before the thirtieth calendar day following the effective date of this Order or (b) later than three months after the effective date of this Order, unless such period is extended for good cause by the Board of Governors of the Federal Reserve System or by the Federal Reserve Bank of Richmond pursuant to delegated authority.

By order of the Federal Reserve Bank of Richmond, acting pursuant to delegated authority for the Board of Governors of the Federal Reserve System, effective June 30, 1977.

ROBERT F. BLACK,
President.

[FR Doc.77-19409 Filed 7-7-77;8:45 am]

REPUBLIC OF TEXAS CORP.
Acquisition of Bank

Republic of Texas Corporation, Dallas, Texas, has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a) (3)) to acquire 100 percent, less directors' qualling shares, of the voting shares of First Bank & Trust, Carrollton, Texas. The factors the Board will consider in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842 (c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be reviewed, or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be reviewed, or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be reviewed, or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be reviewed, or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be reviewed, or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be reviewed.


GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc.77-19413 Filed 7-7-77;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration

ADVISORY COMMITTEE

Notice of Meetings; Correction

In FR Doc. 77-16995 appearing on page 30906 in the Federal Register of Friday, June 17, 1977: On page 30901, entry No. 8, “Neurological Device Classification Panel,” under the column “Type of meeting and contact person,” is corrected to read “Open public hearing July 22, 9 a.m. to 10 p.m.; open committee discussion July 22, 10 a.m. to 4 p.m.; July 23, 9 a.m. to 4 p.m. * * * ”

Dated July 1, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-16941 Filed 7-7-77;8:45 am]

SIERRA PETROLEUM Co., INC.
Acquisition of Bank

Sierra Petroleum Co., Inc. (Applicant), Wichita, Kansas, has applied for the Board's approval under § 3(a) (3) of the Bank Holding Company Act (12 U.S.C. § 1842(a) (3)) to acquire 24.9 percent of the voting shares of Twin Lakes Financial Corporation, Wichita, Kansas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than July 23, 1977.


GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc.77-19410 Filed 7-7-77;8:45 am]

TWIN LAKES FINANCIAL CORP.
Formation of Bank Holding Company

Twin Lakes Financial Corporation, Wichita, Kansas, has applied for the Board's approval under § 3(a) (1) of the Bank Holding Company Act (12 U.S.C. § 1842(a) (1)) to become a bank holding company through acquisition of 98.9 percent of the voting shares of Twin Lakes State Bank, Wichita, Kansas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be reviewed, or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be reviewed.


GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc.77-19412 Filed 7-7-77;8:45 am]

ELANCO PRODUCTS CO., ET AL.
Penicillin-Streptomycin Premixes; Extension of Time To File Data Supporting Request for Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice extends to August 10, 1977, the time for filing data upon which a request for hearing relies concerning a proposal to withdraw approval of new animal drug applications for penicillin-streptomycin premixes.

DATES: Written appearances requesting a hearing must be submitted by July 11, 1977; data supporting the request must be filed by August 10, 1977.

ADDRESS: Written submissions to the Hearing Clerk (HFC-20), Food and
Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Donald Gable, Bureau of Veterinary Medicine (HFF-100), Food and Drug Administration, the Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, (301-443-4213).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is extending until August 10, 1977, the time for filing data to support a request for hearing on the subject notice, published in the Federal Register of June 10, 1977 (42 FR 29999), proposing to withdraw approval of new animal drug applications providing for use of penicillin-streptomycin preemixes.

The June 10, 1977, notice gave interested persons until July 11, 1977, to file the data.

The Director of the Bureau of Veterinary Medicine, FDA, has received a request for an extension of an additional 30 days to respond to the subject notice. Because of the amount of scientific material which must be reviewed and evaluated, the request for an additional 30 days is granted.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512, 21 Stat. 343-381 (21 U.S.C. 360b)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.9) (formerly 21 CFR 5.29) prior to recodification published in the Federal Register of March 15, 1977 (42 FR 14302), be amended to provide for the safe use of polyamidol-epichlorohydrin resin, modified by reaction with formaldehyde, as a wet strength agent in the manufacture of paper and paperboard for food-contact use.

The environmental impact analysis report and other relevant materials have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m. Monday through Friday.

Dated: June 24, 1977.

HOWARD R. ROBERTS, Acting Director, Bureau of Foods.

[FR Doc.77-19403 Filed 7-7-77; 8:45 am] Food and Drug Administration [Docket No. TFR-0055]

LIBBY, McNEIL & LIBBY, INC.

Canned Pears Deviating From Identity Standards; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTI0N: Notice.

SUMMARY: This document announces that a temporary permit has been issued to Libby, McNeil & Libby, Inc., as requested, to market a new style of canned pears designated as "chunky." The finished product deviates from the standard of identity prescribed in §175(a) (formerly §175.1) allowing the company to conduct interstate marketing tests of canned pears that deviate from the standard of identity prescribed in §145.-150 (formerly §150.7) prior to recodification published in the Federal Register of March 15, 1977 (42 FR 14302) and provides for the temporary marketing of pears cut into units predominately greater than 1/2 inch and less than 1 1/2 inches in the largest dimension and designated as "chunky" pears, an optional style not provided for in the standard. The product will be packed in heavy syrup and will contain artificial strawberry flavor both of which are already provided for by the standard.

This permit provides for the market testing of 50,000 cases of twenty-four 16-ounce cans of test product. The product will be packed by Libby, McNeil & Libby, Inc., in Sunnyvale, California, and will be marketed in Western New York State, the States of Iowa and Nebraska, and the cities of Erie, Pennsylvania, and Moline and Rock Island, Illinois.

In addition to the name "chunky pears," the principal display panel will contain the words "in heavy syrup." The ingredients used will be declared on the label in accordance with Food, Drug, and Cosmetic Act (21 U.S.C. 341).

Dated: June 29, 1977.

WILLIAM F. RANDOLPH, Acting Associate Commissioner for Compliance.

[FR Doc.77-10028 Filed 7-7-77; 8:45 am] [Docket No. TFR-0048]

METABOLIC, INC.

Hearing and Prehearing Conference on Proposed Revocation of U.S. License No. 415

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a formal evidentiary public hearing, and a prehearing conference, on the factual issues relating to the Bureau of Biologics' proposed revocation of U.S. License No. 415 issued to Metabolic, Inc., 4520 Yonkum Blvd., Houston, TX, for the manufacture of four biological products at six locations.

DATES: Hearing July 25, 1977, beginning at 9 a.m.; prehearing conference
NOTICES

July 19, beginning at 1 p.m.; written
notices of participation by July 18.

ADDRESSES: Prehearing conference and
hearing will be held in FDA Hearing
Room, Rm. 4-A-33, 5600 Fishers Lane,
Rockville, Md. Written notices of
participation identified by the above
docket number to FDA Hearing Clerk,
Rm. 4–65, 5600 Fishers Lane, Rockville,
MD 20857.

FOR FURTHER INFORMATION CON- TACT:
John F. Harty, Jr., Compliance Regu-
lations Policy Staff (HPC–10), Food
and Drug Administration, Department
of Health, Education, and Welfare,
5600 Fishers Lane, Rockville, MD
20857; 301–443–4530.

SUPPLEMENTARY INFORMATION: A
notice of opportunity for a hearing was
published in the Federal Register of
May 13, 1977 (42 FR 24323), on the
Bureau of Biologics’ proposal to revoke U.S.
License No. 415. Significant deviations
from standard biological procedures and
the failure to submit products for lot
release and/or licensure were cited as
grounds for the proposed revocation.

The notice was preceded by a suspen-
sion pursuant to 21 CFR 12.85(b) of
locations operating under the license on
February 25, 1977. The remaining
locations were suspended on April 26, 1977.

The Notice further informed Metabolic,
Inc., would not delay the ad-
ministrative proceedings, a notice was
invited the licensee to submit a written
request for a hearing.

Upon May 3, 1977, the licensee, Meta-
bolite, Inc., filed suit in the United States
District Court for the Southern District
of Texas to compel the Food and Drug
Administration to release the suspension.

On May 20, 1977, the Commissioner
directed that Metabolic, Inc., pursue its
administrative remedy on the ultimate
question of revocation. (Civil No.
H77CA676).

In accordance with applicable regu-
lations, the Commissioner notes that
deviations in order to legally support revoca-
tion

1. Whether more than the maximum
permmissible amount of whole blood was
removed from donors at one time.

2. Whether the amount of whole blood
removed from donors within a 7-day
period exceeded the maximum possible
amount, or whether donors were plas-
mapheresed more than twice within 7
days.

3a. Whether samples of blood for the
serum protein electrophoresis test were
drawn at least every 4 months, or
whether the results were in the
 donor record file and available for
physician review and, in each case, do-
 nors continued to be plasma-
pheresed.

b. Whether donors were plasma-
pheresed beyond the date when the required
annual physical examination was to
have been performed.

4. Whether equipment was properly
standardized and/or performing in the
manner for which it was designed so as
to assure compliance with the require-
ments prescribed by FDA for Source
Plasma (Human), Surface Antigen (Hem-
ophilus), and other products. (To
assign to this item in its request for a hearing
discussed the use of a refractometer in
testing protein control values).

The hearing, however, will consider cen-
trifuges for plasma separation, trip scales
used to control plasma donations and
hematocrit centrifuges.

5. Whether Source Plasma (Human)
was stored at a temperature of -20° C or
colder.

6. Whether there were adequate pro-
cedures for notifying collection facilities
and donors of a reactive test for hepatitis
B surface antigen (HBsAg).

7. Whether records of each step in the
manufacture, and distribution of prod-
ucts were made in such a manner that
 successive steps in the manufacture and
distribution of any lot could be traced,
including identification for hepatitis
testing of donor samples and the stor-
age, location, and shipment of plasma
received from the collections locations.

Whether there was an adequate con-
trol and supervision of management and
other employees by the responsible head
of the establishment to assure compli-
ance with applicable regulations, with
the terms of its license, including Meta-
bolite standard operating procedures and
with other directives from the respons-
able head, particularly with respect to
overbilling; donor identification and
plasma collection and separation pro-
cedures.

9. Whether Metabolic has (a) manu-
factured and shipped in interstate com-
mmerce Pertussis Immune Globulin
without a license; or (b) manufactured
and shipped in interstate commerce any
bulk fraction without a license and/or
without first having obtained lot release
from the Bureau; or (c) processed a
sample-size amount of Immune Serum
Globulin with high purity titer, sub-
mitted it to the Bureau as representa-
tive of a lot, and released Bureau
release, processed the lot.

10. Whether Metabolic shipped in
interstate commerce a biological product
after suspension of a portion of its li-
cense on February 25, 1977.

These issues involve provisions of the
Public Health Service Act and appli-
cable regulations in 21 CFR Parts 600, 600,
610, and 640, which were identified with
particularity in the Notice of Opportu-
nity for Hearing.

The objectionable conditions which
form the basis for the Bureau’s action
were noted during the following inspec-
tions of locations suspended in Febru-
ary: Corpus Christi, January-February
1977; Houston (Almeda Street), April
1976, February 1977; Houston (La-
Branch Street), April 1976 and Febru-
ary 1977; Houston fractionation facility
(Yoakum Boulevard and additional
storage locations), February and April
1977. In addition, objectionable con-
ditions reflected in the issues on which a
hearing is granted were observed by FDA
officials in three locations not suspended
in February but listed in the Notice of
Opportunity for Hearing and in the sus-
pension letter of April 26, 1977 which ad-
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license or from published biologics regulations need not be shown to have resulted in some demonstrable public harm; improper manufacturing practices must be halted because they create a risk of harm, which may become manifest at any particular time, place, or manner, or not at all. (See United States v. Bel-Mar Laboratories, Inc., 284 F. 2d 875 (7th C.A. 1960).) Metabolic's contentions do not demonstrate that the deviations from the license terms or regulations sufficient to justify revocation.

At this time, however, the Commissioner is denying Metabolic's request that he lift the suspension letters on the grounds that it is insufficiently and properly adverse. That procedure includes the following basic requirements: (1) The license application, particularly standard operating procedures, is revised as necessary, (2) The applicant begins operation on a pilot basis; and (3) An inspection is conducted to determine whether the applicant appears to be operating in compliance with the license, the standard operating procedures, and all applicable regulations. Reinstatement without prior inspection would be inconsistent with the obligation of FDA to protect the public health by ensuring that the premarket licensure scheme established by section 352 of the Public Health Service Act.

Metabolic has also requested that FDA approve for release all products that have been submitted to the Bureau of Biologics for approval. That request is denied at this time. Questions of fact surrounding the Metabolic licensure and lot release practices (see item 9 above) must be first resolved, since these questions bear upon Metabolic's approach to the basic statutory and regulatory scheme. If the hearing should disclose and the Commissioner conclude that the Metabolic license should not be revoked, the Commissioner will review the question of the release of products now on hand.

Metabolic objected to that portion of the Notice of Opportunity for Hearing which incorporated by reference deficiencies noted in the February and April suspension letters on the grounds that this constituted inadequate specification of the basis for the hearing. Metabolic also contended that these letters had been "sufficiently" and properly answered. The Commissioner believes incorporation by reference is proper.

Metabolic's request that the hearing be held in Houston, Texas, is denied. The Administrative Law Judge and all Bureau of Biologics personnel are in Rockville and cannot be moved without significant inconvenience.

The prehearing conference will begin July 19, 1977 at 1 p.m. and the hearing will begin July 25, 1977 at 9 a.m., unless otherwise ordered. The presiding Administrative Law Judge will be Daniel J. Davidson.

Any participant may appear in person, or with counsel or other qualified representative, and may be heard with respect to matters relevant to the issues under consideration. Nonparty participants shall disclose data and information pursuant to § 12.38 by 5 days after the last day of the hearing.

Dated: July 6, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

Health Resources Administration

ADVISORY COMMITTEE

Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-458), announcements are made of the following National Advisory bodies scheduled to meet during the months of July and August 1977:

**NOTICES**

**35223**

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES

U. S. C., and the Determination by the Deputy Administrator, Health Resources Administration, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Mr. David McFall, National Center for Health Services Research, Room 7-50A, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, Telephone (301) 436-6508.

Name: National Advisory Council on Nurse Training.

Dated: June 29, 1977.

JAMES A. WALSH,
Associate Administrator for Operations and Management.

[FR Doc.77-19210 Filed 7-7-77;8:45 am]

ADVISORY COMMITTEE

Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory bodies scheduled to meet during the months of August and September 1977:

Name: National Advisory Council on Health Professions Education.

Secretary and Administrator, Health Resources Administration, pursuant to Pub. L. 92-463, announcement is made in accordance with provisions set forth in section 552b(c) (6), Title 5 U.S.C., and the Determination by the Deputy Administrator, Health Resources Administration, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Mr. David McFall, National Center for Health Services Research, Room 7-50A, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, Telephone (301) 436-6508.

Place: Wright/Farman Conference Room, National Institutes of Health, Building 10, Bethesda, Maryland 20892.

Purpose. The Committee is changed with the initial review of grant applications for Federal assistance in the program areas administered by the National Center for Health Services Research.

Agenda. The open session of the meeting of September 25, 1977, will be devoted to a discussion of review procedures. During the closed session, the Study Section will be reviewing Health Services Policy Analysis Center grant applications relating to the responsibility for analyzing existing and proposed national policies that are designed to improve the performance of the health care system. The closing is in accordance with provisions set forth in section 552b(c) (6), Title 5 U.S.C., and the Determination by the Deputy Administrator, Health Resources Administration, pursuant to Pub. L. 92-463.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should contact Mr. David McFall, National Center for Health Services Research, Room 7-50A, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782, Telephone (301) 436-6916.

Special. Agenda Items are subject to change as priorities dictate.

Dated: June 29, 1977.

JAMES A. WALSH,
Associate Administrator for Operations and Management.

[FR Doc.77-19211 Filed 7-7-77;8:45 am]

LONG-TERM CARE ADVISORY COMMITTEE

Announcement of Meeting Cancellation

In Federal Register Document 77-18951 appearing at page 28926 in the issue for Monday, June 6, 1977, the July 14-15, 1977, meeting of the "Long-Term Care Advisory Committee" has been cancelled. The meeting was to be rescheduled at a later date, and announcement made in the Federal Register accordingly.

Dated June 29, 1977.

JAMES A. WALSH,
Associate Administrator for Operations and Management.

[FR Doc.77-19213 Filed 7-7-77;8:45 am]

National Institutes of Health ADVISORY COMMITTEES

Open Meetings

Pursuant to Public Law 92-463, notice is hereby given of the meetings of committees advisory to the National Cancer Institute.

These meetings will be entirely open to the public to discuss issues relating to committee business as indicated in the notice. Attendance will be limited to space available. Meetings will be held at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014, unless otherwise stated.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31,
Executive Secretary: Dr. Richard A. Talma, Building 31A, Room 11A46, National Institutes of Health. Phone: 301/496-7630.

EXPERIMENTAL DESIGN SUBGROUP OF THE CLEARINGHOUSE ON ENVIRONMENTAL CARCINOGENS

Dates: August 30, 1977; 8:30 a.m.—adjournment.
Place: Building 31C, Conference Room 10, National Institutes of Health.
Times: Open for the entire meeting.
Agenda: To discuss chemicals for bioassay and other matters relevant to experimental design.
Executive Secretary: Dr. J. Dan Recer, Building 31, Room 3A16, National Institutes of Health. Phone: 301/496-7630.

REVIEW OF CONTRACT PROPOSALS

Meetings
Pursuant to Public Law 92-463, notice is hereby given of the meetings of contract proposals. These meetings will be open to the public to discuss administrative details or other issues relating to contract proposals, as indicated, and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposals.

EXECUTIVE SECRETARY: To review the activities of the Committee on Cancer Immunotherapy, National Cancer Institute, August 15, 1977, Building 10, Room 4B14, National Institutes of Health. This meeting will be open to the public on August 18, 1977, from 1:15 p.m. to 1:45 p.m. to consider administrative details. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92-463, the meeting will be closed to the public on August 17, 1977, from 1:45 p.m. to adjournment, for the review, discussion and evaluation of individual contract proposals. These proposals and the discussions could reveal confidential information concerning individuals associated with the proposals.

Mrs. Marjorie F. Early, Committee Management Officer, National Cancer Institute, Building 31, Room 3A09, National Institutes of Health. Phone 301/496-6616.

(Notice published in the Federal Register, Vol. 42, 552b(c) (4) and 552b(c) (6), Title 5, U.S. Code and Section 10(d) of Public Law 92-463, for the review, discussion and evaluation of individual contract proposals, as indicated. These proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposals.)
NOTICES

Cardiology Advisory Committee

Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Cardiology Advisory Committee, National Heart, Lung, and Blood Institute, September 23, 1977, National Institutes of Health, Building 31, Conference Room 8.

The entire meeting will be open to the public from 8:30 A.M. to 5:00 P.M. Attendance by the public will be limited to space available.

Mr. York Oomen, Chief, Public Inquiries and Reports Branch, National Heart, Lung, and Blood Institute, Federal Building, Room 5A03, National Institutes of Health, Bethesda, Maryland 20014, phone (301) 496-4236, will provide summaries of the meeting and rosters of the Committee members.

Peter L. Frommer, M.D., Associate Director for Cardiology, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, Federal Building, Room 320, Bethesda, Maryland 20014, phone (301) 496-5421, will furnish substantive program information.

Dated: June 27, 1977.

Suzanne L. Fremau, Committee Management Officer, National Institutes of Health.
[FR Doc. 77-19264 Filed 7-7-77; 8:45 am]

Advisory Committee

Amended Notice of Meeting

Notice is hereby given of a change in the meeting time of the National Commission on Digestive Diseases, National Institute of Arthritis, Metabolism, and Digestive Diseases, which was published in the Federal Register on June 14, 1977, 42 FR 30433.

This Commission was to have convened at 8:30 a.m. on July 21, 1977, but has been changed to 9:30 a.m. The entire meeting will be open to the public from 9:30 a.m. to 5:00 p.m., July 22, 1977.


Suzanne L. Fremau, Committee Management Officer, National Institutes of Health.
[FR Doc. 77-19264 Filed 7-7-77; 8:45 am]

Planning and Agenda Work Group of the National Advisory Research Resources Council

Meeting

Notice is hereby given of the meeting of the Planning and Agenda Work Group of the National Advisory Research Resources Council (NARRC) on Tuesday, August 16, 1977, from 9:00 a.m. to 3:00 p.m., in Room 5B03, Building 31, National Institutes of Health, Bethesda, Maryland 20014. The entire meeting will be open to the public. The Planning and Agenda Work Group will discuss the development of Council Agenda for the September 19-20 meeting of the NARRC. Council to Council communications, and subject matter for the annual Council review of the Biotechnology Resources Program of the Division of Research Resources. Attendance by the public will be limited to space available.

Mr. James Augustine, Information Officer, Division of Research Resources, National Institutes of Health, Room 5B13, Building 31, Bethesda, Maryland 20014 (301) 496-5545, will provide summaries of the meeting and rosters of the Work Group members, and Dr. James P. O’Connell, Deputy Director, Division of Research Resources, National Institutes of Health, Room 5B03, Building 31, Bethesda, Maryland 20014 (301) 496-6029, will furnish substantive program information.


Suzanne L. Fremau, Committee Management Officer, National Institutes of Health.
[FR Doc. 77-19266 Filed 7-7-77; 8:45 am]

Allergy and Immunology Research Committee

Amended Notice of Meeting

Notice is hereby given of changes in the meeting date and place of the Allergy and Immunology Research Committee, National Institute of Allergy and Infectious Diseases, which was published in the Federal Register on June 10, 1977 (42 FR 30006).

The Committee was to have met on July 20, 1977, in Conference Room 8 but has been changed to meet on July 29, 1977, in Conference Room 6.

Dated: June 27, 1977.

Suzanne L. Fremau, Committee Management Officer, National Institutes of Health.
[FR Doc. 77-19266 Filed 7-7-77; 8:45 am]

Host-Phage Vector

Notice of Workshop

Notice is hereby given of a Workshop on Design of Tests for ER3 Host-Phage Vector Systems sponsored by the Recombinant DNA Molecule Program Advisory Committee at the National Institutes of Health, Conference Room 9, Building 31C, 9000 Rockville Pike, Bethesda, Maryland, 20014, July 19, 1977 from 9:00 a.m. to 6:00 p.m.

Further information may be obtained from Dr. William J. Garland, Executive Secretary, Recombinant DNA Molecule Program Advisory Committee, NIGMS, NIH, Building 31, Room 4A52, Bethesda, Maryland—telephone 301/496-2323. The workshop will be open to the public. Attendance by the public will be limited to space available.


Suzanne L. Fremau, Committee Management Officer, National Institutes of Health.
[FR Doc. 77-19268 Filed 7-7-77; 8:45 am]

Minority Access to Research Careers Review Committee

Amended Notice of Meeting

The date for the meeting of the Minority Access to Research Careers Review Committee scheduled to begin on Thursday, July 21, 1977, at 9 a.m. has been changed to Wednesday, July 20, 1977, at 9 a.m. in Wilson Hall, Building 1, National Institutes of Health, Bethesda, Maryland. The Committee will meet July 21, 22, and 23 in Conference Room 8, Building 31C, National Institutes of Health, Bethesda, Maryland. The open portion of the meeting will begin at 8:30 a.m. on July 20.

The agenda and other information relating to the committee meeting, as published in the Federal Register (42 FR 30560) Wednesday, June 15, 1977, remain unchanged.

Dated: June 27, 1977.

Suzanne L. Fremau, Committee Management Officer, National Institute of Health.
[FR Doc. 77-19269 Filed 7-7-77; 8:45 am]

Public Health Service

Coal Gasification

Request for Information


ACTION: Notice of request for information.

SUMMARY: This notice solicits information concerning coal gasification. The information will be used in the development of criteria for a recommended standard for occupational exposures in the coal gasification industry.

DATES: Comments concerning this notice should be submitted by October 5, 1977.

ADDRESSES: Comments and recommendations should be submitted in writing to: Mr. Vernon E. Rose, Director, Division of Criteria Documentation and Standards Development, National Institute for Occupational Safety and Health, 5600 Fishers Lane (Park Bldg, Rm 3-18), Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Murray L. Cohen, Project Administrator, Priorities and Research Analysis Branch, NIOSH, 301-443-2100.
SUPPLEMENTARY INFORMATION: Section 20(a)(3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 659(a)(3)) provides that the Secretary of Health, Education, and Welfare, on the basis of information available to him, shall develop criteria dealing with toxic materials which will describe exposure levels that are safe for various periods of employment. Section 20(a)(4) of the Act authorizes the National Institute for Occupational Safety and Health (NIOSH) to conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems including those created by new technology. Section 25(c) authorizes NIOSH to develop recommended occupational safety and health standards and to perform all functions of the Secretary of Health, Education, and Welfare, under sections 20 and 21 of the Act.

In this particular process-oriented recommended standard, NIOSH does not plan to recommend workplace environmental limits for all products or intermediates involved in coal gasification. Because of the vast number of chemical species, their varying toxicities, the unique safety hazards, and because the potential for exposure to suspected chemical carcinogens is exceedingly important consideration, work practices and engineering controls designed to limit occupational exposure, methods to educate the employee and employer, and methods of biological workplace monitoring will be recommended in addition to specific environmental limits.

The criteria document will include among other items an evaluation of available information relative to the areas listed below. Any person having information or data in any of these areas or in other areas considered relevant to the establishment of a safe and healthful occupational environment involving vinyls is requested to submit such information, with accompanying documentation.

1. Establishment of safe occupational environmental levels for such agents including levels for acute and chronic exposure to airborne concentrations of the chemical agents as well as safe practices concerning direct contact with such agents.

2. Establishment of biologic standards i.e., the levels of such agents, metabolites, or other effects of exposure which may be present within man without his suffering ill effects taking into consideration (a) the correlation of airborne concentrations of, and extent of exposure to such substances with effects on specific biologic systems of man such as the circulatory, respiratory, urinary, and nervous system, and (b) the analytical methods for determining the amount of the substance which may be present within man.

3. Engineering controls, including ventilation, environmental temperature, humidity, and housekeeping and sanitation procedures, with attention to the technological feasibility of such controls.

4. Specifications for the conditions under which personal protective devices should be required.

5. The need for medical examinations for workers exposed to such agents, the frequency of such examinations, and the specific diagnostic tests which should be used and the rationale of their selection.

6. Work practices or procedures which may be instituted for control of the workplace environment in normal operations and those which may be instituted when emergency or unusual situations occur.

7. Types of records concerning occupational exposure to such agents that employers should be required to maintain.

This criteria document will include among other items an evaluation of available information relative to the areas listed below.

Any person having information or data in any of the areas listed below, or in other areas considered relevant to the establishment of a safe and healthful occupational environment involving vinyls, is requested to submit such information, with accompanying documentation.

1. Establishment of safe occupational environmental levels for such agents including levels for acute and chronic exposure to airborne concentrations of the chemical agents as well as safe practices concerning direct contact with such agents.

2. Establishment of biologic standards i.e., the levels of such agents, metabolites, or other effects of exposure which may be present within man without his suffering ill effects taking into consideration (a) the correlation of airborne concentrations of, and extent of exposure to such substances with effects on specific biologic systems of man such as the circulatory, respiratory, urinary, and nervous system, and (b) the analytical methods for determining the amount of the substance which may be present within man.

3. Engineering controls, including ventilation, environmental temperature, humidity, and housekeeping and sanitation procedures, with attention to the technological feasibility of such controls.

4. Specifications for the conditions under which personal protective devices should be required.

5. Methods, including instruments, for air sampling and sample analysis of the chemical agents and methods of measuring levels of exposure to the physical agents.

6. The need for medical-examinations for workers exposed to such agents, the frequency of such examinations, and the specific diagnostic tests which should be used and the rationale of their selection.

7. Work practices or procedures which may be instituted for control of the workplace environment in normal operations and those which may be instituted when occupational environmental levels are temporarily exceeded or where peak concentrations of chemical agents in man are reached.

8. The types of records concerning occupational exposure to such agents that employers should be required to maintain.
9. Warning devices and labels which should be required for the prevention of occupational diseases and hazards caused by such agents.

All information received concerning these substances, except that information which is trade secret and protected by section 15 of the Act, will be available for public inspection at the foregoing address.


EDWARD J. BAER,
Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. 77-19399 Filed 7-7-77: 8:45 am]

Social Security Administration

[Docket No. 77-21]

GEORGIA STATE AFDC PLAN AMENDMENT AND GEORGIA COMPLIANCE WITH STATE AFDC PLAN

Notice Regarding Petition for Hearing

Please take notice that the Social Security Administration, Department of Health, Education, and Welfare, received on April 12, 1977, a petition for a hearing to reconsider the Department's rejection of an amendment to Georgia's State plan which was submitted by State Manual Transmittal No. 76-13, pursuant to section 1116 of the Social Security Act, 42 U.S.C. 616(a) (2) and implementing regulations appearing at 45 CFR 201.4. The Social Security Administration hereby notifies petitioner, the State of Georgia, that it grants that request. In addition, the Social Security Administration also hereby notifies the State of Georgia of its intention also to consider at this hearing the matter of whether Georgia is failing to comply with its State plan in the administration of its AFDC program pursuant to section 406(a) of the Social Security Act, 42 U.S.C. 606(a) and implementing regulations at 45 CFR 201.6.

1. The hearing shall commence on Wednesday, July 20, 1977, at 10:00 a.m. in Room 735, 50 Seventh Street NW, Atlanta, Georgia 30303, or at such other time and place as may be fixed, pursuant to 45 CFR 212.2(b)(1), by the presiding officer designated pursuant to 45 CFR 212.21. The hearing shall continue from day to day thereafter until completed.

2. The issues to be considered at the hearing are: (a) whether the amendment submitted by the State of Georgia to its State plan approved under title IV of the Social Security Act, 42 U.S.C. 601 et seq., by Georgia Manual Transmittal 75-12 on treatment of lump sum payments meets the requirements for approval. These requirements are set forth in that Title and implementing Federal Regulations at 45 CFR Part 201, et seq.; and

(b) whether in the administration of its approved State plan under title IV of the Social Security Act, 42 U.S.C. 601 et seq., Georgia is failing to comply with those provisions regarding the treatment of lump sum payments.

3. Pursuant to 45 CFR 213.11, a copy of this notice shall be published as soon as practicable in the Federal Register.

In witness whereof, the Social Security Administration has caused this notice to be issued at Washington, D.C., this 15th day of June 1977.

JAMES B. CARDWELL,

[FR Doc. 77-19637 Filed 7-7-77: 10:16 am]

NOTICES

(b) whether in the administration of its approved State plan under title IV of the Social Security Act, 42 U.S.C. 601 et seq., Georgia is failing to comply with those provisions regarding the treatment of lump sum payments.

3. Pursuant to 45 CFR 213.11, a copy of this notice shall be published as soon as practicable in the Federal Register.

In witness whereof, the Social Security Administration has caused this notice to be issued at Washington, D.C., this 15th day of June 1977.

JAMES B. CARDWELL,

Department of the Interior

Bureau of Indian Affairs

NATIVE GROUPS APPLICATIONS

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Commissioner of Indian Affairs by 230 DM 2.

The Alaska Native Claims Settlement Act of December 18, 1971 (Pub. L. 92-203, 95 Stat. 748-710), provides for the settlement of certain land claims of Alaska Natives and for other purposes. Accordingly, pursuant to the authority contained in 14(h) (2) of the said Act of December 18, 1971, and subpart 365.6 of said regulations, notice is hereby given that the following Native Groups have filed application for determination as to their eligibility.

<table>
<thead>
<tr>
<th>BLM serial No.</th>
<th>Name of native group</th>
<th>Location</th>
<th>Date of filing</th>
</tr>
</thead>
</table>

This notice will be published in one or more newspapers of general circulation in Alaska, once a week for three consecutive weeks.

Protest to any of the applications listed herein must be filed with the Bureau of Indian Affairs by July 30, 1977. Such protest shall be mailed to the Director, Bureau of Land Management, Post Office Box 36800, Juneau, Alaska 99802.

RAYMOND V. BUTLER,
Acting Deputy Commissioner of Indian Affairs.

[FR Doc. 77-19316 Filed 7-7-77: 8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Serial No. X-13325]

IDAHO

Proposed Withdrawal and Reservation of Lands

Correction

In FR Doc. 77-16932 appearing at page 30547 in the issue for Wednesday, June 15, 1977, on page 30548 in the first line of the seventh paragraph, the effective date reading "July 13, 1977" should be corrected to read "June 14, 1977."

[ES 17904]

FLORIDA

Proposed Withdrawal and Reservation of Land

Correction

In FR Doc. 77-18136, appearing at page 22332 in the issue of Friday, June 24, 1977, the date in the second column, ninth line from the bottom of the document should be corrected to read June 24, 1976.

LOWELL J. UPY,
Director, Eastern States.

[FR Doc. 77-19406 Filed 7-7-77: 8:45 am]

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES

35229

received under 43 CFR 6224, Viable Coral Communities located on the Outer Continental Shelf.

Applicant: Jack H. Thompson, Jr., Texas A&M University.


Documents and other information submitted in connection with this application are available for public inspection during normal business hours at the New Orleans Outer Continental Shelf Office, 500 Camp Street/Suite 941, New Orleans, Louisiana 70130.

Interested persons may comment on this application by submitting written data, views or arguments to the Manager, New Orleans OCS Office at his address above. All relevant comments received on or before August 5, 1972 will be considered.

HAROLD P. STREVERING, Acting Manager.

JUNE 20, 1977.

MONTANA

Opportunity for Public Hearing and Republi- cation of Proposed Withdrawal


The Department of Agriculture filed application, Serial No. M 924, on November 8, 1966, for a withdrawal in relation to the following described lands:

PRINCIPAL MERIDIAN, MONTANA

BEAVERHEAD NATIONAL FOREST

TRAPPER CREEK CHARCOAL KILNS AREA

T. 3 S., R. 10 W.,
Sec. 6, W1/2 of Lot 1.
Total area—21.85 acres.

CANYON CREEK CHARCOAL KILNS AREA

T. 2 S., R. 10 W.,
Sec. 5, W1/2 SEC. 1 and SEC. 2.
Total area—20 acres.

The areas described aggregate 41.85 in Beaverhead County, Montana.

The applicant desires that the lands be reserved as the contain unique brick charcoal kilns which the applicant desires to preserve for historical purposes.

A notice of the proposed withdrawal was published in the Federal Register on December 1, 1966, Volume No. 232, Page No. 15953, Document No. 66-12850.

Pursuant to section 204(h) of the Federal Land Policy and Management Act of 1976, 90 Stat. 2354, notice is hereby given that an opportunity for a public hearing is afforded in connection with the pending withdrawal application. All interested persons who desire to be heard on the proposed withdrawal must file a written request for a hearing with the State Director, Bureau of Land Management, P.O. Box 30157, Billings, Montana 59107, on or before August 8, 1977. Notice of the public hearing will be published in the Federal Register, giving the time and place of such hearing. The hearing will be scheduled and conducted in accordance with BLM Manual Sec. 2351.16 B. All previous comments submitted in connection with the withdrawal application have been included in the record and will be considered in making a final determination on the application.

In lieu of or in addition to attendance at a scheduled public hearing, written comments or objections to the pending withdrawal application have been filed with the undersigned authorized officer of the Bureau of Land Management on or before August 8, 1977.

The above-described lands are temporarily segregated from the operation of the public land laws, including the mining laws, to the extent that the withdrawal applied for, if and when effected, would prevent any form of disposal or appropriation under such laws. Current administrative jurisdiction over the segregated lands will not be affected by the temporary segregation. In accordance with section 204(g) of the Federal Land Policy and Management Act of 1976 the segregative effect of the pending withdrawal application will terminate on October 20, 1991, unless sooner terminated by action of the Secretary of the Interior.

All communications (except for public hearing requests) in connection with the pending withdrawal application should be addressed to the Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, Department of the Interior, P.O. Box 30157, Billings, Montana 59107.

ROLAND F. LEE, Chief, Branch of Lands and Minerals Operations.

JUNE 20, 1977.

MONTANA

Opportunity for Public Hearing and Republi- cation of Notice of Proposed Withdrawal

JULY 1, 1977.

The Department of Agriculture filed application, Serial No. M 1169, on January 3, 1967, for a withdrawal in relation to the following described lands:

PRINCIPAL MERIDIAN, MONTANA

LOLO NATIONAL FOREST

SAVENAG SINKUEY, BIG CREEK ADDITION

T. 19 N., R. 20 W.,
Sec. 27, S1/2, NW1/4, SE1/4, SW1/4, and SE1/4.

The area described contains 280 acres in Mineral County, Montana.


Pursuant to section 204(h) of the Federal Land Policy and Management Act of 1976, 90 Stat. 2754, notice is hereby given that an opportunity for a public hearing is afforded in connection with the pending withdrawal-application. All interested persons who desire to be heard on the proposed withdrawal must file a written request for a hearing with

the State Director, Bureau of Land Management, P.O. Box 30157, Billings, Montana 59107, on or before August 10, 1977.

Notice of the public hearing will be published in the Federal Register, giving the time and place of such hearing. The hearing will be scheduled and conducted in accordance with BLM Manual Sec. 2351.16 B. All previous comments submitted in connection with the withdrawal application have been included in the record and will be considered in making a final determination on the application.

In lieu of or in addition to attendance at a scheduled public hearing, written comments or objections to the pending withdrawal application may be filed with the undersigned authorized officer of the Bureau of Land Management on or before August 10, 1977.

The above-described lands are temporarily segregated from the operation of the public land laws, including the mining laws, to the extent that the withdrawal applied for, if and when effected, would prevent any form of disposal or appropriation under such laws. Current administrative jurisdiction over the segregated lands will not be affected by the temporary segregation. In accordance with section 204(g) of the Federal Land Policy and Management Act of 1976 the segregative effect of the pending withdrawal application will terminate on October 20, 1991, unless sooner terminated by action of the Secretary of the Interior.

All communications (except for public hearing requests) in connection with the pending withdrawal application should be addressed to the Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, Department of the Interior, P.O. Box 30157, Billings, Montana 59107.

ROLAND F. LEE, Chief, Branch of Lands and Minerals Operations.

JUNE 20, 1977.

NEW MEXICO

Applications


Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 165), as amended by the Act of November 16, 1973 (87 Stat. 1776), Transwestern Pipeline Company has applied for three 4-inch and one 6-inch natural gas pipeline rights-of-way across the following lands:

SALEN CO PRINCIPAL MERIDIAN, NEW MEXICO

T. 18 S., R. 25 E.,
Sec. 5, SW1/4, SE1/4, and SE1/4.

T. 20 S., R. 25 E.,
Sec. 14, W1/2.

T. 20 S., R. 25 E.,
Sec. 12, W1/2.

T. 20 S., R. 25 E.,
Sec. 7, lot 3 and S1/4.

T. 22 S., R. 25 E.,
Sec. 19, lots 1 and 2.

T. 23 S., R. 25 E.,
Sec. 12, SW1/4.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES

These pipelines will convey natural gas across 3,568 miles of public lands in Eddy County, New Mexico. The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the applications should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, New Mexico 88201.

FRED E. PADILLA, Chief, Branch of Lands and Minerals Operations.

NEW MEXICO

Application


Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Company has applied for two 4½-inch natural gas pipeline rights-of-way across the following lands:

New Mexico Principal Meridian, New Mexico

T. 19 S., R. 28 E., Sec. 6, lot 2 and SW¼NE¼.

These pipelines will convey natural gas across 9,318 acres of a mile of public land in Eddy County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, New Mexico 88201.

FRED E. PADILLA, Chief, Branch of Lands and Minerals Operations.

NOTICE

R/W Application for Pipeline


Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920 (31 Stat. 440) as amended (30 U.S.C. 185), Northwest Pipeline Corporation, 315 East 200 South, Salt Lake City, Utah 84111, has applied for a right of way for a 6½" o.d. and a 4½" o.d. natural gas pipelines for the Trail Canyon Gathering System approximately 19 miles long, across the following Public Lands:

Sixth Principal Meridian, Rio Blanco County, Colorado

T. 3 S., R. 100 W., Secs. 1, 2, 3, 10, 11, 12, 19, 20, 21, 22, 23, 24, 32, 33, 34, and 35.

Application


Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended (30 U.S.C. 185), Colorado Interstate Gas Company of Colorado Springs, Colorado filed an application for a right-of-way to construct 8 inch O.D. and 8 inch O.D. pipelines, a 1 inch "sweet" gas line, 8 inch "pig" launching facilities, an electric control cable and power cable for the purpose of processing "sour" gas across the following described public lands:

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES

FEDERAL REGISTER, VOL 42, NO. 131—FRIDAY, JULY 8, 1977

SIXTH PRINCIPAL MERICAN, WYOMING
T. 18 N., R. 98 W., Sec. 29 N 1/2 W 1/2, NE 1/4 NW 1/4, Sec. 32, N 1/2 W 1/2, SW 1/4 NE 1/4, E 1/2 NW 1/4.

The pipelines will connect the Higgins No. 4 Well at a location in sec. 32, T. 18 N., R. 98 W., Sweetwater County, Wyoming, into existing pipeline facilities at a location in sec. T. 18 N., R. 98 W. The related facilities are to be utilized in the operation and maintenance of the gas pipelines.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, Highway 187 North, P.O. Box 1869, Rock Springs, Wyoming 82901.

HEATHER L. ROSS,
Deputy Assistant Secretary of the Interior.

[FR Doc.77-18490 Filed 7-7-77;8:45 am]

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-26]

CERTAIN SOLDER REMOVAL WICKS
Order Concerning Commission Determination

Upon consideration of the presiding officer’s recommended determination and the record in this proceeding, the Commission hereby orders the termination of investigation No. 337-TA-26, Certain Solder Removal Wicks, on the basis of a determination that no violation of section 337 of the Tariff Act of 1930, as amended, exists.

Copies of the Commission Memorandum Opinion in support of the Commission action are available to the public during official working hours at the Office of the Secretary, United States International Trade Commission, 701 E Street NW., Washington, D.C. 20436.

Issued: June 29, 1977.

By order of the Commission.

KENNETH R. MASON,
Secretary.

METAL-WALLED ABOVE-GROUND SWIMMING POOLS FROM JAPAN

Determination of Likelihood of Injury

On March 29, 1977, the United States International Trade Commission received advice from the Department of the Treasury that metal-walled above-ground swimming pools from Japan are being, or are likely to be, sold in the United States at less than fair value within the meaning of the Antidumping Act, 1921, as amended.

On the basis of the investigation, the Commission must find that an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of metal-walled above-ground swimming pools from Japan which the Department of the Treasury has determined are being, or are likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended.

Issued: June 29, 1977.

By order of the Commission.

KENNETH R. MASON,
Secretary.

STATEMENT OF REASONS FOR AFFIRMATIVE DETERMINATION OF VICE CHAIRMAN

JOSEPH O. PARKER AND COMMISSIONERS

GEORGE M. MOORE AND CATHERINE BEDELL

On April 5, 1977, the U.S. International Trade Commission instituted investigation No. AA1921-165 under section 201 (a) of the Antidumping Act, 1921, as amended. This investigation was made to determine whether an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation into the United States of metal-walled above-ground swimming pools from Japan which the Department of the Treasury has determined are being, or are likely to be, sold at less than fair value (LTFV) within the meaning of the act.

In order to make an affirmative decision, the Commission must find two conditions satisfied in this investigation. First, it must find that an industry in the United States is being or is likely to be injured or is prevented from being established.

Second, any injury or likelihood of injury must be by reason of the importation into the United States of the class or kind of foreign merchandise which the Treasury has determined is being, or is likely to be, sold at LTFV.

We have determined that an industry in the United States is likely to be injured by reason of the importation of the subject articles which the Department of the Treasury has determined are being or are likely to be sold at LTFV. LTFV SALES

The Department of the Treasury investigated U.S. imports of metal-walled above-ground swimming pools from Japan during the period of investigation, and we find that the subject articles are being or are likely to be sold at LTFV.

Prevention of the establishment of an industry is not an issue in the instant case and will not be discussed further. —
Japan during the period November 1, 1975, through April 30, 1976. For that period, Asahi Chemical Industry Co., Ltd. (Asahi) supplied approximately 90 percent of all Japanese exports of above-ground pools, to the United States, according to information developed by the Department of Commerce. Price comparisons were made on almost all sales of the subject merchandise sold in the United States by Asahi during the period of investigation. Margins were found on all sizes of metal-walled above-ground pools exported by Asahi to the United States.

THE IMPORTED ARTICLE AND THE DOMESTIC INDUSTRY

Metal-walled above-ground swimming pools are recreational pool structures which either are installed as a unit and transported on a truck or are installed as a unit and transported on a truck. Above-ground swimming pools are normally categorized into two groups: Splashers and family pools. Splashers, which are circular, range from about 6 feet to 12 feet in diameter, and 1 foot to 3 feet in depth. Family pools, which are circular or oval, are generally 15 feet or more in diameter and 4 feet in depth, although certain large models are up to 3 feet in depth at certain points.

We have considered the relevant domestic industry in this investigation to consist of the U.S. facilities devoted to the production of metal-walled above-ground swimming pools. There are eight known manufacturers of metal-walled above-ground swimming pools in the United States, three of which account for more than 80 percent of annual U.S. producers' shipments. Sales of family pools accounted for approximately 50 percent of the value of U.S. producers' shipments of all above-ground pools in 1975 and 1976.

LIKELIHOOD OF INJURY BY REASON OF LTFV SALES

U.S. imports from Japan of all metal-walled above-ground pools have accounted for over 60 percent of apparent U.S. consumption from 1975 through January-March 1977. In 1976, the year in which most LTFV sales occurred, imports from Japan climbed to their highest level for the 1975-76 period. To fully understand the effect of imports of metal-walled above-ground pools from Japan on the domestic industry, it is necessary to review the recent history of such imports with respect to specific pool categories.

Imports of splashers from Japan first entered the U.S. market in significant quantities in the late 1960's. Such imports increased so rapidly that by 1976 they accounted for almost 90 percent of apparent U.S. consumption of such pools. A number of these imports, in 1976, were found by Treasury to be sold in the United States at LTFV.

In 1975, the first imports of family pools from Japan (which were from Asahi) entered the U.S. market, accounting for less than 5 percent of apparent U.S. consumption of such pools in that year. In 1976, however, such imports increased significantly and accounted for more than 10 percent of apparent U.S. consumption of family pools. All the family pools imported from Japan during 1975, and most of those imported during 1976, entered during the period in which Treasury found LTFV sales.

The recent increase in imports of metal-walled above-ground pools from Japan, particularly family pools, together with a drop in demand in 1975, has had an impact on the operations of U.S. producers. U.S. producers' shipments of all metal-walled above-ground pools declined from a peak of 249,000 pools in 1974 to 91,000 pools in 1975 and then increased to 133,000 pools in 1976—still 47 percent below the 1974 level. Shipments of family pools, which as indicated above constitute about 90 percent of the value of annual U.S. producers' shipments of all metal-walled above-ground pools, declined from 123,000 pools in 1974 to 46,000 pools in 1975, and then increased to 78,000 pools in 1976—38 percent below the 1974 level.

The average number of production and related workers engaged in the manufacture of above-ground pools followed a trend similar to that for producers' shipments, declining from 611 in 1974 to 426 in 1976 and then increasing slightly to 415 in 1976—32 percent below the 1974 level. The LTFTV imports, if allowed to continue, could well exacerbate a trend of declining profits which the domestic industry has experienced in recent years. The net operating profit for the 3 U.S. producers, which account for over 80 percent of the U.S. industry's shipments, declined from $5.6 million in 1974 to $2.7 million in 1975. In 1976, despite an increase in net sales, net operating profit continued to decline to $2.5 million. The ratio of net operating profit to net sales for the 3 firms on their above-ground swimming pool operations declined from 13.7 percent in 1974 to 11.9 percent in 1975 and to 7.5 percent in 1976.

There is additional evidence that the domestic producers lost sales to LTFTV imports from Japan and, if such imports continue, it is likely that they will injure the domestic industry. U.S. producers and Commission staff determined that sales lost to LTFTV imports totaled $2.3 million in 1975 and $4.4 million in 1976. Official sales of several of the firms listed by U.S. producers indicated that sales of domestically produced pools because of increased purchases of Japanese pools accounted for over 60 percent of total sales by Asahi and other domestic producers.

CONCLUSION

On the basis of the evidence developed during this investigation, we have determined that an industry in the United States is likely to be injured by reason of the importation of metal-walled above-ground swimming pools from Japan which the Department of the Treasury has determined are being, or are likely to be, sold at LTFV.
STATEMENT OF REASONS FOR NEGATIVE DETERMINATION OF CHAIRMAN DANIEL MINCZER AND COMMISSIONER IZAK H. ANSONI

On March 29, 1977, the United States International Trade Commission (Commission) received advice from the Department of the Treasury (Treasury) that metal-walled above-ground swimming pools from Japan are being sold in the United States at less than fair value (LTFV) within the meaning of the Anti-dumping Act of 1921, as amended (19 U.S.C. 160(a)). Accordingly, on April 5, 1977, the Commission instituted Investigation No. AAI921-165 under section 201(a) of the Act to determine whether an industry in the United States is being or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States.

Before the Commission may find in the affirmative in this investigation, it is necessary that the following two conditions be met:

1. An industry in the United States is being or is likely to be injured, or is prevented from being established; and
2. The requisite injury must be by reason of importation into the United States of the merchandise which Treasury has determined is being, or is likely to be, sold at less than fair value within the meaning of the Anti-dumping Act of 1921, as amended.

DETERMINATION

On the basis of information obtained in the investigation, we determine that there is no injury or likelihood of injury to an industry in the United States by reason of the importation of metal-walled above-ground swimming pools from Japan.

THE IMPORTED ARTICLE AND THE DOMESTIC INDUSTRY

Metal-walled above-ground swimming pools, the imported articles which are the subject of investigation, are recreational structures which can be taken apart and reassembled. They differ from other types of swimming pools in that they are non-inflatable unlike many children's pools and are transportable as opposed to the larger in-ground pools. The above-ground pools involved in this investigation are normally categorized as "splashing" pools, which are generally smaller units, and the larger "family pools," generally having a diameter of 15 feet or more. Approximately eight U.S. firms manufacture metal-walled above-ground swimming pools. These firms are the most likely to be affected by LTFV imports, and for the purposes of this determination are treated as the relevant domestic industry. Of the firms comprising this industry, the three largest account for over 80 percent of the total U.S. production of the pools in question.

NO INJURY BY REASON OF LTFV SALES

The information gathered during the investigation indicates that the second condition as set out above, which must be met prior to an affirmative finding, is not satisfied in the instant case, i.e., any injury experienced by the domestic industry involved in the production of the subject swimming pools is not by reason of LTFV imports.

IMPORT PENETRATION AND LOST SALES

The proportion of the U.S. market captured by pools imported from Japan is decreasing. The ratio of imports to total U.S. consumption of the subject swimming pools dropped by almost 3 percent from 1975 to 1976. Further data indicate that during the first quarter of 1977 for all pool sizes. Of particular importance is the marked decline in sales of family pools, for which the ratio decreased by more than 60 percent from the rate in the first quarter of 1976. This sharp decline has significant significance because family pools constitute the vast bulk of the value of all above-ground swimming pools sold in the country. Thus, the importation of such imports has had a continuing adverse impact on domestic operations. On the other hand, the import penetration is very slight in the area of first concern to the domestic industry (sales of family pools represent approximately 90 percent of the value of U.S. producers' shipments), and as the report reveals, this penetration is decreasing.

Furthermore, available data indicate that the current impact of LTFV margins is much less important than the overall Japanese price advantage with respect to this product. The Japanese price advantage in the sale of above-ground metal-walled pools is substantial, at 20-25 percent. Any injury to the domestic industry, therefore, would seem to be attributable to this significant price advantage and not to the 3.5-percent average weighted dumping margin. Although other factors such as financing arrangements and arrangements and delivery terms somewhat mitigate the considerable Japanese price advantage, it remains highly influential. When contrasted to the relatively low dumping margin, price advantage appears to be a more persuasive cause of any injury which the domestic industry may have suffered.

U.S. PRODUCERS' SHIPMENTS, EMPLOYMENT, AND PROFITABILITY

The declines experienced by the domestic industry during 1975 in the areas of shipments, employment, and profitability were not attributable to import competition, but rather to a strong and increasing demand for above-ground pools. In 1975, however, total apparent U.S. consumption of above-ground metal-walled pools plummeted by 43 percent, and predictably, shipments, employment, and profitability followed a parallel course. As the economy took a healthier turn, U.S. producers' shipments rose from 91,000 pools in 1975 to 153,000 pools in 1976, an increase of 60 percent over the previous year.

Employment followed a similar upward course in 1976, and the figures for the first quarter of 1977, which were at a level 19 percent above the averages for the corresponding period in the previous year, clearly indicate continuing gains in this area. Advances also are present in U.S. producers' net operating profits for overall company operations. Following 1975's slide to $4.6 million from $8.5 million from the previous year, net operating profits soared to $13.6 million in 1976—the highest figure in the 1972-76 period. The ratio of net operating profits to net sales, for overall company operations similarly increased to 10 percent in 1976 from a low of 6.2 percent in 1975. Thus, in terms of sales, employment, and profitability, 1976 was a highly prosperous year for U.S. producers. These figures make clear that the depressed state of production affairs for the domestic industry resulted not from LTFV import sales, but rather because of the prevailing domestic market patterns during the period in question. One additional factor which has had a continuing adverse impact on domestic operations is weather conditions, particularly the acute water shortages currently being experienced in the West. This situation helps explain why, in spite of the sharp increase in U.S. producers' overall operations, the above-ground swimming pool figures still lay behind their earlier record levels.

NO LIKELIHOOD OF INJURY BY REASON OF LTFV IMPORTS

The above-mentioned reasons which dictate a finding that a U.S. industry is not being injured by reason of LTFV sales of imported metal-walled above-ground swimming pools from Japan, also apply to the issue of likelihood of injury. The Commission has received assurances that any sales which possibly could be interpreted as having been at LTFV have been terminated and will not occur in the future. Further, U.S. imports from Japan are substantially declining, which is especially significant as noted earlier with regard to family pools. These imports dropped by almost 60 percent from January-March 1976 to the corresponding period in 1977, while the ratio of such imports to consumption declined to more than 50 percent in the same period.

CONCLUSION

On the basis of the factors set forth above, we have determined that an industry in the United States is not being and is not likely to be injured by reason of the importation of metal-walled above-ground swimming pools from Japan which the Department of the
In the event that comments or objections to this proposal are raised, the Administrator of DEA shall order a public hearing in the Federal Register summarizing the issues to be heard and setting the time for the hearing. The establishment of the interim aggregate production quota for ecgonine for conversion is effective on July 8, 1977.

Dated: July 1, 1977,

PETER B. BENETING, Administrator.

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**CONTROLLED SUBSTANCES**

**Proposed 1977 Aggregate Production Quota for Ecgonine for Conversion**

Section 306 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for all controlled substances in Schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration pursuant to §100.100 of Title 28 of the Code of Federal Regulations.

Ecgonine is a naturally occurring bi-product derived from the processing of coca leaves. There is no direct medical usage of this substance in the United States and thus, all quantities which are produced are destroyed.

DEA has now been advised that a domestic manufacturer of cocaine desires to convert quantities of ecgonine to cocaine in addition to producing cocaine directly from coca leaves. This change of process will not result in the production of cocaine in excess of the limitations established by the aggregate production quota for cocaine for a given year.

In order to allow for this conversion from ecgonine, quantities of ecgonine must be produced under the restrictions of a quota. No quota has been established thus far in 1977 for this substance.

To provide for the legitimate needs of this substance for 1977, the Drug Enforcement Administration hereby establishes an interim 1977 aggregate production quota for ecgonine for conversion of 700 kilograms as anhydrous base. In addition, based upon consideration of the above factors, the Administrator of the Drug Enforcement Administration does hereby propose that the aggregate production quota for this substance for 1977 be established at 700 kilograms, expressed in terms of anhydrous base.

All interested persons are invited to submit their comments and objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537.

The Administrator of the Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative, and must be received by August 8, 1977. If a person believes that one or more issues raised by him warrants a full adversary-type hearing, he should so state and summarize the reasons for his belief.
will not have an adverse effect upon existing competitive enterprises in the area. The Secretary of Labor’s review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.
2. Employment trends in the same industry in the local area.
3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.
4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).
5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice to:

Deputy Assistant Secretary for Employment and Training, 1015 5th Street NW., Washington, D.C. 20210.

Signed at Washington, D.C., this 5th day of July 1977.

Ernest G. Green,
Assistant Secretary for Employment and Training.

Applications received during the week ending July 1, 1977

<table>
<thead>
<tr>
<th>Name of applicant</th>
<th>Location of Enterprise</th>
<th>Principal Product or Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trooper, Inc.</td>
<td>Waxahachie, Texas</td>
<td>Manufacture of women’s and men’s work clothing.</td>
</tr>
<tr>
<td>Leon’s Causie</td>
<td>Batavia, N.Y.</td>
<td>Manufacture of portable high pressure steam.</td>
</tr>
<tr>
<td>Hick’s Automotive Service</td>
<td>Clinton, N.C.</td>
<td>Automotive repair and sales.</td>
</tr>
<tr>
<td>W. E. Bailey &amp; Sons, Inc.</td>
<td>Beanblossom, N.C.</td>
<td>Direct point storage and processing warehouse.</td>
</tr>
<tr>
<td>Holiday Holiday Mills, Inc. (tenant of town of Elgin)</td>
<td>Piqua, Ohio</td>
<td>Finishing, packaging and sales of bakery products.</td>
</tr>
<tr>
<td>Judy Branch Deby, Inc.</td>
<td>Clifton, N.J.</td>
<td>Manufacture of high voltage steam.</td>
</tr>
<tr>
<td>Don Rosen Supermarkets, Inc.</td>
<td>Harris, Ark.</td>
<td>Retail grocers and meat.</td>
</tr>
<tr>
<td>HMA Industries, Inc.</td>
<td>Middletown, Ohio</td>
<td>制造一定量的汽油。</td>
</tr>
<tr>
<td>Britt Tech Corp.</td>
<td>Britt, Iowa</td>
<td>Manufacture of portable high pressure steam.</td>
</tr>
<tr>
<td>Farm Products Elevator Corp.</td>
<td>Schuyler, Neb.</td>
<td>Grain storage facility.</td>
</tr>
<tr>
<td>Julius Pools and Hazel Furniture</td>
<td>Abington, Colo.</td>
<td>Hospitality and restaurant business.</td>
</tr>
</tbody>
</table>

[FR Doc.77-19496 Filed 7-7;7:8:45 am]

Pension and Welfare Benefit Programs

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[Prohibited Transaction Exemption 77-8; Application No. D-201]

EMPLOYEE BENEFIT PLANS

Class Exemption Involving Transfer of Individual Life Insurance Contracts and Annuities From Employee Benefit Plans to Plan Participants, Certain Beneficiaries of Plan Participants, Employers, and Other Employee Benefit Plans

Correction

In FR Doc.77-17666 appearing at page 31574 in the issue for Tuesday, June 21, 1977, in the first line, middle column, page 31574, "C.B. 722" should read "C.B. 722"; and in the last line of the paragraph titled "Exemption," middle column, page 31575, "C.B. 22" should read "C.B. 722."

NATIONAL SCIENCE FOUNDATION

SCIENCE APPLICATIONS TASK FORCE

Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

NAME: Science Applications Task Force.

DATE AND TIME: July 26, 1977—9 a.m.—5 p.m.; July 27, 1977—9 a.m.—4 p.m.

PLACE: Room 546, National Science Foundation, 1800 G Street NW., Washington, D.C. 20550.

TYPE OF MEETING: Partially open. July 26—8 a.m.—5 p.m.—Open to public observers. July 27—9 a.m.—12 noon—Closed session; 1:30 p.m.—4 p.m.—Open to public observers.

CONTACT PERSON:

Gilbert B. Devey, Executive Secretary, Science Applications Task Force, National Science Foundation, Telephone 202-549-6608. Persons interested in attending the meeting should inform the Executive Secretary before 5 p.m. on July 20, 1977.

SUMMARY MINUTES: May be obtained from the Committee Management Coordination Staff, Division of Personnel and Management, Room 248, National Science Foundation, Washington, D.C. 20550.

PURPOSE OF ADVISORY GROUP:

The purpose of the NSF Task Force on Science Applications is to provide advice and assessments and make recommendations to the NSF Director on science applications programs and related organization and management issues.


REASON FOR CLOSING: The disclosure of the intended content could constitute an unwarranted invasion of individuals’ personal privacy, and this session is closed in accordance with exemption 6 of the Government in the Sunshine Act of 1977.

AUTHORITY FOR CLOSING: This determination was made on June 27, 1977, pursuant to provisions of section 10(d) of Pub. L. 92-453.

M. Rebecca Winkler,
Acting Committee, Management Officer.

July 1, 1977.

[FR Doc.77-19413 Filed 7-7-77:8:45 am]

RENEGOTIATION BOARD

EXCESSIVE PROFITS AND REFUNDS

Interest Rate

Correction

In FR Doc.77-18076 appearing on page 32339 in the issue for Friday, June 24, 1977, in the ninth line, "1½" should be corrected to read "1¼."

EXEMPTION OF FOREIGN MILITARY SALES

Recision of Interpretation No. 80

Correction

In FR Doc.77-18075 appearing on page 32339 in the issue for Friday, June 24, 1977, the date above the signature, "June 2, 1977" should be corrected to read "June 21, 1977."
SECURITIES AND EXCHANGE COMMISSION
(File No. 500-1)

CAL-AM CORP.
Suspension of Trading

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the securities of Cal-Am Corporation being traded on a national securities exchange or otherwise is required in the public interest and for the protection of investors;

Therefore, pursuant to section 12(b) of the Securities Exchange Act of 1934, trading in such securities on a national securities exchange or otherwise is suspended, for the period from 3:00 p.m. (EDT) on June 28, 1977 through July 7, 1977.

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc.77-19509 Filed 7-7-77; 8:45 am]

CHICAGO BOARD OPTIONS EXCHANGE, INC.
Self-Regulatory Organizations; Proposed Rule Change

Pursuant to section 19(b) (1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b) (1) as amended by Pub. L. No. 94-29 (June 4, 1975), notice is hereby given that on June 13, 1977, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

EXCHANGE'S STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The proposed rule change amends present rules of the Chicago Board Options Exchange, Incorporated ("CBOE") so as to enable options on debt securities issued by the United States Government or agencies thereof ("Government securities") to be traded on CBOE.

Although most of CBOE's current rules are consistent with the trading of options on Government securities, there are certain qualitative and quantitative differences between stocks, which presently underlie CBOE options, and Government securities that necessitate amendments to several CBOE rules. The proposed rule change reflects amendments to CBOE rules that are presently applicable only to trading of options on underlying stocks as to make those rules also applicable to trading of options on underlying Government securities. However, in drafting each proposed amendment, the same substantive basis or policy followed in formulating a rule with respect to options on underlying stocks has been retained, modified only as necessary to reflect the particular standards or practices of the Government securities market. Certain of the proposed amendments are more substantive than others, and merit a brief explanation.

The position limits proposed in Rule 4.11 reflect the Government securities market is largely an institutional market in which the average trade size is $1,000,000 principal amount (i.e., the equivalent of 10 Government securities options having a unit of trading of $100,000 principal amount of the underlying Government security). In view of this large average trade size, it is necessary that position limits for Government securities options be sufficiently large to provide useful hedging opportunities for institutions and other Government securities traders. At the same time, position limits should continue to serve their fundamental purpose of preventing potential trading abuses. To meet these objectives, it is proposed that position limits vary with the original public issuance (the amount issued to and available for trading by public investors) of underlying Government securities, according to the schedule set forth in proposed Rule 4.11. A similar rationale applied to exercise limits (Rule 4.12).

Rule 4.17, which currently restricts on certain out-of-the-money options on underlying stocks, was developed only after considerable trading experience. In the absence of such experience for Government securities options, it is not clear what sort of similar rule, if any, would be appropriate for Government securities options. Accordingly, it is proposed initially to limit the applicability of Rule 4.17 solely to options on underlying stocks; however, CBOE will closely monitor the need for a corresponding rule for Government securities options.

The purpose of Rules 5.3 and 5.4, in establishing criteria for the listing and delisting of options covering particular Government securities, is to ensure that the Government securities chosen for options trading are widely held and actively traded. For this reason, it is provided that only the larger Government issues may be selected as underlying securities, and that even these will ordinarily remain as underlying securities only for a year or two after initial listing, since CBOE will ordinarily not introduce series with new expiration months on an underlying note or bond six months after the inception of options trading on that particular underlying Government security. After six months, CBOE will ordinarily commence options trading on a more recently issued Government note or bond.

Although not reflected in Rule 5.6 governing the terms of options, it will be the policy of CBOE to open additional series of options covering a particular underlying Government security at one percentage, point intervals whenever the quotation for the underlying security reaches the mid-point between such intervals. (I.e., options having an exercise price of 103 will be opened when the underlying security is quoted at 102 1/2 or above, or 103 1/2 or below.)

Under Rules 6.3 (Trading Halts) and 6.4 (Suspension of Trading), it is proposed that the appropriate officials have authority to halt or suspend trading in Government securities options when conditions detrimental to the maintenance of a fair and orderly market are present. Included among such conditions is the unavailability of current quotations in the underlying Government security. This reflects that Government securities are ordinarily traded on the basis of current quotations, not last sale reports; it is intended that CBOE options on Government securities will also be traded on the basis of such current quotations.

Under Rule 6.73 (b), it is proposed that a Floor Broker handling an order in a Government securities option that is dependent upon a quotation for the underlying security shall be responsible for satisfying the dependency requirement on the basis of the most reliable information reasonably available to him concerning current quotations for the underlying Government security. Thus, the Floor Broker is not limited to quotation display mechanism, but may also utilize such information obtained from other reliable sources.

Separate market-maker obligations for Government security options are proposed in Rule 8.7(b) with respect both to the spread between the "bid" and "ask" for options and to the amount by which a bid or offer may be raised or lowered from the previous transaction. These separate, specific requirements of Rule 8.7(b) reflect the unique characteristics of the Government securities market, including that it is a dealer market, and that Government securities are less volatile than stocks.

It is proposed to amend CBOE's rules relating to account approval, suitability of recommendations, and 1933 Act disclosure (Rules 9.7, 9.9, and 9.15) to provide separate account approval and disclosure requirements for options on Government securities, and to impose on all recommendations relating to Government security options the higher suitability standards that presently apply to recommendations of certain writing transactions.

Rule 11.3 (Delivery and Payment) will be amended to make it explicit that, in accordance with the standard procedures in the Government securities market with respect to the treatment of accrued interest, the exercising holder of a call option or the writer of a put option, upon exercise of an exercise notice must pay both the exercise price of the Government security option plus interest on the underlying Government security accrued from the last interest payment date to but not including the exercise settlement date.

It is proposed to amend Rule 12.3 to provide minimum margin requirements for option contracts on Government se-
ing Government notes and bonds as the of developing such a market, and select-

- from members
- of providing a market in options on such
- income securities to assess the feasibility
- market or in the market for fixed in-
- economic developments which affect the
- changes in interest rates and other eco-
- in Government securities resulting from
- hedge against adverse price fluctuations
- in Government securities. This follows
- the existing pattern reflected in Rule 12.3,
- whereby minimum margin require-
ments respecting short positions in op-
tions dealt in on an exchange relating to
underlying stocks are comparable to pro-
prietary haircut requirements under Rule 15c-3-1. Rule 12.3 will exempt from customer margin requirements those persons who are Government securities dealers reporting their positions to the New York Federal Reserve Bank, since those dealers have no margin require-
ments respecting their short positions in Government securities themselves.

EXCHANGE'S STATEMENT OF BASIS
AND PURPOSE

The purpose of the proposed rule change is to implement CBOE's market for the trading of options on Government securities.

The proposed rule change is adopted pursuant to section 6(b)(5) of the Securities Exchange Act of 1934, as amended, in that the rules proposed hereby are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest in connection with transactions in options covering underlying Government securities.

CBOE believes that its proposed market for options on Government securities is consistent with the standards of the Security Exchange Act of 1934, as amended, because it is designed to provide the same increased investment flexibility with respect to Government securities as the present options market provides with respect to stocks. CBOE's discussions with Government securities investors and primary dealers have strengthened its conclusion that such a market is both feasible and in the interests of investors. The basic economic function of a Government securities option will be essentially similar to that of an option on common stock: To separate the risks and opportunities of investing in securities, and to redistribute the risks and opportunities be-

 tween the holder and writer of the op-
tion. CBOE expects that Government se-
curities options will be used primarily to hedge against adverse price fluctuations in Government securities resulting from changes in interest rates and other econ-
omic developments which affect the money and capital markets.

In January 1976, CBOE established a Fixed Income Securities Task Force con-
isting of CBOE members and commer-
cial banks expressed in the options market or in the market for fixed in-
come securities to the feasibility of providing a market in options on such securities. Comments received informally from members of the Task Force and other potential participants in such an options market were generally in favor of developing such a market, and select-
ing Government bonds as the underlying fixed income securities, as re-

lected in the proposed rule change. Formal comments on the proposed rule change have not been collected or re-
cived.

CBOE believes that the proposed rule change will not impose any burden on competition.

On or before August 12, 1977, or within such longer period (i) as the Commis-
sion may designate up to 90 days of such date if it finds such longer period to be appropriate, or (ii) as to which the above-men-
tioned self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to deter-
mine whether the proposed rule change should be disapproved.

Interested persons are invited to sub-
mit written data, views and arguments concerning the foregoing. Persons de-
siring to make written submissions should file 5 copies thereof with the Sec-
curities Exchange Commission, 1100 L Street NW., Washington, D.C. 20549. Copies of the filing with respect to the foregoing and, all written submission will be available for inspect-

ing and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-men-
tioned self-regulatory organization. All submissions should refer to the file num-
ber referenced in the caption above and should be submitted on or before July 29, 1977.

For the Commission by the Division of Market Regulation, pursuant to dele-

gated authority.

GEORGE A. FITZSIMMONS,
Secretary.


[FR Doc. 77-19510 Filed 7-7-77; 8:45 am]

DEPARTMENT OF STATE

[Public Notice CM-7/87]

STUDY GROUP 5 OF THE U.S. NATIONAL COMMITTEE, INTERNATIONAL TELE-

GRAPH AND TELEPHONE CONSULTATIVE COMMITTEE (CCITT)

Meeting

The Department of State announces that Study Group 5 of the U.S. CCITT National Committee will meet on July 26, 1977, at 10:00 a.m. in Room 5611 of the Department of Commerce, 1325 G Street,

N.W., Washington, D.C. This Study Group deals with matters in telecommu-
nications relating to the development of the International digital data transmis-
sion services.

The agenda for the July 26 meeting will include consideration of the follow-
ing:


2. Approval of draft Provisional Recommendations as amended by CCITT Study Groups VII and XVII.

3. Identification of subjects for U.S. con-
tributions to December 1977 Working Party meetings of CCITT Study Groups VI and to the April 1978 meeting of Study Group VII:

User Facilities (X.2);Datagram; Routing

principles for interworking of data networks with telephone/telex networks; and Other.

4. Other business.

All participants are requested to use the main entrance to the Department of Commerce on 14th Street. Members of the general public who desire to attend the meeting on July 26 will be admitted up to the limit of the meeting room.

Dated: June 29, 1977.

ARTHUR L. FREEMAN,
Chairman,
U.S. National Committee.

[FR Doc.77-19524 Filed 7-7-77; 8:45 am]

[Public Notice CM-7/87]

SHIPPING COORDINATING COMMITTEE,
SUBCOMMITTEE ON SAFETY OF LIFE AT SEA

Meeting

The working group on standards of training and watchkeeping of the Sub-
committee on Safety of Life at Sea will conduct an open meeting at 9:30 a.m.

on August 4, 1977 in Room 8334 at the Department of Transportation, 400 Sev-
enth St., S.W., Washington, D.C.

The business of this meeting will be to review the report (if available) of the Joint IMCO/ILO Committee on Training (5th Session); and develop the US position on watchkeeping require-
mements in the annex to the draft con-
vention.

For further information, contact Cap-
tain J. P. Dawley, United States Coast
Guard, G-MVP/82, Washington, D.C.

20509, (area code 202) 426-1500.

The Chairman will entertain com-

ments from the public as time permits.

RICHARD K. BANK,
Chairman, Shipping Coordinating Committee.


[FR Doc.77-19633 Filed 7-7-77; 8:45 am]

Agency for International Development

MISSION DIRECTOR AND DEPUTY MISSION DIRECTOR, USAID INDONESIA

Redelegation of Authority No. 164-10
(Rev.)

Pursuant to the authority delegated to me by A.LD. Delegations of Authority
No. 5, dated December 29, 1961 (27 FR 449), as amended, with respect to Loan
Agreements; No. 38, dated April 10, 1964 (29 FR 12681), as amended, with respect to Project Agreements, Trust Fund
Agreements, and Grants to International Organizations; No. 99, dated April 27, 1973 (38 FR 12801), as amended, with respect to Project Agreements, Trust Fund
Agreements, and Grants to International Organizations; and No. 112, dated October 12, 1975 (40 FR 48955), with respect to other authorities and functions delegated to me, I hereby
redesignate to the Mission Director and
Deputy Mission Director, USAID/Indonesia, and to any person acting in their official capacity, authority to exercise any of the following functions, retaining for myself concurrent authority to exercise any of the functions herein redelegated:

1. Authority to negotiate and execute loan and grant agreements and amendments thereto, with respect to loans and grants authorized under the Foreign Assistance Act of 1961, as amended (the Act), in accordance with the terms of such loan or grant, such grant agreements for purposes of this authority and all other authorities contained in this redelegation shall mean agreements with foreign governments, foreign government agencies and international organizations having a membership consisting primarily of such foreign governments;

2. Authority to implement loan and grant agreements with respect to loans and grants authorized under the Act and loans authorized by the Board of Directors of the corporate Development Loan Fund, including the following:

(a) Authority to prepare, negotiate, sign and deliver letters of implementation;

(b) Authority to review and approve documents and evidence submitted by borrowers or grantees in satisfaction of conditions precedent to financing under such loan or grant agreements;

(c) Authority to negotiate, execute and implement all agreements and other documents ancillary to such loan and grant agreements;

(d) Authority to sign or approve Project Implementation Orders—Technical Services (PIO/T); and

(e) Authority to approve contractors, review and approve the terms of contracts, amendments and modifications thereto, and invitations for bids with respect to such contracts financed by funds made available under such loan or grant agreements.

The authorities enumerated above may be redelegated by the individuals listed above, as appropriate, but not successively redelegated, except that the authority described above in paragraph 1 with respect to execution of loan agreements and amendments may not be redelegated.

The authorities enumerated above in paragraph 1 with respect to execution of loan agreements is also hereby redelegated under the same terms and conditions set forth herein to the U.S. Ambassador to Bangladesh.

This Redelegation of Authority is effective immediately.


MICHAEL H. B. ADLER,
Acting Assistant Administrator, Bureau for Asia.

[FR Doc. 77-19338 Filed 7-7-77; 8:45 am]

MISSION DIRECTOR AND DEPUTY MISSION DIRECTOR, USAID BANGLADESH

Reinforcement of Authority (Revised)

Pursuant to the authority delegated to me by AID Delegations of Authority No. 5, dated December 29, 1961 (27 FR 4494), as amended, with respect to Loan Agreements; No. 38, dated April 10, 1964 (29 FR 5250), as amended, with respect to Project Agreements, Trust Fund Agreements, and Grants to International Organizations; No. 49, dated April 27, 1973 (38 FR 12834), with respect to Contracting and Related Functions; and No. 112, dated October 12, 1975 (40 FR 49559), with respect to other authorities and functions delegated to me, I hereby redelegate to the Mission Director and Deputy Mission Director, USAID/Bangladesh, and to any person acting in their official capacity, authority to exercise any of the following functions, retaining for myself concurrent authority to exercise any of the functions herein redelegated:

1. Authority to negotiate and execute loan and grant agreements and amendments thereto, with respect to loans and grants authorized under the Foreign Assistance Act of 1961, as amended (the Act), in accordance with the terms of the authorization of such loan or grant; such grant agreements for purposes of this authority and all other authorities contained in this redelegation shall mean agreements with foreign governments, foreign government agencies and international organizations having a membership consisting primarily of such foreign governments;

2. Authority to implement loan and grant agreements with respect to loans and grants authorized under the Act and other authorities concurrently authorized to exercise any of the functions herein redelegated:

(a) Authority to prepare, negotiate, sign and deliver letters of implementation;

(b) Authority to review and approve documents and evidence submitted by borrowers or grantees in satisfaction of conditions precedent to financing under such loan or grant agreements;

(c) Authority to negotiate, execute and implement all agreements and other documents ancillary to such loan and grant agreements;

(d) Authority to sign or approve Project Implementation Orders—Technical Services (PIO/T); and

(e) Authority to approve contractors, review and approve the terms of contracts, amendments and modifications thereto, and invitations for bids with respect to such contracts financed by funds made available under such loan or grant agreements.

The authorities enumerated above may be redelegated by the individuals listed above, as appropriate, but not successively redelegated, except that the authority described above in paragraph 1 with respect to execution of loan agreements and amendments may not be redelegated.

The authorities enumerated above in paragraph 1 with respect to execution of loan agreements is also hereby redelegated under the same terms and conditions set forth herein to the U.S. Ambassador to Bangladesh.

This Redelegation of Authority is effective immediately.


MICHAEL H. B. ADLER,
Acting Assistant Administrator, Bureau for Asia.

[FR Doc. 77-19338 Filed 7-7-77; 8:45 am]
tracts, amendments and modifications thereto, and invitations for bids with respect to such contracts financed by funds made available under such loan or grant agreements.

The authorities enumerated above may be redelegated by the individuals listed above, as appropriate, but not successively redelegated, except that the authority described above in paragraph 1 with respect to execution of loan agreements and amendments may not be redelegated.

The authority enumerated above in paragraph 1 with respect to execution of loan agreements is also hereby redelegated under the same terms and conditions set forth herein to the U.S. Ambassador to the Philippines.

Delegation of Authority No. 111 dated September 23, 1975 (40 FR 45451) is hereby rescinded.

This Redelegation of Authority is effective immediately.


MICHAEL H. B. ADLER,
Acting Assistant Administrator,
Bureau for Asia.

[FR Doc.77-19390 Filed 7-7-77; 8:45 am]

MISSION DIRECTOR AND DEPUTY MISSION DIRECTOR, USAID PAKISTAN

Redelegation of Authority No. 164–11

(Purposely)

Pursuant to the authority delegated to me by A.I.D. Delegations of Authority No. 5, dated December 29, 1961 (27 FR 449), as amended, with respect to Loan Agreements; No. 38, dated April 10, 1964 (29 FR 5286), as amended, with respect to Project Agreements, Trust Fund Agreements, and Grants to International Organizations; No. 59, dated April 27, 1973 (38 FR 12634), with respect to Contracting and Related Functions; and No. 112, dated October 12, 1975 (40 FR 49355), with respect to other authorities and functions delegated to me, I hereby redelegate to the Mission Director and Deputy Mission Director, USAID/Pakistan, and to any person acting in their official capacity, authority to exercise any of the following functions, retaining for myself concurrent authority to exercise any of the functions herein redelegated:

1. Authority to negotiate and execute loan and grant agreements and amendments thereto, with respect to loans and grants authorized under the Foreign Assistance Act of 1961, as amended (the Act), in accordance with the terms of the authorization of such loan or grant; such grant agreements for purposes of this authority and all other authorities contained in this redelegation shall mean agreements with foreign governments, foreign government agencies and international organizations having a membership consisting primarily of such foreign governments;

2. Authority to implement loan and grant agreements with respect to loans and grants authorized under the Act and loans authorized by the Board of Directors of the corporate Development Loan Fund, including the following:

(a) Authority to prepare, negotiate, sign and deliver letters of implementation;

(b) Authority to review and approve documents and other evidence submitted by borrowers or grantees in satisfaction of conditions precedent to financing under such loan or grant agreements;

(c) Authority to negotiate, execute and implement all agreements and other documents ancillary to such loan and grant agreements;

(d) Authority to sign or approve Project Implementation Orders—Technical Services (PIO/T); and

(e) Authority to approve contractors, review and approve the terms of contracts, amendments and modifications thereto, and invitations for bids with respect to such contracts financed by funds made available under such loan or grant agreements.

The authorities enumerated above may be redelegated by the individuals listed above, as appropriate, but not successively redelegated, except that the authority described above in paragraph 1 with respect to execution of loan agreements and amendments may not be redelegated.

The authority enumerated above in paragraph 1 with respect to execution of loan agreements is also hereby redelegated under the same terms and conditions set forth herein to the U.S. Ambassador to Pakistan.

Redelegation of Authority No. 164–5 dated June 26, 1972 (37 FR 13646) is hereby rescinded.

This Redelegation of Authority is effective immediately.


MICHAEL H. B. ADLER,
Acting Assistant Administrator,
Bureau for Asia.

[FR Doc.77-19391 Filed 7-7-77; 8:45 am]

DEPARTMENT OF THE TREASURY

Office of the Secretary

[T.D. Order 106; (Rev. 14)]

SUPERVISION OF BUREAUS AND OFFICES, DELEGATION OF CERTAIN AUTHORITY, AND ORDER OF SUCCESSION IN THE TREASURY DEPARTMENT

1. The Deputy Secretary shall be under the direct supervision of the Secretary.

2. The following officials shall be under the supervision of the Secretary, and shall report to him through the Deputy Secretary:

Under Secretary for Monetary Affairs
Under Secretary
General Counsel
Assistant Secretary (Tax Policy)
Commissioner, Internal Revenue Service
Comptroller of the Currency
Assistant Secretary (Legislative Affairs)
Assistant Secretary (Economic Policy)
Assistant Secretary (Domestic Finance)
Assistant Secretary (Public Affairs)
Executive Secretary

3. The following officials shall be under the supervision of the Under Secretary for Monetary Affairs, and shall exercise supervision over those officers and
organizational entities indicated thereunder:
Assistant Secretary (International Affairs)
Deputy Assistant Secretary for Trade and Investment Policy
Deputy Assistant Secretary, Commodities and Natural Resources
Deputy Assistant Secretary for International Monetary Affairs
Deputy Assistant Secretary for Developing Nations
Deputy to the Assistant Secretary for Saudi Arabian Affairs
Deputy to the Assistant Secretary and Secretary of International Monetary Group
Inspector General for International Finance
(The Assistant Secretary (Domestic Finance) reports through the Under Secretary for Monetary Affairs for debt management purposes.)
Fiscal Assistant Secretary

4. The following officials shall be under the supervision of the Under Secretary, and shall exercise supervision over those officers and organizational entities indicated thereunder:
Assistant Secretary (Administration)
Deputy Assistant Secretary
Office of Administrative Programs
Office of Audit
Office of Budget and Program Analysis
Office of Computer Science
Office of Equal Opportunity Program
Office of Management and Organization
Office of Personnel
Chief Deputy to the Under Secretary (Enforcement and Operations)
Office of Enforcement
Office of Operations
United States Secret Service
Bureau of Alcohol, Tobacco and Firearms
Federal Law Enforcement Training Center
United States Customs Service
Office of Foreign Assets Control
Treasurer of the United States
United States Savings Bonds Division
Director of the Mint
Bureau of the Mint
Director, Bureau of Engraving and Printing
Bureau of Engraving and Printing

5. The following officials shall exercise supervision over those officers and organizational entities indicated thereunder:
General Counsel
Deputy General Counsel
Legal Division
Office of Director of Practice
Office of Tariff Affairs
Assistant Secretary (Tax Policy)
Deputy Assistant Secretary for Tax Legislation
Assistant Secretary for Tax Policy Economics
Office of Tax Analysis
Office of Tax Legislative Counsel (also part of Legal Division)
Office of International Tax Counsel (also part of Legal Division)
Office of Industrial Economics
Assistant Secretary (Legislative Affairs)
Deputy Assistant Secretary (Legislative Affairs)
Office of Legislative Affairs
Assistant Secretary (Economic Policy)
Deputy Assistant Secretary for Domestic Economic Analysis
Office of Financial Analysis
Deputy Assistants Secretary for International Economic Analysis
Assistant Secretary (Domestic Finance)
(Also reports to Under Secretary for Monetary Affairs for debt management purposes.)
Deputy Assistant Secretary for Capital Markets Policy
Office of Securities Market Policies
Office of Capital Markets Legislation
Deputy Assistant Secretary for State and Local Finance
Office of Municipal Finance
Office of the Deputy to the Assistant Secretary for New York City Finance
Office of Urban Economics
Deputy Assistant Secretary for Debt Management
Assistant Secretary (Domestic Finance)
Deputy Assistant Secretary for Trade and Finance
Assistant Secretary (International Affairs)

6. The following officials shall exercise supervision over those officers and organizational entities indicated thereunder:
Chief Deputy to the Under Secretary, the General Counsel, and the Assistant Secretaries are authorized to perform any functions of the Secretary is authorized to perform. Each of these officials shall perform functions under this authority in his own capacity and under his own title and shall be responsible for referring to the Secretary any matter on which actions should appropriately be taken by the Secretary. Each of these officials will ordinarily perform under this authority only functions which arise out of, relate to, or concern the activities or functions of, or the laws administered by or relating to the bureaus, offices, or other organizational units over which he had supervision. Any action heretofore taken by any of these officials in his own capacity and under this own title is hereby affirmed and ratified as the action of the Secretary.

7. The following officers shall, in the order of succession indicated, act as Secretary of the Treasury in case of the death, resignation, absence, or sickness of the Secretary and other officers succeeding him, until a successor is appointed, or until the absence or sickness shall cease:
A. Deputy Secretary
B. Under Secretary for Monetary Affairs
C. Under Secretary
D. General Counsel
E. Assistant Secretaries, or Deputy Under Secretaries, appointed by the President with Senate confirmation, in the order in which they took the oath of office as Assistant Secretary, or Deputy Under Secretary.

8. Treasury Department Order No. 100 (Revision 13) and No. 150 (Revision 13—Amendment 1) are rescinded effective this date.
Dated: July 1, 1977.

W. Michael Blumenthal
Secretary of the Treasury

[FED Doc. 77-19493 Filed 7-7-77; 8:45 am]
INTERSTATE COMMERCE COMMISSION

ASSIGNMENT OF HEARINGS

JULY 5, 1977.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only, and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 118899 Sub 145, Container Transit, Inc., now assigned July 19, 1977 at Chicago, Illinois is being postponed to September 12, 1977 (2 days) at Chicago, Illinois in a hearing room to be later designated.

MC 142193 Sub (1), N.A.T. Transportation, Inc., now assigned September 15, 1977 (1 day) at Chicago, Illinois, in a hearing room to be later designated.

MC 28652 Sub (1), K & E Delivery, Inc., now assigned September 18, 1977 at Chicago, Illinois, has been postponed indefinitely.

MC 142747, David L. Tate, Hamer L. Tate, Alicia L. Hill, Tate & Gerald Ess, d/b/a Tate Cheese Company, now being assigned September 16, 1977 (1 day) at Chicago, Illinois, in a hearing room to be later designated.

MC 128375 (Sub-151), Crete Carrier Corp., now being assigned September 18, 1977 (2 days) at Chicago, Illinois, in a hearing room to be later designated.

MC 142719 (Sub-1), Robert J. Kirkpatrick, d/b/a / Kirk's Towing Service, now being assigned September 19, 1977 (2 days) at Chicago, Illinois, in a hearing room to be later designated.

MC 129773, Frather Auto Sales, Inc., now being assigned September 21, 1977 (3 days) at Chicago, Illinois, in a hearing room to be later designated.

MC 93376 (Sub No. 14) McVey Trucking, Inc., now assigned August 3, 1977 at Chicago, Illinois to December 30, 1977 (2 days) at Chicago, Illinois, and at the Solicitor's Office in a hearing room to be later designated.

MC 140484 Sub 20, Laster Coggins Trucking Co., Inc. now assigned August 9, 1977 at Lexington, Kentucky and will be held at the Holiday Inn North, 1950 Newport Pike.

MC 123048 Sub 349, Diamond Transportation System, Inc. now assigned August 8, 1977 at Lexington, Kentucky and will be held at the Holiday Inn North, 1950 Newport Pike.

MC 6 Sub No. 16 Burlington Northern, Inc., Abandonment Between Maryville and Barnard, in Nadacounty, Missouri, now being assigned September 10, 1977 (2 days) for hearing in Maryville, Missouri.

In a hearing room to be later designated.

MC 162827 Sub No. 456 Frozen Food Express, Inc., now being assigned September 15, 1977 (2 days) for hearing in Kansas City, Missouri, in a hearing room to be later designated.

MC F-1313 Kaw Transport Company—Control—Royal Transport, Inc. now being assigned September 19, 1977 (1 week) for hearing in Kansas City, Missouri, in a hearing room to be later designated.

MC 2622 Sub 13, The Kelley Transit Co., Inc. now being assigned October 12, 1977 (3 days) at Hartford, Connecticut in a hearing room to be later designated.

MC 10189 Sub 29, Eastern Transportation Co., Inc. now being assigned October 17, 1977 (1 week) at Augusta, Maine in a hearing room to be later designated.

MC 6319 Sub No. 8 California Cartage Co., Inc. now assigned July 14, 1977 in Los Angeles, California is cancelled and application dismissed.

MC 112473 (Sub-281), CRST, Inc., now assigned July 15, 1977 at Chicago, Illinois, hearing cancelled and the application is dismissed.

MC 12827 Sub 250, Midwestern Distribution, Inc. now being assigned October 4, 1977 at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC 141033 Sub 6, Express Contract Car- rier Corp. now being assigned November 1, 1977 at the Offices of the Interstate Commerce Commission in Washington, D.C.

MC 106544 (Sub-No. 239), Superior Trucking Company, Inc. now being assigned September 7, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 108541 (Sub-No. 87), Mois Trucking Company, Inc. now assigned September 7, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 106365 (Sub-No. 35), Armellini Express Lines, Inc. now being assigned September 8, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 21866 (Sub-No. 87), West Motor Freight, Inc., now being assigned September 8, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 108311 (Sub-No. 7), Thomas Motor Tours, Inc., now being assigned September 27, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 133786 (Sub-No. 42), George Appell, now being assigned September 27, 1977, at the Offices of the Interstate Commerce Commission, Washington, D.C.

H. G. Homme, Jr.,
Acting Secretary.

[Doc.77-19511 Filed 7-7-778:45 am]

FOURTH SECTION APPLICATION FOR RELIEF

JULY 5, 1977.

An application, as summarized below, has been filed requesting relief from the requirements of section 4 of the Interstate Commerce Act to permit common carriers named or described in the application to maintain higher rates and charges at intermediate points than those sought to be established at more distant points.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the General Rules of Practice (49 CFR 1100.40) and filed by July 8, 1977.

FSA No. 43392—Returned Shipments of Oyster Shells from and to Calumet, Louisiana, and Points in Western Trunk Line Territory Filed by Southwestern Freight Bureau, Agent (No. B–50), for interested rail carriers. Rates on oyster shells, crushed or ground, in closed cars, as described in the application, from Calumet, Louisiana, to points in western trunk-line territory, also returned shipments in the reverse direction. Grounds for relief—Market competition and returned shipments. Tariff—Supplement 18 to Southwestern Freight Bureau, Agent, tariff 127–E, I.C.C. No. 5128. Rates published to become effective on August 5, 1977.

By the Commission.

H. G. Homme, Jr.,
Acting Secretary.

[Doc.77-19512 Filed 7-7-778:45 am]
[Notice No. 86]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

JULY 1, 1977.

The following are notices of filing of applications for temporary authority, under section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1151.3. These rules provide that if provided, copies of protests to an application may be filed with the field official named in the Federal Register publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the Federal Register. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide if approved, and the type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specified, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Room 300, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

No. MC 3281 (Sub-No. 9TA), filed June 23, 1977. Applicant: POWELL TRUCK LINE COMPANY, 166 Main Street, Searcy, Ark. 72143. Applicant's representative: Warren A. Goff, 208 Clark Tower, Memphis, Tenn. 38137. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: General commodities, except Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and articles which require special handling because of size or weight: Between Memphis, Tenn., and Little Rock, Ark., and their commercial zones, as follows: (1) From Memphis, Tenn., to Little Rock, Ark., over U.S. Highway 64, thence over U.S. Highway 67 to Little Rock, Ark., and return over the same route, serving no intermediate points, (2) from Memphis, Tenn., over Interstate Highway 40 to Little Rock, Ark., and return over the same route, serving no intermediate points, for 180 days. Supporting shipper: Southland, Inc., 1101 S. Main St., Dallas, Texas. 75205. Applicant has also filed (110) statements of support attached to the application which may be examined at the field office named below. Send protests to: District Supervisor William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, Ark. 72201.

No. MC 59264 (Sub-No. 62TA), filed June 21, 1977. Applicant: SMITH & ANtONIO TRANSPORT, INC., 1866 New Brunswick, NJ. 08902. Applicant's representative: Herbert Burstein, 2373 One World Trade Center, New York, N.Y. 10046. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Containers, metal cans and ends, from plant site of Ball Corp. in or near Williamsburg, Va., to plant sites of Carlating National Breweries, Inc., in or near Baltimore, Md., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ball Corp., 345 South High Street, Muncie, Ind. 47302. Send protests to: District Supervisor Robert S. H. Vance, Interstate Commerce Commission, 9 Clinton Street, Newark, N.J. 07102.

No. MC 102567 (Sub-No. 192TA), filed June 22, 1977. Applicant: MCMNANN TRANSPORT, INC., 4256 Meadow Lane, P.O. Drawer 5357, Bossier City, La. 71101. Applicant's representative: Joe C. Day, 2040 Loop West, Suite 204, Houston, Tex. 77018. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Sodium salt solvents, in bulk, in tank truck vehicles, from plant site of Merlichem Co. and/or storage facilities of Merlichem Co., in Houston, Tex., to all points in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Oklahoma, for 180 days. Supporting shipper: Merlichem Co., 1914 Haden Road, Houston, Tex. 77015. Send protests to: District Supervisor Ray C. Armstrong, Jr., 701 Loyola Ave., 9038 Federal Bldg., New Orleans, La. 70113.

No. MC 106396 (Sub-No. 775TA), filed June 21, 1977. Applicant: NATIONAL TRAILER CONVOY, INC., 525 S. Main, P.O. Box 3329, Tulsa, Okla. 74103. Applicant's representative: Norman Burdette, same address as applicant. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Plant constructed commercial buildings, in sections, from Aberdeen, S. Dak., to points in Kansas, Missouri, Illinois, North Dakota, Nebraska, Colorado, Wyoming, Montana, Idaho, Utah, Arizona, Wisconsin, Minnesota, and Iowa, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Associated Contractors of America, Inc., 224 6th Avenue SE, Aberdeen, S. Dak. 57401. Send protests to: District Supervisor Joe Green, Rm. 240, District Supervisor, Interstate Commerce Commission, Rm. 105, Federal Bldg. and Court House, 111 South Wolcott, Casper, Wyo. 82601.

No. MC 107515 (Sub-No. 108TA), filed June 20, 1977. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 368, 3001 Jonesboro Road SE, Forrest Park, Ga. 30050. Applicant's representative: Alan E. Serby, 3379 Peachtree Road NE, Suite 316, Atlanta, Ga. 30326. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: Condensed milk by-products, in vehicles, equipped with mechanical refrigeration from the plant site of R. R. Donnelly & Son, Chicago, Ill., to Memphis, Tenn., Atlanta, Ga., and Jacksonville, Fla., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: U.S. News and World Report, Inc., 360 E. 22nd Street, Chicago, Ill. 60616. Send protests to: E. A. Bryant, District Supervisor, Interstate Commerce Commission, Room 300, 1235 West Peachtree Street NW, Atlanta, Ga. 30309.

No. MC 107515 (Sub-No. 108TA), filed June 20, 1977. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 306, 3001 Jonesboro Road SE, Forrest Park, Ga. 30050. Applicant's representative: Alan E. Serby, 3379 Peachtree Road NE, Suite 316, Atlanta, Ga. 30326. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: Compressed natural gas and meat by-products in vehicles, equipped with mechanical refrigeration from the plant site and/or warehouse facilities of Dixie Packers, Inc., P.O. Box 223, Madison, Fla., to points in New Mexico, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Dixie Packers, Inc., P.O. Box 223, Madison, Fla. 32340. Send protests to: E. A. Bryant, District Supervisor, Interstate Commerce Commission, Room 300, 1235 West Peachtree Street, Atlanta, Ga. 30309.

No. MC 113325 (Sub-No. 146TA), filed June 20, 1977. Applicant: SLAY TRANSPORTATION CO., INC., 2001 S. 7th Street, St. Louis, Mo. 63110. Applicant's representative: T. M. Tahan (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Lime, in bulk, from Ash Grove plant at or near Sequoia, Mo., to Bayway, N.J., by motor vehicle, over irregular routes, transporting: Lime, in bulk, from Ash Grove plant at or near Sequoia, Mo., to Bayway, N.J.,
NOTICES 35243

for 180 days. Supporting shipper: Exxon Chemical Co., P.O. Box 3272, Houston, Tex. 77001. Send protests to: J. P. Werthmann, District Supervisor, Interstate Commerce Commission, Room 300, 1252 West Peachtree Street NW., Atlanta, Ga. 30309.

No. MC 115841 (Sub-No. 541TA), filed June 21, 1977. Applicant: INTERSTATE REFRIGERATED TRANSPORTATION, INC., P.O. Box 168, Concord, Tenn. 37322. Applicant’s representative: Mike G. Moneymaker, 2014 Executive Park Drive, Suite 110, Bldg. 100, Knoxville, Tenn. 37919. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Smoked and cured meats, from the facilities of Vogue Foods Products at or near Philadelphia, Pa., to points in West Virginia, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Hygrade Food Products Corporation, 8400 Executive Avenue, Philadelphia, Pa. 19153. Send protests to: District Supervisor Joe J. Tate, Bureau of Operations, Interstate Commerce Commission, Suite A-422-U.S. Courthouse, 801 Broadway, Nashville, Tenn. 37203.

No. MC 115831 (Sub-No. 45TA), filed June 20, 1977. Applicant: J & M TRANSPORTATION CO., INC., P.O. Box 485, Milledgeville, Ga. 31061. Applicant’s representative: Paul M. Daniel, 1600 Federal Building, Atlanta, Ga. 30303. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Composition board, from the facilities of the United States Gypsum Company, Greenville, Miss., to points in Texas, Oklahoma, Illinois, Indiana, Michigan, and Ohio, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: United States Gypsum Company, 101 South Wacker Drive, Chicago, Ill. 60606. Send protests to: E. A. Bryant, District Supervisor, Interstate Commerce Commission, Room 300, 1252 West Peachtree Street NW., Atlanta, Ga. 30309.

No. MC 115831 (Sub-No. 285TA), filed June 20, 1977. Applicant: J & M TRANSPORTATION CO., INC., P.O. Box 485, Milledgeville, Ga. 31061. Applicant’s representative: Paul M. Daniel, 1600 Federal Building, Atlanta, Ga. 30303. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Lumber, from Opelika, Ala., to points in Florida, Georgia, Louisiana, Mississippi, Tennessee, North Carolina, and South Carolina, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: McMillan Bloedel, Inc., 1250 Brown Marx Building, Birmingham, Ala. 35203. Send protests to: E. A. Bryant, District Supervisor, Interstate Commerce Commission, Room 300, 1252 West Peachtree Street NW., Atlanta, Ga. 30309.

Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cement, from Fulton, Mass., to points in Connecticut, Massachusetts, New Hampshire, Vermont, Rhode Island and New York, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Independent Cement Corporation, 65 William St., Wellesley, Mass. 02181. Send protests to: Robert A. Radler, District Supervisor, P.O. Box 1167, Albany, N.Y. 12201.

No. MC 118399 (Sub-No. 707TA), filed June 20, 1977. Applicant: CONTRACT FREIGHTERS, INC., 2900 Davis Blvd. P.O. Box 1375, Joplin, Mo. 64801. Applicant’s representative: David L. Sitton (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Milk beverages, in containers, from Ft. Worth, Tex., to Blytheville and Paragould, Ark., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Ed Roleston, Inc., P.O. Box 16, Paragould, Ark. 72450. Send protests to: John V. Barry, District Supervisor, Interstate Commerce Commission—B, 600 Federal Building, 911 Walnut Street, Kansas City, Mo. 64106.

No. MC 118670 (Sub-No. 37TA), filed June 22, 1977. Applicant: THE VICTOR TRANSIT CORPORATION, 5250 Este Avenue, Cincinnati, Ohio 45222. Applicant’s representative: Robert H. Kinker, 314 W. Main St., P.O. Box 464, Frankfort, Ky. 40601. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Paper, fibreboard, pulpboard or strawboard, other than corrugated, from Carthage, Ind., to Illinois, Ohio, West Virginia, and Louisville, Ky., and its commercial zone, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: James R. Raudenbush, Central Traffic Manager, Container Corporation of America, 500 E. North Avenue, Carol Stream, Ill. 60118. Send protests to: Paul J. Lowry, District Supervisor, Bureau of Operations—Interstate Commerce Commission, 5543 Federal Building, 550 Main Street, Cincinnati, Ohio 45202.

No. MC 124230 (Sub-No. 327TA), filed June 15, 1977. Applicant: C. B. JOHNSTON, INC., P.O. Drawer S, Cortez, Colo. 81321. Applicant’s representative: David E. Driggers, 1600 Lincoln Center, 1600 Lincoln Street, Denver, Colo. 80224. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Ore and ore concentrates, from Tempe, Ariz., to the facilities of Union Carbide Corporation at or near Bishop, Calif., for 180 days. Supporting shipper: Union Carbide Corporation, One California Street, San Francisco, Calif. 94111. Send protests to: Herbert C. Ruoff, District Supervisor, 492 U.S. Customs House, 721 19th Street, Denver, Colo. 80202.
NOTICES

No. MC 124511 (Sub-No. 37TA), filed June 17, 1977. Applicant: JOHN F. OLIVER, P.O. Box 46, El Paso, Texas, 79912. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Meat products, in bulk, in dump vehicles, from South St. Paul, Minn., and Dubuque, Iowa to facilities of the state of Wisconsin at Chippewa Falls, Wis., and Menomonie, Wis., for 180 days. Supporting shipper: Reiss Coal Company, Sheboygan, Wis., 53081. Send protests to: Richard C. Alexander, 710 N. Plankinton Ave., Milwaukee, Wis. 53203.

No. MC 136215 (Sub-No. 17TA), filed June 21, 1977. Applicant: OLEN BURGER TRUCKING, INC., Route 9, Box 25-A, Philadelphia, Miss. 38650. Applicant's representative: Fred W. Johnson, Jr., 1500 Deposit Guaranty Plaza, P.O. Box 22628, Jackson, Miss. 39205. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Particleboard, from the facilities of Weyerhaeuser Company at Adel, Ga., to points in Alabama, Arkansas, Florida, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee and Virginia, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Weyerhaeuser Company, 141362 (Sub-No. 37TA), filed June 17, 1977. Applicant: CHEEROKEE LINES, INC., P.O. Box 152, 80 E. Moses, Cushing, Okla. 74323. Applicant's representative: Donald L. Stern, Suite 500, Univac Bldg., 7100 W. Center Rd., Omaha, Nebr. 68106. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Temporary, computed solids, in bulk, in dump vehicles, from South St. Paul, Minn., and Dubuque, Iowa to facilities of the state of Wisconsin at Chippewa Falls, Wis., and Menomonie, Wis., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Reiss Coal Company, Sheboygan, Wis., 53081. Send protests to: Richard C. Alexander, 710 N. Plankinton Ave., Milwaukee, Wis. 53203.

No. MC 135953 (Sub-No. 17TA), filed June 21, 1977. Applicant: CHEROKEE LINES, INC., P.O. Box 152, 80 E. Moses, Cushing, Okla. 74323. Applicant's representative: Donald L. Stern, Suite 500, Univac Bldg., 7100 W. Center Rd., Omaha, Nebr. 68106. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cured, preserved neats, in bulk, in dump vehicles, from Land O'Frost, Inc., at Searcy, Ark., to points in California, Oregon, Washington, Idaho, Montana, Utah, Colorado, Wyoming, Arizona and Nevada, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Land O'Frost, Inc., 1800 East Chicago Avenue, Lansing, Ill. 60438. Send protests to: District Supervisor Joe Green, Rm. 240, Old-Post Office Bldg., 215 Northwest Third St., Oklahoma City, Okla. 73102.

No. MC 136828 (Sub-No. 28TA), filed June 17, 1977. Applicant: LUISI TRUCK LINES, INC., P.O. Box 406, New Walla Walla Highway No. 11, Milton-Freewater, Oreg. 97862. Applicant's representative: Philip G. Skofstad, P.O. Box 594, Gresham, Oreg. 97030. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Meat and meat products, in bulk, in dump vehicles, from Portland, Clackamas, Sublimity, Eugene and Medford, Oreg., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Petroleum, Long Beach, Calif., to Clerksdale, Ariz., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: I.M.C. Industry Group, Inc., Carbon Products Division, 1270 Pier G. Avenue, Long Beach, Calif. 90802. Send protests to: Irene Carlos, Transportation Department, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, Calif. 90012.

No. MC 136545 (Sub-No. 10TA), filed June 20, 1977. Applicant: NUSISSBERGER BROS. TRUCKING CO., INC., 1108 Railread St., P.O. Box 95, Prentice, Wis. 54556. Applicant's representative: Richard A. Westley, 4500 Regent St., Milwaukee, Wis. 53205. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Portable wheel crushers, from the plantsite of the La Font Corporation at Chillicothe, Ohio, to points in Kentucky, Tennessee and Virginia, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Independent Cement Company, 65 W. Gilbert Ave., Driver Street, Wellesley Office Park, Wellesley, Mass. 02181. Send protests to: Max Gorenstein, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 150 Causeway Street, Boston, Mass. 02114.


No. MC 142778 (Sub-No. 3TA), filed June 20, 1977. Applicant: DON BAKER, R.R. 2, McLeansboro, Ill. 62859. Applicant's representative: Don Baker (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Coal, in bulk, in dump vehicles, from
Saline, Franklin, Jefferson, Williamson, Gallatin, Marion, Hamilton, Hardin, Pope, and Jackson Counties in Illinois, to points south of State Route 32 in Indiana, for 180 days. Supporting shipper: John P. Masselinck, Fuel Manager, Public Service Company of Indiana, 260 E. Main Street, Plainfield, Ind. 46168. Send protests to: Harold C. Jolliff, District Supervisor, Interstate Commerce Commission, P.O. Box 2416, Springfield, Ill. 62705.

No. MC 145413, (Sub-No. 17A), filed June 22, 1977. Applicant: A & B Wilson Sons, Inc., 261 Squawbrook Road, North Haledon, N.J. 07508. Applicant's representative: Edward L. Nehez, 167 Fairfield Road (P.O. Box 1409), Fairfield, N.J. 07008. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Place goods, in individual rolls, and materials and supplies used in the dyeing or finishing of piece goods, between the plant sites of Brandenly-Fishkill, Inc., at Beacon, N.Y., on the one hand, and, on the other New York, N.Y. and points in the New York, N.Y. Commercial Zone as defined by the Commission, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Supreme Cedar Products, Inc., Route 1, Box 140, Concrete, Wash. Send protests to: District Supervisor Joel Morrows, Interstate Commerce Commission, 9 Clinton Street, Newark, N.J. 07102.

WATER APPLICATION

W-976 (Sub-No. 2TA), filed June 17, 1977. Applicant: LYKES BROS. STEAMSHIP CO., INC., 300 Pydras Street, New Orleans, La. 70113. Applicant's representative: A. P. Babin (same address as applicant). Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: (1) five pieces Nuclear Reactor Components consisting of two (2) reactors each 35'2" x 23'4 1/4" x 23'4 1/4" /840,000 lbs; one (1) Service Support Equipment 16'7" x 12'8" x 15'9" /35,600 lbs; two (2) Closure Heads each 19'6" x 10'6" /200,500 lbs. From: Port of New Orleans, La, To: Port of Longview, Wash., via the Panama Canal by Steamship, for 90 days. Supporting shipper: The Babcock & Wilcox Company, S. Ladich, Manager of Transportation Operations, 20 So, Van Buren Avenue, Barberton, Ohio 44203. Send protests to: District Supervisor Ray C. Armstrong, Jr., 7610 Columbia Avenue, Westlake, Ohio 44145 Federal Building, New Orleans, La. 70113. By the Commission.

H. G. HOMME, Jr., Acting Secretary.

[FR Doc.77-19513 Filed 7-7-77; 8:45 am]

PETITIONS, APPLICATIONS, FINANCE MATTERS (INCLUDING TEMPORARY AUTHORITIES), RAILROAD ABANDONMENTS, ROUTE CHANGES, ALTERNATE ROUTE DEVIATIONS, AND INTRASTATE APPLICATIONS

JULY 1, 1977.

PETITIONS FOR MODIFICATION, INTERPRETATION, OR RESTATEMENT OF OPERATING AUTHORITY

The following petitions seek modification or interpretation of existing operating authority, or restate ment of terminated operating rights authority. The Commission has recently provided for easier identification of substantive petition matters and all documents should clearly specify the "docket," "sub," and "suffix" (e.g. M1, M2 numbers) identified by the Federal Register notice.

An original and one copy of protests to the granting of the requested authority must be filed with the Commission on or before August 8, 1977. Petitioners shall comply with Special Rule 247(d) of the Commission's General Rules of Practice (49 CFR 1100.247) and shall include concise concise summary of protestant's interest in the proceeding and copies of its conflicting authorities. Verified statements in opposition should not be tendered at this time. A copy of the protest, for pick-up and delivery, must be delivered upon a petitioner's representative, or petitioner if no representative is named.

No. MC 730 (Sub-No. 149) (NOTE: filing of petition to modify a certificate), filed May 12, 1977. Petition: PACIFIC INTERMOUNTAIN EXPRESS CO., a corporation, 1417 Clay Street, P.O. Box 958, Oakland, Calif. 94604. Petitioning representative: Alfred M. Krebs (same address as petitioner). Petitioner holds a motor common carrier certificate in No. MC 730 (Sub-No. 149), issued July 31, 1950, authorizing transportation as a common carrier by motor vehicle, over irregular routes, of general commodities (except those of unusual value, Class A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment, (1) from Salt Lake City, Utah, to Seattle, Wash., serving all intermediate points in Utah restricted to pick-up only, those in Idaho east of Burley, Idaho (including the city of Idaho Falls), and those in Idaho west of Burley, Idaho, and in Oregon and Washington restricted to delivery only as follows: (A) from Salt Lake City, Utah, over the above-described routes covering the transportation of fish, frozen fruits, cheese, horticultural bulbs, and frozen vegetables, to Seattle; and also over the following described routes: (1) from Ogden, Utah on the above described route, to Washington Highway 10 to Wenatchee, Wash., and thence over Washington Highway 2 to Teanaway, Wash.; (2) from Walla Walla, Wash., over U.S. Highway 10 to Walla Walla, Wash.; and (3) from Fall City, Wash., over Washington Highway 2 via Redmond and Bothell, Wash., to Seattle, Wash., by the instant petition, petitioner seeks to modify the authority above, so as to read: "General commodities (except those of unusual value, Class A and B explosives, household goods, as defined by the Commission, commodities in bulk, and those requiring special equipment, (1) from Salt Lake City, Utah, over the above-described routes covering the transportation of fish, frozen fruits, cheese, horticultural bulbs, and frozen vegetables to Seattle, Wash., serving all intermediate points, and return over the same routes; and also over

Copies of Special Rule 247 (as amended) can be obtained by written request to the Secretary, Interstate Commerce Commission, Washington, D.C. 20423.
the following described routes: (3) from Quincy, Wash., over Washington Highway 10 to Wenatchee, Wash., and thence over Washington Highway 2 to Tenay- way, Wash.; (b) from Walla Walla, Wash., over U.S. Highway 410 to Wallula, Wash.; and (c) from Walla Walla, Wash., over Washington Highway 2 via Redmond, and Bothell, Wash., to Seattle, Wash.

No. MC 3603 and MC 3600 (Sub-Nos. 4 and 5) (M1) (Notice of filing of petition to delete restriction), filed June 3, 1977. Petitioner: FRANK MARTZ COACH COMPANY, a corporation, 239 Old River Road, Wilkes-Barre, Pa. 18702. Petitioner's representative: S. Berne Smith, P.O. Box 1166, Harrisburg, Pa. 17108. Petitioner holds a motor common carrier certificate in No. MC 3600 and (Sub-Nos. 4 and 5), issued November 24, 1942, September 5, 1967, and November 4, 1968, respectively, authorizing transportation, as pertinent, on regular routes, as follows: No. MC 3600 authorizes passengers and their baggage, and express and newspapers passengers and their baggage, and express and newspapers vehicles, with passengers, during the season extending from the 15th day of May to the 1st day of October, both inclusive, between the junction of U.S. Highway 32 and New Jersey Highway 30 near Clifton, N.J., and Atlantic City, N.J., serving all intermediate points; from the junction of U.S. Highway 22 and New Jersey Highway 30 near Clifton, N.J., and Atlantic City, N.J., serving all intermediate points; No. MC 3600 (Sub-No. 4) authorizes passengers and their baggage, and express and newspapers in the same vehicle with passengers, during the season extending from May 15 to October 15, both inclusive, of each year, between the Lehigh Valley interchange on the Pennsylvania Turnpike to Junction New Jersey Turnpike, thence over new Jersey Turnpike, thence over U.S. Highway 30 near Hammonton, N.J., and thence over U.S. Highway 30 to Atlantic City, N.J., and return over the same route; No. MC 3600 (Sub-No. 4) authorizes passengers and their baggage, and express and newspapers in the same vehicle with passengers, during the season extending from May 15 to October 15, both inclusive, of each year, between the Lehigh Valley interchange on the Pennsylvania Turnpike to Junction New Jersey Turnpike, thence over New Jersey Turnpike to the Camden-Philadelphia interchange, thence over New Jersey Highway 73 to Junction U.S. Highway 30, and thence over U.S. Highway 30 to Junction U.S. Highway 208, and return over the same route; and

No. MC 3600 (Sub-No. 5) authorizes passengers and their baggage, and express and newspapers in the same vehicle with passengers, during the season extending from May 15 to October 15, both inclusive, of each year, between the junction of the Northeast Extension of the Pennsylvania Turnpike and Atlantic City, N.J., in connection with carrier's presently authorized regular route operations between Scranton and Wilkes-Barre, Pa., and Atlantic City, N.J., serving all intermediate points, but not serving the junction of Northeast Extension of the Pennsylvania Turnpike to Valley Forge Interchange (Sub-No. 24), thence over Interstate Highways 76 and 76 to junction New Jersey Highway 42, thence over New Jersey Highway 42 to Junction Atlantic City Expressway, and thence over Atlantic City Expressway to Atlantic City, and return over the same route. By the instant petition, petitioner requests a finding by the Commission that the authority to serve Woodbridge, N.J., in lieu of Woodbridge, N.J., to WilmingtoN, Del., Baltimore, Md., and named points in New Jersey, New York, Connecticut, Pennsylvania, and the District of Columbia, under contracts with various named shippers. By the instant petition, petitioner requests a finding by the Commission that the authority to serve Woodbridge, N.J., encompasses authority to serve Edison, N.J., in lieu of Woodbridge, N.J., as the origin point.

Motor Carrier, Broker, Water Carrier and Freight Forwarder Operating Rights Applications

The following applications are governed by Special Rule 247 of the Commission's General Rules of Practice (49 CFR § 1100.247). These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission on or before August 8, 1977. Failure to seasonably file a protest will be construed as a waiver of the right to protest. A protest under these rules should comply with section 247(d) (2) of the rules of practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (including a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application), and describe in detail the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed, and shall specify with particularity the facts, matters and things relied upon. A protest shall not include issues or allegations phrased generally. Protests not in reasonable compliance with the requirements of the rules may be rejected. The oral proceeding (including a copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon the applicant's representative, or applicant if not representative is named. If the protest includes a request for oral hearing, such requests shall meet the requirements of section 247(d) (4) of the special rules, and shall include the certification required therein.

Section 247(f) further provides, in part, that an applicant who does not intend timely to prosecute its application shall promptly request dismissal thereof, and that failure to prosecute an application under procedures ordered by the Commission will result in dismissal of the application.

Further processing steps will be by Commission order which will be served on each party of record. Broadening amendments will not be accepted after the date of this publication except for good cause shown and restrictive amendments will not be entertained following publication in the Federal Register of a notice that the proceeding has been assigned for oral hearing.

Each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

No. MC 730 (Sub-No. 405), filed May 19, 1977. Applicant: Pacific Interstate Mountain Express Co., A Corporation, 1417 Clay Street, P.O. Box 958, Oakland, California 94612. Applicant's representative: R. C. Coolidge (same address as applicant). Authority sought to operate as a common carrier, over irregular routes, transporting: Liquidified petroleum gas, in bulk, in tank vehicles, from points in the United States in and west of Texas, in Colorado, Wyoming and Montana (except Alaska and Hawaii) to points in the United States in and east of Louisiana, Arkansas, Oklahoma, Kansas, Nebraska, South Dakota and North Dakota.

Note—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either San Francisco or Los Angeles, Calif.

No. MC 3602 (Sub-No. 15), filed May 31, 1977. Applicant: The Adley Corporation d.b.a. ADLEY EXPRESS COMPANY, 10990 Roe Avenue, Shawnee Mission, KS 66202. Applicant's representative: Edward G. Bazelon, 39 South LaSalle St., Chicago, IL 60603. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: General commodities (except household goods as defined by the Commission, commodities in bulk, and com-
modities requiring special equipment): between Richmond, Va., and junction U.S. Highway 60 at or near Newport News, Va.; from junction U.S. Highway 60 at or near Newport News, Va., to junction Virginia Highway 258 at or near Newport News, Va.; from junction Virginia Highway 258 at or near Newport News, Va., thence over U.S. Highway 29 at or near Amherst, thence over U.S. Highway 29 to Lynchburg, and return over the same route; (17) between Lynchburg, Va., and junction U.S. Highway 24 and Virginia Highway 24 as an alternate route for operating convenience only: from Lynchburg over U.S. Highway 29 to junction Virginia Highway 24, U.S. Highway 24 and the same route; (19) between Lynchburg, Va., and junction U.S. Highway 501 and Virginia Highway 24 as an alternate route for operating convenience only: from Lynchburg over U.S. Highway 501 to junction Virginia Highway 24, as an alternate route for operating convenience only: from Lynchburg over U.S. Highway 501 to junction Virginia Highway 24, and return over the same route; (16) between Richmond, Va., and points in connection with routes U.S. Highway 50 and Virginia Highway 49 to Lynchburg, Va., as an alternate route for operating convenience only: from junction U.S. Highway 50 over Virginia Highway 49 to Lynchburg, thence over Virginia Highway 168 to its junction with Colonial National Parkway; thence over Colonial National Parkway to the site of Hartsville Nuclear Plant located at or near Hartsville, Tenn., as an offroute point in connection with carrier's presently authorized routes.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests that it be held at Chattanooga, Tenn., or Washington, D.C.

No. MC 2920 (Sub-No. 305) filed May 26, 1977. Applicant: REISCH TRANSPORTATION INC., P.O. Drawer 630, Mt. Holly, New Jersey 08060. Applicant's representative: S. E. Somers, Jr. (same address as applicant). Authority sought to operate as a common carrier by motor vehicle over irregular routes transporting household goods and containers, restricted to the transportation of traffic having a prior or subsequent movement, in containers, beyond the points authorized, and further restricted to the performance of pick-up and delivery service in connection with packing, crating, and containerization or unpacking, uncrating and decontainerization of such traffic, between points in New York City, Ulster, Dutchess, Nassau, Suffolk, Westchester, Rockland, Orange and Putnam Counties, New York; New Castle County, Delaware; Chester, Bucks, Lancaster, Dauphin, Berks, Lehigh, Northampton and Lebanon Counties, Pennsylvania; and points in New Jersey (except Sussex, Passaic, and Bergen Counties), a non-radial movement.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests that it be held in Mt. Holly, New Jersey.

No. MC 3117 (Sub-No. 3) filed May 26, 1977. Applicant: PARAGON VANLINES, INC., P.O. Drawer 630, Mt. Holly, New Jersey 08060. Applicant's representative: S. E. Somers, Jr. (same address as applicant). Authority sought to operate as a common carrier by motor vehicle over irregular routes transporting household goods in containers, restricted to the transportation of traffic having a prior or subsequent movement, in containers, beyond the points authorized, and further restricted to the performance of pick-up and delivery service in connection with packing, crating, and containerization or unpacking, uncrating and decontainerization of such traffic, between points in New York City, Ulster, Dutchess, Nassau, Suffolk, Westchester, Rockland, Orange and Putnam Counties, New York; New Castle County, Delaware; Philadelphia, Delaware, Montgomery, Chester, Bucks, Lancaster, Dauphin, Berks, Lehigh, Northampton and Lebanon Counties, Pennsylvania; and points in New Jersey (except Sussex, Passaic, and Bergen Counties), a non-radial movement.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests that it be held in Mt. Holly, New Jersey.
NOTICES

CO., doing business as THE WAGGONERS, P.O. Box 990, Livingston, Mont. 59047. Applicant, temporary representative: Jacob P. Billig, 2033 K Street, NW., Washington, D.C. 20006. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting agri-cultural commodities in bulk, in tank vessels used in the processing, packing, storing, handling and marketing of tobacco, and (b) unmanufactured tobacco when moving on the same vehicles at the same time with the commodities described above, between points in Florida, Georgia, Kentucky, Maryland, North Carolina, Ohio, South Carolina, Tennessee, Virginia, and West Virginia.

Note.—If a hearing is deemed necessary, the applicant requests that it be held at similar applications at either Raleigh, N.C., or Washington, D.C.

No. MC 28385 (Sub-No. 491), filed May 31, 1977. Applicant: H. W. GABER, INC., R. D. No. 3, Box 200, Chambersburg, Pa. 17201. Applicant's representative: Christian V. Graf, 407 North Front Street, Harrisonburg, VA 22801. Applicant's representative: John F. Rhodes (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Garden, lawn, turf, and golf course equipment, snow blowers, and parts and accessories therefor, from the plantsite and warehouses of The Toro Company located at or near Windom, Minnesota, and at or near Temiskaming, Ont., to points in Conn., Del., Md., Mass., N.H., N.J., N.Y., Ohio, Pa., and at or near Tomah, Wis., to points in SD., Minn., MN; Chicago, Ill., or St. Louis, Mo., or Kansas City, Kan., or Denver, Colo., or Louisville, Ky., or Elkhart, Ind., or Osage Falls, Idaho; Tulsa and Checotah, Okla.; Umatilla and Stayton, Oreg.; Mansfield and Dennison, Tex. and Spokane and Ferndale, Wash. on the one hand, and, on the other, points in Arkansas, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oklahoma, Oregon, Texas, Utah, Washington and Wyoming.


No. MC 26509 (Sub-No. 28) filed May 31, 1977. Applicant: LOOMIS ARMORED CAR SERVICE, INC., 821 Sunnyside Street, San Francisco, California 94111. Applicant's representative: George H. Hart, 1100 IBM Building, Seattle, Washington 98101. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Coin and currency, (1) between Minneapolis, Minnesota, on the one hand, and, on the other, Superior, Wisconsin; (2) between Minneapolis, Minnesota, on the one hand, and, on the other, points in Montana, North Dakota, South Dakota, Wisconsin, and Minnesota, on the one hand, and, on the other, points in South Dakota, under a continuing contract, or contracts, with Federal Reserve Bank of Minneapolis.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests that it be held at Minneapolis, Minn.; San Francisco, Calif.; or Seattle, Wash.


Note.—If a hearing is deemed necessary, the applicant requests that it be held at Milwaukee, Wis.; or any other place in Wisconsin.

No. MC 32882 (Sub-No. 77), filed June 21, 1977. Applicant: MITCHELL BROS. TRUCK LINES, 3841 N. Columbia, P.O. Box 17039, Portland, Ore. 97217. Applicant's representative: Dave R. Parker, 2310 Colorado State Bank Bldg., 1600 Broadway, Denver, Colo. 80202. Authority sought to operate as a common carrier, by motor-vehicle, over irregular routes, transporting: Aluminum, aluminum products, and supplies, materials and equipment used in the manufacture of aluminum and aluminum products (except in bulk), between the plantsite and facilities of Alumax, Inc., at or near Casa Grande, Ariz., Long Beach, Riverside, Visalia, Perris Valley and Woodland, Calif.; Lovelock, Nev.; and Twin Falls, Idaho; Tulsa and Checotah, Okla.; Umatilla and Stayton, Oreg.; Mansfield and Dennison, Tex. and Spokane and Ferndale, Wash. on the one hand, and, on the other, points in Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oklahoma, Oregon, Texas, Utah, Washington and Wyoming.


No. MC 35059 (Sub-No. 15), filed May 31, 1977. Applicant: NORTH STATE MOTOR LINES, INC., U.S. 301 By-Pass South, P.O. Box 4108, Rocky Mount, North Carolina 27801. Applicant's representative: Louis J. Amato, P.O. Box E, Bowling Green, Kentucky 42101. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting (1) (a) Materials, supplies and equipment (except commodities in bulk, in tank vessels used in the processing, packing, storing, handling and marketing of tobacco, and (b) unmanufactured tobacco when moving on the same vehicles at the same time with the commodities described above, between points in Florida, Georgia, Kentucky, Maryland, North Carolina, Ohio, South Carolina, Tennessee, Virginia, and West Virginia.

Note.—If a hearing is deemed necessary, the applicant requests that it be held at Dallas, Texas.
trict of Columbia and points in the above
named destination states to the plant sites of
the Curtis Corporation at New
London, Wis.

Note.—If a hearing is deemed necessary, applicant requests it be held at Milwaukee or Madison, Wis.

No. MC 41404 (Sub-No. 127) filed May 25, 1977. Applicant: ARGO-COLLIER TRUCK LINES CORPORATION, Post Office Box 440, Martin, Tenn. 38237. Applicant's representative: Mark L. Horne (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Food products and food ingredients (except oleomargarine, shortening, and salad oil), in vehicles equipped with mechanical refrigeration, from the plant and storage facilities of Archer Daniels Midland Company, located at Decatur, Ill., to points in Alabama, Florida, Georgia, Kentucky, Louisi-
ana, Mississippi, North Carolina, South Carolina, and Tennessee restricted to shipments originating at the named origi-

No.—Common control may be involved.

If a hearing is deemed necessary, applicant requests it be held at Pittsburgh, Pa., or Washington, D.C.

No. MC 56679 (Sub-No. 30) filed June 17, 1977. Applicant: TRANSPORT CORP., 125 Milton Ave., E.S. Atlanta, Ga., 30315. Applicant's representative: R. J. Reynolds, III, Candlier Building, Atlanta, Ga., 30303. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: General commodities (except those of unusual value, Class A and B explosives, household goods as defined by the Interstate Commerce Commission, and those requiring special equipment). (1) Between Atlanta, Georgia, and Carters-
ville, Georgia, serving no intermediate points, but serving the termini of Atlanta, Georgia, Cartersville, Georgia, and all points within their respective commercial zones, from Atlanta, Georgia, to Cartersville, Georgia, over U.S. Highway 41, and return over the same route. Restriction: No point may be served by operating over Interstate Highway 75 between Atlanta, Georgia, and Cartersville, Georgia, and over all roads and portions of roads connecting completed portions of Interstate Highway 75 and U.S. Highway 41 and return over the same route.


No. MC 47583 (Sub-No. 50) filed June 2, 1977. Applicant:FileVersion 11, INC., 1020 Sunshine Road, Kan-

sas City, Kan., 66115. Applicant's representative: S. Hults, P.O. Box 225, Lawrence, Kan., 66044. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Cellulose insulation, in bags, blowing machines and replacement parts and supplies for blowing machines, from the plant site and storage facilities of General Fiber Corporation, at or near Commerce City, Colorado, to points in Arkansas and Louisiana; and (2) materials, equipment, and supplies used in the manufacture and distribution of cellulose insulation except commod-
ities in bulk, from points in Arkansas and Louisiana, to the plant site and storage facilities of General Fiber Corpora-
tion, at or near Commerce City, Colorado.

No.—Common control may be involved.

If a hearing is deemed necessary, the applicant requests it be held in Kansas City, Missouri.

No. MC 48213 (Sub-No. 46) filed May 18, 1977. Applicant: C. E. LIZZA, INC., P.O. Box 387, Ligonier, Pa., 15658. Applicant's representative William A. Gray, 2310 Grant Building, Pittsburgh, Pa., 15219. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Explosives and fireworks from New Castle, Pa., to points in Michigan and Minnesota, un-
der a continuing contract of contracts with Vitale Fireworks Manufacturing Company, of New Castle, Pa.

Note.—Common control may be involved.

If a hearing is deemed necessary, applicant requests it be held at Pittsburgh, Pa., or Washington, D.C.
Tennessee, serving no intermediate points, but serving the termini of Chattanooga, Tennessee, and Knoxville, Tennessee, and all points within their respective counties. From Des Moines, Iowa, to points in Iowa, and serving the termini of Des Moines, Iowa, to Omaha, Nebraska.

Note.—If a hearing is deemed necessary, the applicant requests that it be held at either Des Moines, Iowa or Omaha, Nebraska.

No. MC 67121 (Sub-No. 9) filed May 18, 1977. Applicant: HARP TRANSPORTATION LINE, INC., P.O. Box 1159, St. Joseph, Missouri 64802. Applicant's representative: John H. Lewis, The 1650 Grant Street Building, Denver, Colorado 80203. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: general commodities (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, in bulk, and those requiring special equipment): Between Rangely, Colorado and Dinosaur, Colorado, serving all intermediate points: From Rangely, Colo., over Colorado Highway 24, Dinosaur, Colo., and return over the same route.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests that it be held at either Des Moines, Iowa or Omaha, Nebraska.


Note.—The purpose of this partial republication is to indicate applicant's correct docket number as MC 78228 (Sub-No. 63) in lieu of MC 72228 (Sub-No. 41) as previously published. The rest of the publication remains as previously published.

No. MC 58585 (Sub-No. 143) filed May 27, 1977. Applicant: WALES TRANSPORTATION, INC., P.O. Box 1900, Dallas, Tex. 75222. Applicant's representative: James W. Highover, 136 Wynne-wood Prod. Bldg., Dallas, Tex. 75224. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Plastic pipe, aluminum, aluminum pipe, and machinery, from Spokane, Wash., to points in the United States and out of New Mexico, Colorado, Nebraska, South Dakota, and North Dakota; and (2) metal building materials and supplies, from Denver, Colo., and Minneapolis, Minn., to points in the United States in and east of New Mexico, Colorado, Nebraska, South Dakota, and North Dakota; and (3) steel used in the manufacture of metal building materials and supplies, from Spokane and Tacoma, Wash., to Denver, Colorado and Minneapolis, Minn.

Note.—If a hearing is deemed necessary, the applicant requests that it be held at Dallas, Tex.

No. MC 82478 (Sub-No. 10), filed May 27, 1977. Applicant: I C L INTERNATIONAL CARRIERS, INC., 1333 College Avenue, Windsor, Ontario, Canada N9C3Y9. Applicant's representative: Joseph P. Allen, 7101 W. Jefferson, Detroit, Mich. 48226. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Nepheline Syenite, in bulk in dump or hopper bottom vehicles, from the ports of entry on the International Boundary line between the United States and Canada, located at Detroit and Port Huron, Mich., to Toledo, Ohio, restricted to the transportation of foreign commerce from Oakville, Ontario, to Buffalo, N.Y., or from Buffalo, N.Y., to Oakville, Ontario, Canada.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Detroit, Mich., or Warren, D.C.


Note.—If a hearing is deemed necessary, applicant requests it be held at New York, N.Y.

No. MC 95540 (Sub-No. 982) filed May 23, 1977. Applicant: WATKINS MOTOR LINES, INC., 1144 West Griffin Road, P.O. Box 1636, Lakeland, Florida 33802. Applicant's representative: Benly W. Fincher (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Floor sweeping compounds and absorbents (except in bulk) (1) From the facilities of the Oil-Dri Corporation of America, located at or near Ripley, Miss., to points in Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois (except Chicago), Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri (except St. Louis), Nebraska, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Texas, Virginia, West Virginia, Wisconsin, and the District of Columbia and (2) from the facilities of the Oil-Dri Corporation of America, located at or near Richfield, Ohio, to points in Arkansas, Colorado, Delaware, Illinois, Iowa, Indiana, (except Richardson, Gary, and Hammond and points in their respective commercial zones), Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, Texas, Vermont, West Virginia, and Wisconsin.
NOTICE

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

53521

Docket Number MC 95876 (Sub-No. 200), filed March 17, 1977. Applicant: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Avenue North, St. Cloud, Minn. 56301. Applicant's representative: Donald A. Morken, 1000 First National Bank Bldg., Marshall, Minnesota, Minn. 55602. Authority sought to operate as a common carrier, over irregular routes, transporting: (1) Tractors; (2) agricultural implements and farm machinery; (3) parts, attachments, and accessories, for tractors, farm machinery, and agricultural implements; (4) equipment designed for use with tractors; and (5) equipment, materials, and supplies used in the manufacture and distribution of the commodities named in (1), (2), (3), and (4), between Winneconne and Neenah, Wis., on the one hand, and points in the United States (except Alaska and Hawaii), on the other.

Notes.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either Chicago, Ill., Washington, D.C., or Tampa, Fla.

No. MC 95876 (Sub-No. 200), filed March 17, 1977. Applicant: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Avenue North, St. Cloud, Minn. 56301. Applicant's representative: Robert D. Cisvold, 1000 First National Bank Bldg., Marshall, Minnesota, Minn. 55602. Authority sought to operate as a common carrier, over irregular routes, transporting: (1) Tractors; (2) agricultural implements and farm machinery; (3) parts, attachments, and accessories, for tractors, farm machinery, and agricultural implements; (4) equipment designed for use with tractors; and (5) equipment, materials, and supplies used in the manufacture and distribution of the commodities named in (1), (2), (3), and (4), between Winneconne and Neenah, Wis., on the one hand, and points in the United States (except Alaska and Hawaii), on the other.

Notes.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either San Francisco, Calif., or Reno, Nev. The purpose of this request is to permit applicant to "serve the terminals for purposes of joinder only" from the previous publication.

No. MC 95945 (Sub-No. 58), filed May 4, 1977. Applicant: JIMMY STEIN MOTOR LINES, INC., P.O. Box 2260, Mobile, Ala. 36601. Applicant's representative: J. Douglas Harris, 1406 Unlon Bank Tower, Montgomery, Ala. 36114. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, in connection with applicant's regular routes, transporting: (1) Collecting machinery and farm machinery; (2) farm equipment, farm machinery, and agricultural implements; (3) building materials, paper, newsprint, and those of unusual value; (4) General commodi-
ties; (5) Dreadlocks, Ill., serving all intermediate points. (12) Between Mobile and Selma, Ala., via Linden, Ala., serving all intermediate points.

Notes.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C., or Minneapolis, Minn.

No. MC 95945 (Sub-No. 201), filed May 4, 1977. Applicant: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Avenue North, St. Cloud, Minn. 56301. Applicant's representative: Robert D. Cisvold, 1000 First National Bank Bldg., Marshall, Minnesota, Minn. 55602. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, in connection with applicant's regular routes, transporting: (1) Collecting machinery and farm machinery; (2) farm equipment, farm machinery, and agricultural implements; (3) building materials, paper, newsprint, and those of unusual value; (4) General commodi-
ties; (5) Dreadlocks, Ill., serving all intermediate points.

Notes.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C., or Minneapolis, Minn.

No. MC 99565 (Sub-No. 15) (correction), filing date May 18, 1977, published in the Federal Register issue of June 23, 1977, republished as corrected this issue. Applicant: FORE WAY EXPRESS, INC., 204 S. Bellis Street, Wausau, Wis. 54401. Applicant's representative: Nancy J. Johnson, 4506 Regent Street, Suite 100, Madison, Wis. 53705. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: General commodities except those of unusual value, Classes A and B explosives, commodities in bulk, household goods as defined by the Commission, and those requiring special equipment; serving all intermediate points. (4) Between Linden, Ala., and Pine Hill, Ala., over Alabama State Highway No. 10, serving all intermediate points.

Notes.—This application is made to convert Certificate of Convenience and Necessity issued to Jimmy Stein Motor Lines, Inc., to a certificate of convenience and necessity. Moreover, in addition thereto, extend service to Meridian, Miss., as described in paragraph 1. If a hearing is deemed necessary, the applicant requests it be held at either Montgomery or Mobile, Ala.

No. MC 100666 (Sub-No. 347) filed May 23, 1977. Applicant: MELTON TRUCK LINES, INC., P.O. Box 7666, Shreveport, La. 71107. Applicant's representative: Wilburn L. Williamson, 280 Restaurant Rd., Minneapolis, Minn. 55401. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: General commodities except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, and those requiring special equipment; serving all intermediate points. (9) Between Silas, Ala., and the site of the Jackson Lock and Dam located near U.S. Highway No. 84 and return. (10) Between McIntosh, Ala., and Citronelle, Ala., over County Highway No. 35 and return serving all intermediate points. (11) Between Mt. Vernon, Ala., and County Highway No. 98 and return serving all intermediate points. (12) Between Silas, Ala., and Grove Hill, Ala., over U.S. Highway No. 4 and return serving all intermediate points. (13) From Camden, Ala., on Alabama Highway No. 17 to Water Valley and Melvin, Ala., over County Highway No. 16 back to Alabama State Highway No. 17 making Nechanish, Ill., Gougeolousa, and Land, Ala. (14) Between Pine Hill, Ala., and the plant site of MacMillan Bloedel, Inc., near Pine Hill, Ala., over Alabama Highway No. 10, to be tacked at Pine Hill, Ala., with existing authority. (15) Between Chatom, Ala., and the plant site of Phillips Petroleum Co., Chatom Plant, over Alabama State Highway No. 58 approximately 9 miles west of Chatom, to be tacked at Chatom with existing authority. Irregular routes: (18) Voting machines between points in Mobile County, Ala.
NOTICES

73112. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Floor sweeping compounds and absorbents (except compounds from the facilities of Oil-Dri Corp. of America, located at or near Ochlocknee, Ga., to points in Iowa, Kansas, Missouri, and Texas, resting or intervaling at the above described facilities.

Note.—If a hearing is deemed necessary, applicant requests it be held at Chicago, III.


Note.—Common control may be involved.

If a hearing is deemed necessary, applicant requests it be held at New York, N.Y.

No. MC 106674 (Sub-No. 236) filed May 26, 1977. Applicant: SCHILLI MOTOR LINES, INC., P.O. Box 123, Remington, Ind. 47977. Applicant’s representative: Linda J. Swolly (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Construction materials (except commodities in bulk), from the plant site and warehouse facilities of the Johns-Manville Sales Corp., located at or near Natchez, Miss., to the plant site and warehouse facilities of the Celotex Corp., located at or near Elizabethtown, Ky., restricted to shipments originating at and destined to points as named above.

Note.—If a hearing is deemed necessary, applicant requests it be held in either Chicago, Ill., or Indianapolis, Ind.

Docket No. MC 107012 (Sub-No. 239), filed May 31, 1977. Applicant: NORTH AMERICAN VAN LINES, INC., Lincoln Highway East and Meyer Road, P.O. Box 289, Fort Wayne, Ind. 46801. Applicant’s representative: David D. Bishop (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Tow and games, from the plant site and storage facilities of Ideal Toy Co., located at or near Newark, N.J., to Atlanta, Ga., Dallas, Tex., Chicago, Ill., and Las Vegas, Nev., and (2) Sporting goods and recreational and physical fitness equipment, toys, and games, from Carson, Compton, and Dominguez, Calif., to points in the United States (except Alaska and Hawaii).

Note.—Common control may be involved.

If a hearing is deemed necessary, applicant requests it be held at either Chicago, Ill., or Washington, D.C.

No. MC 107496 (Sub-No. 1085), filed May 21, 1977. Applicant: RIAN TRANSPORT CORP., 1200 Ruan Center, 666 Grand-Avenue, Des Moines, Iowa 50309. Applicant’s representative: E. Check, P.O. Box 855, Des Moines, Iowa 50304. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Fly ash, in bulk, from points in Pike County, Ind., to points in Illinois, Kentucky, Arkansas, and Tennessee; and (2) Crushed gypsum rock, in bulk, in dump vehicles, from Sperry, Iowa, to points in Missouri.

Note.—Common control may be involved.

If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.

No. MC 107515 (Sub-No. 1081), filed May 26, 1977. Applicant: REFRIGERATED TRANSPORT CORP., INC., P.O. Box 308, Forest Park, Ga. 30295. Applicant’s representative: Alan E. Schry, 3379 Peachtree Road NE., Suite 375, Atlanta, Ga. 30326. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs, in vehicles equipped with mechanical refrigeration, from the facilities of Food Products, Inc., located at or near Greenville, S.C., to the facilities of Jeno’s, Inc., located at Duluth, Minn., and Superior, Wis.

Note.—Applicant holds contract carrier authority in MC 126438 (Sub-No. 2) and other sub., therefore dual operations may be involved. If a hearing is deemed necessary, the applicant requests it be held at Duluth, Minn.


Note.—Common control may be involved.

If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 109835 (Sub-No. 11), filed June 2, 1977. Applicant: MASHKINE FREIGHT LINES, INC., 64 Oakland Avenue, East Hartford, Conn. 06108. Applicant’s representative: Gerald A. Josloff, 50 State Street, Hartford, Conn. 06103. Authority sought to operate as a common carrier by motor vehicle, over irregular routes, transporting: Caroline Pacers, related accessories, instruction booklets, specification sheets and identification charts: Between Freeport and Houston, Tex., on traffic having an immediately prior or subsequent movement by air.

Note.—Applicant holds motor contract carrier authority in No. MC 111270 and subthereunder, and therefore dual operations...
NOTICES

may be involved. Common control may also be involved. If a hearing is deemed necessary, applicant requests it be held at Boston, Texas or Washington, D.C.

No. MC 112184 (Sub-No. 54), filed May 31, 1977. Applicant: THE MAN- FRED MOTOR TRANSPORT COMPANY, A Corporation, 2535 Mays Avenue, Newberry, Ohio 44065. Applicant's representative: John P. McMahon, 100 East Broad Street, Columbus, Ohio 43215. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: paint and paint products, in bulk, in tank vehicles from Cleveland, Ohio to Ports of Entry on the International Boundary Line between the United States and Canada, located at Detroit, Mich., and points which lie between Buffalo and Youngstown, New York, including Buffalo and Youngstown, New York for furtherance to the province of Ontario, Canada, under a continuing contract or contracts with PPG Industries, Inc.

Note.—Applicant holds common carrier authority in No. MC 128302 and substitutes thereunder; therefore, dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at either Columbus, Ohio or Washington, D.C.

No. MC 112529 (Sub-No. 340), filed June 1, 1977. Applicant: MCKENZIE TANK LINES, INC., P.O. Box 1200, Tallahassee, Fla. 32302. Applicant's representative: Thomas F. Panebianco (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Chemicals, in bulk, from the site of Alpine Laboratories located in Baldwin County, Ala., to points in the United States (except Alaska and Hawaii).

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Atlanta, Ga.

No. MC 115888 (Sub-No. 24), filed May 23, 1977. Applicant: RUSSELL TRUCKING LINE, INC., 2011 Cleveland Road, Sandusky, Ohio 44870. Applicant's representative: John P. McMahon, 100 East Broad Street, Columbus, Ohio 43215. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Gypsum, gypsum products, building materials and materials and supplies used in the manufacture, installation or distribution thereof between the plantsite and facilities of the United States Gypsum Company located at River Rouge, Michigan, on the one hand, and, on the other, points in Illinois, Indiana, Iowa, Michigan, Ohio, Pennsylvania, West Virginia and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests it be held with similar applications.

No. MC 113678 (Sub-No. 672), filed May 27, 1977. Applicant: CURTIS INC., 4810 Fonttac Street, Commerce City, Colo. 80022. Applicant's representative: Richard A. Peterson, P.O. Box 81849, Lincoln, Neb. 68501. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Printed matter, and materials, equipment, and supplies used in the manufacture, sale, and distribution of printed matter (except commodities in bulk), between Taunton, Mass.; Hammond and Indianapolis, Ind.; Versailles and Lexington, Ky.; Ossining, N.Y.; Nashville, Tenn.; and points in the Chicago, Ill. Commercial Zone, on the one hand, and, on the other, points in the United States (except Alaska and Hawaii).

Note.—If a hearing is deemed necessary, applicant requests it be held on a consolidated hearing with similar applications at Chicago, Ill.

No. MC 114211 (Sub-No. 305), filed May 25, 1977. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Daniel C. Sullivan, Suite 1600, 10 South La Salle, Chicago, Illinois 60603. Authority sought to operate as a common carrier, over irregular routes, by motor vehicle, transporting: Treated lumber mill products from Jef- ferson County, Arkansas to points in Minnesota, Iowa, Nebraska, South Dakota, and North Dakota.

Note.—If a hearing is deemed necessary, applicant requests it be held at either Little Rock, Arkansas or Fort Smith, Arkansas.


Note.—Applicant holds contract carrier authority in No. MC 125168 and substitutes thereunder; therefore, dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Salt Lake City, Utah.


Note.—If a hearing is deemed necessary, applicant requests it be held at Charleston, S.C.

No. MC 114569 (Sub-No. 179), filed May 16, 1977. Applicant: SHAEFFER TRANSPORTING, INC., P.O. Box 418, New Kingstown, Pa. 17072. Applicant's representative: N. L. Cummins (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: foodstuffs (except in bulk in tank vehicles) and articles manufactured for pets from the plantsite of Beatrice Foods Co., located at or near Menomonie, Vesper, and Cameron, Wisconsin, and the storage facilities of Sunna Division, Beatrice Foods Co., located at or near Eau Claire and Wisconsin Rapids, Wisconsin to points in New York, Pennsylvania, Maryland, Delaware, New Jersey, Connecticut, Massachusetts, Vermont, New Hampshire, Rhode Island, Maine, Virginia, West Virginia, Ohio and the District of Columbia, restricted to the traffic of Sunna Division, Beatrice Foods Co., originating at the above origins and destined to the named destinations.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Madison, Wisconsin or Washington, D.C.

No. MC 115162 (Sub-No. 367), filed May 26, 1977. Applicant: POOLE TRUCK LINE, INC., Post Office Drawer 500, Evergreen, Alabama 36401. Applicant's representative: Robert E. Tate (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: lumber, between the ports of entry on the International Boundary Line between the United States and Canada, located at points in Michigan and New York, on the one hand, and, on the other, points in Arkansas, Georgia, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas and Virginia, restricted to traffic in foreign commerce.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Detroit, Michigan or Washington, D.C.

No. MC 115162 (Sub-No. 368), filed May 26, 1977. Applicant: POOLE TRUCK LINE, INC., Post Office Drawer 500, Evergreen, Alabama 36401. Applicant's representative: Robert E. Tate (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Ground clay, floor sweeping compounds and absorbents (except in bulk) from the plantsite and warehouse sites of Oil-Dri Corporation of America located at or near Ochlocknee, Georgia to points in the United States in and east of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma and Texas; and (2) Floor sweeping compounds and absorbents (except in bulk) from the plantsite and warehouse sites of Oil-Dri Corporation of America located at or near Belo, Mississippi to points in the United States in and east of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma and Texas.

Note.—If a hearing is deemed necessary the applicant requests it be held at either Chicago, Illinois or Washington, D.C.
NOTICES

No. MC 115648 (Sub-No. 28), filed May 31, 1977. Applicant: LOCK TRUCKING INC., P.O. Box 278, Wheatland, Wyoming, 82201. Applicant's representative: Ward A. White, P.O. Box 566, Cheyenne, Wyoming 82001. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Stone, from points in Platte County, Wyoming to those points in Texas which are (a) on and west of U.S. Highway 45 (Interstate Highway 45) and south of U.S. Highway 80 (Interstate Highway 20), and (b) on and north of U.S. Highway 80 (Interstate Highway 20) and east of U.S. Highway 75 (Interstate Highway 45).

Note.—If a hearing is deemed necessary, applicant requests it be held at either Cheyenne, Wyo., or Denver, Colo.

No. MC 115606 (Sub-No. 286), filed May 31, 1977. Applicant: W. J. DIGBY, INC., P.O. Box 5088 Terminal Annex, Denver, Colorado 80217. Applicant's representative: Charles J. Kimball, 550 Capital Life Building, First and 17th Street, Denver, Colorado 80203. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Meals, meat products, meats and meat products distributed by meat packhouses (except hides and commodities in bulk), as defined in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificate No. MC 1203 and 766. From the plant site and warehouse facilities of Wilson Foods Corporation at Albert Lea and Hopkins, Minnesota, and Cedar Rapids and Des Moines, Iowa, to points in Arizona, California, Idaho, Nevada, Oregon, Utah, and Washington restricted to the transportation of traffic originating at the above named origins and destined to the named destination.

Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at Denver, Colo.

No. MC 110014 (Sub-No. 82), filed May 31, 1977. Applicant: OLIVER TRUCKING COMPANY, INC., P.O. Box 55, Winchester, Virginia 22661. Applicant's representative: Louis J. Amato, P.O. Box E, Bowling Green, Kentucky 42101. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Eating: Stone, from points in Platte County, Wyoming to those points in Texas which are (a) on and west of U.S. Highway 45 (Interstate Highway 45) and south of U.S. Highway 80 (Interstate Highway 20), and (b) on and north of U.S. Highway 80 (Interstate Highway 20) and east of U.S. Highway 75 (Interstate Highway 45).

Note.—If a hearing is deemed necessary, applicant requests it be held at either Hopewell, Virginia, or Louisville, Kentucky.

No. MC 116725, (Sub-No. 23), filed June 1, 1977. Applicant: INDIAN VALLEY ENTERPRISES, INC., 685 Maple Ave, Harleysville, Pennsylvania. Applicant's representative: John W. Frame, P.O. Box 626, 2207 Old Gettysburg Road, Camp Hill, Pa. 17010. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs, between the plant sites or facilities of Keller Creamery Co. (a division of Beatrice Foods Co.) located at or near Sommerville, Pa., on the one hand, and, on the other, points in Pennsylvania, New York, New Jersey, Delaware, Maryland, Virginia, West Virginia, Maine, New Hampshire, Vermont, Connecticut, Massachusetts, Rhode Island, and the District of Columbia.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Harrisburg, Pa.


Note.—If a hearing is deemed necessary, the applicant requests it be held at Cleveland, Ohio or New York, N.Y.

Docket number: MC 117370 (Sub-No. 29), filed May 27, 1977. Applicant: STAFFORD TRUCKING, INC., 2165 Hollybuck Lane, Elm Grove, Wis. 53122. Applicant's representative: Nancy J. Johnson, 4506 Regent Street, Suite 100, Madison, Wis. 53705. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Silicon products, from South Windsor, Conn. and points in New London County, Conn., to points in Delaware, Indiana, Maine, Michigan, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont and Virginia.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at either Madison or Milwaukee, Wis., or Chicago, Ill.

No. MC 118159 (Sub-No. 213), filed June 1, 1977. Applicant: NATIONAL REFRIGERATED TRUCKING INC., P.O. Box 5166, Dawsonville, Ga. 30132. Applicant's representative: Darren G. Armbruster, (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Prepared foods, from Sea Cliff, Wis., to points in Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New York, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia and the District of Columbia.

Note.—If a hearing is deemed necessary, the applicant requests it be held at either Raleigh, N.C., or Washington, D.C.

No. MC 116932 (Sub-No. 145), filed May 31, 1977. Applicant: JERRY LIPPS, INC., 130 S. Frederick St. Cape Girardeau, Mo. 63701. Applicant's representative: Robert M. Pearce, P.O. Box 1111, Bowling Green, KY 42101. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Plywood; paneling; gypsum board; composition board; and molding from the facilities of American Gyro-Tex Company located at or near Jacksonville, Fla., to points in the United States in and east of Minnesota, Iowa, Nebraska, Kansas, Oklahoma and Texas.

Note.—Applicant holds contract carrier authority in No. MC 125614, therefore dual operations may be involved. Common control may also be involved. If a hearing is deemed necessary, the applicant requests that it be held at either Jacksonville, Fl. or Washington, D.C.

No. MC 118230 (correction) (Sub-No. 99), filed May 31, 1977. Published in Federal Register issue of June 16, 1977, republished as corrected this Issue. Applicant: LIQUID TRANSPORT CORP., 3901 Madison Avenue, Indianapolis, Ind. 46227. Applicant's representative: Robert W. Loser, 1009 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs, meat packinghouses, and Aliments prepared foods, in bulk, in tank vehicles, from Indianapolis, Ind., to points in Illinois, Iowa, Indiana, Kentucky, Michigan, Ohio, Pennsylvania, Tennessee, Wisconsin, and West Virginia, restricted against the transportation of traffic originating at the facilities of National Starich and Chemical Corporation, at Indianapolis, Indiana.

Note.—The purpose of this republication is to correct the territorial description in this proceeding. Applicant is controlled by Ecoff Chemical Corporation, at Indianapolis, Ind., under a contract carrier authority under Docket No. MC-125161 and MC-125161 (Sub-No. 1), therefore dual operations may be involved. Common control may also be involved. If a hearing is deemed necessary, applicant requests that it be held at either Indianapolis, Ind. or Chicago, Ill.


Note.—Applicant states this application is filed solely to add this commodity to their
NOTICES

FEDERAL REGISTER, VOL 42, NO. 131—FRIDAY, JULY 8, 1977

existing pertinent Certificate issued in MC
116619 (Sub-No. 29). If a hearing is deemed necessary, the applicant requests it be held at Chicago, Ill.

No. MC 119729 (Sub-No. 92), filed May 19, 1977. Applicant: N.A.B. TRANSPORTING INC., 1218 W. Edgewood Avenue, Indianapolis, Ind. 46217. Applicant's representative: James L. Beatty, 130 East Washington Street, Suite One Thousand, Indianapolis, Ind. 46204. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Floor sweeping compounds and absorbents, from the plantsite of Oil-Dri Corp. of America, located at or near Ripley, Miss., to points in Illinois, Indiana, Iowa, Ohio, and Tennessee, and absorbents, in bulk, between Havana, Ill., and the other points in the United States (except Alaska and Hawaii).

Note.—If a hearing is deemed necessary, the applicant requests that it be held at Chicago, Ill., or Omaha, Neb.

No. MC 123048 (Sub-No. 550), filed May 23, 1977. Applicant: DIAMOND TRANSPORTATION SERVICE INC., 5621 31st Street, Racine, Wis. 53406. Applicant's representative: Paul C. Gartze, 121 West Doty Street, Madison, Wis. 53703. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Irrigation systems and parts and attachments for irrigation systems; (2) materials, and supplies used in the manufacture, processing, and distribution of the commodities in (1) and (2), when moving in mixed loads with paper bags, from Points In Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Mississippi, South Dakota, Tennessee, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests that the hearing be held in Chicago, Ill., or Omaha, Neb.


Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Liquid fertilizer, in bulk, from the storage and terminal facilities of Allied Chemical Corp., located at or near the Iowa, to points in Arkansas, Illinois (except points in the St. Louis, Mo.-E. St. Louis, Ill., commercial zone), Iowa, Indiana, Kansas, Kentucky, Minnesota, Missouri, Nebraska, South Dakota, Tennessee, and Wisconsin.

Note.—If a hearing is deemed necessary, the applicant requests that the hearing be held in Chicago, Ill., or Omaha, Neb.


Note.—If a hearing is deemed necessary, the applicant requests it be held in Chicago, Ill., or Omaha, Neb.

No. MC 124308 (Sub-No. 29), filed May 27, 1977. Applicant: KENAN TRANSPORT CO., INC., P.O. Box 2729, Chapel Hill, N.C. 27514. Applicant's representative: Richard A. Mahany, 1800 16th Street NW, Washington, D.C. 20036. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Animal and vegetable oils, and animal and vegetable oil products, by-products, in bulk (except such commodities which are chemicals), between Charlotte, N.C., on the one hand, and, on the other, points in Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, West Virginia, Wisconsin, and the District of Columbia.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held in Washington, D.C., Richmond, Va., or Charlotte, N.C.

No. MC 124579 (Sub-No. 18), filed May 26, 1977. Applicant: WHEEL EXPRESS, INC., Route 2, Huron, Ohio. Applicant's representative: James Duvall, Post Office Box 97, 220 West Bridge Street, Dublin, Ohio 43017. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Milk and milk products, (1) from the plantsite and warehouse facilities of Orville-Milk Co., located in Wayne County, Ohio, to points in Indiana, New York, and Pennsylvania; and (2) from Goen, Ind., to the plantsite and warehouse facilities of Orville-Milk Co., located in Wayne County, Ohio.
NOTICES

Applicant's representative: James Duval, Post Office Box 97, 220 West Bridge Street, Dublin, Ohio 43017. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Pipe fittings, cast iron; meter boxes; and equipment, materials and supplies used in the manufacture thereof (except commodities in bulk, in tank vehicles); between California, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nevada, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas, Utah, and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Columbus, Ohio, Denver, Colo., or Washington, D.C.

No. MC 124679 (Sub-No. 78) (correction), filed April 21, 1977, published in the Federal Register Issue of May 26, 1977, republished as corrected this issue. Applicant: C. R. ENGLAND & SONS, INC., 915 West 2100 South, Salt Lake City, Utah 84110. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Sugar and molasses, in bulk, from Findlay and Fremont, Ohio, to points in Indiana, Michigan, New York, Ohio, Pennsylvania, and West Virginia.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Columbus, Ohio, Denver, Colo., or Washington, D.C.

No. MC 124679 (Sub-No. 78) (correction), filed April 21, 1977, published in the Federal Register Issue of May 26, 1977, republished as corrected this issue. Applicant: C. R. ENGLAND & SONS, INC., 915 West 2100 South, Salt Lake City, Utah 84110. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Sugar and molasses, in bulk, from Findlay and Fremont, Ohio, to points in Indiana, Michigan, New York, Ohio, Pennsylvania, and West Virginia.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Columbus, Ohio, Denver, Colo., or Washington, D.C.

No. MC 129794 (Sub-No. 9), filed May 27, 1977. Applicant: P. LIEDEKRA TRUCKING, INC., 110 Patterson Ave., Trenton, N.J. 08610. Applicant's representative: Alan Kahn, 1920 Two Penn Center Plaza, Philadelphia, Pa. 19102. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: General commodities, in containers or in trailers having an immediately prior or subsequent movement by water, by rail, or by truck; and (3) as pertinent: Automobile parts, materials and supplies; and equipment, materials and supplies used in the manufacture thereof (except commodities in bulk, in tank vehicles); between California, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nevada, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas, Utah, and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Philadelphia, Pa., or Washington, D.C.


Note.—If a hearing is deemed necessary, the applicant requests that it be held at Atlanta, Ga.


Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests that it be held at Washington, D.C.

No. MC 128602 (Sub-No. 4), filed May 31, 1977. Applicant: ARDEN E. OLSEN, Route No. 1, Kalispell, Mont. 59901. Applicant's representative: L. D. Trihr, 100 Transwestern Building, 404 North 31st Street, Billings, Mont. 59101. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Beer and empty containers between Kalispell, Mont., on the one hand, and, on the other, Fairfield, Calif., under a continuing contract, or contracts, with Flathead Beverage Co.

Note.—If a hearing is deemed necessary, applicant requests that it be held at either Kalispell or Billings, Mont.

No. MC 128651 (Sub-No. 16), filed May 25, 1977. Applicant: ROBERT H. DIT-TRICH, doing business as Bob Dittrich Trucking, 1000 Norwood Front Street, New Ulm, Minn. 56073. Applicant's representative: Bruce A. Rasmussen, 1160 NorthWestern Bank Building, Minneapolis, Minn. 55402. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Liquid fertilizer, in bulk, in tank vehicles from New Ulm, Minn., to points in Iowa, South Dakota, North Dakota, and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests that it be held at Minneapolis, St. Paul, or Mankato, Minn.

No. MC 129535 (Sub-No. 9), filed May 31, 1977. Applicant: ROYAL'S MOTOR SERVICE, INC., P.O. Box 1124, Grand Prairie, Texas 75050. Applicant's representative: James W. Hightower, 130 Wynnewood Prof. Bldg., Dallas, Texas 75244. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Com-}
NOTICES

freezing boxes, imitation fireplaces and logs, heaters, range hoods, lighting fixtures, exhaust systems, and splashers plates and parts, attachments and accessories thereof and materials, equipment and supplies used in the manufacture and distribution thereof (except commodities in bulk), Between Cleburne, Arkansas and Anytown, Texas, and, on the other, points in the United States (except Alaska and Hawaii).

Note.—Applicant holds motor contrac-

carrier authority in No. MC 136002, and subs thereunder, therefore, dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Dallas, Tex.

No. MC 136009 (Sub-No. 10), filed May 23, 1977. Applicant: WESTERN CARRIERS, INC., 288 Franklin Street, Worcester, Massachusetts 01604. Applicants representative: David M. Marshall, 136 State Street, Suite 200, Springfield, Massachusetts 01103. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Plastic and plastic articles, and materials and supplies used in the manufacture thereof and materials of such commodities (except in bulk in tank trucks), between the facilities of Plastic Packaging Corporation located in West Springfield and Springfield, Massachusetts, on the one hand, and, on the other, points in the United States (except Alaska, Hawaii, Maine, New Hampshire, Vermont, Connecticut and Rhode Island), under a continuing contract, or contracts, with Plastic Packaging Corporation.

Note.—If a hearing is deemed necessary, applicant requests it be held at either Hartford, Conn., Boston, Mass., or Washington, D.C.

No. MC 136009 (Sub-No. 12), filed May 27, 1977. Applicant: OVERLAND EXPRESS, INC., 719 First St., S.W., New Brighton, Minn. 55112. Applicant's representative: Robert P. Sack, P.O. Box 8018, West 80th Street, San Antonio, Tex. 78213. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Foodstuffs (except commodities in bulk) from Minneapolis-St. Paul, Minnesota to points in Ohio.

Note.—If a hearing is deemed necessary, applicant requests it be held at Minneapolis, Minnesota.

No. MC 133928 (Sub-No. 12), filed May 27, 1977. Applicant: OSTERKAMP TRUCKING, INC., 1049 North Glassell Street, Orange, Calif. 92867. Applicant's representative: Patrick E. Quinn, P.O. Box 82028, Lincoln, Nebr. 68501. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Gypsum, gyspum products and building materials, and materials and supplies used in the manufacturing, distribution and installation of the aforementioned commodities. Also sought to operate as a carrier, by motor vehicle, over irregular routes, transporting: Canned citrus juice, from the facilities of Texas Citrus Exchange located at Harlingen and Mission, Tex., to points in New Mexico, Arizona, California, Indiana, Michigan, and the ports of entry on the Pacific Coast.

No. MC 134286 (Sub-No. 26), filed May 31, 1977. Applicant: ILLINOIS EXPRESS, INC., P.O. Box 1694, Sioux City, Iowa 51102. Applicant's representative: Charles J. Farquhar, 160 Compression Center, 1600 Sherman Street, Denver, Colo. 80203. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Foodstuffs; (2) pharmaceutical materials, supplies and products; (3) chemicals; (4) alcoholic beverages; (5) tobacco products; (6) pet foods; (7) such commodities as are dealt in by distribution or consolidation warehouses for the commodities described in (1) through (6); and (8) exempt commodities when moving with regulated commodities, (A) from Kansas City, Kan., and points in the United States in and west of Minnesota, Iowa, Missouri, Arkansas and Louisiana; and (B) from points in the United States and west of Minnesota, Iowa, Missouri, Arkansas and Louisiana to Denver, Colo., restricted against the transportation of commodities in bulk.

Note.—If a hearing is deemed necessary, applicant requests it be held at either Kansas City, Mo., or St. Louis, Mo.

No. MC 134755 (Sub-No. 186), filed May 27, 1977. Applicant: CHARTER EXPRESS, INC., P.O. Box 3772, Springfield, Mo. 65804. Applicant's representative: Larry D. Knox, 600 Hubbell Building, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) truck and trailer suspension systems and parts; and (2) equipment, materials, and supplies (except in bulk) used in the manufacture of truck and trailer parts, including an iron and steel articles, between Marshfield, Mansfield, and Seymour, Mo., on the one hand, and, on the other, points in the United States (except Alaska and Hawaii).

Note.—If a hearing is deemed necessary, applicant requests it be held at either Kansas City, Mo., or St. Louis, Mo.

No. MC 134783 (Sub-No. 2 and 4), filed June 1, 1977. Applicant: FLEETWOOD TRANSPORTATION CORP., 106 Reeves Street, Dinmore, Pa. 18312. Applicant's representative: J. A. Kundtz, 1100 National City Bank Building, Cleveland, Ohio 44114. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Such merchandise as is dealt in by wholesale, retail and chain grocery and food businesses (except commodities in bulk), between the facilities of John Morrell & Company located at or near Laurel, Md., on the one hand, and, on the other, points in Connecticut, Delaware, Massachusetts, Maryland, New Jersey, New York, Pennsylvania, Rhode Island, and Virginia, under continuing contract or contracts with Agfoods, Inc.

Note.—Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C.


Note.—Common control may be involved. If a hearing is deemed necessary, applicant requests it be held at either Kansas City, Mo., or Kansas City, Kan.

No. MC 136055 (Sub-No. 3), filed May 18, 1977. Applicant: JACK D. WHATLEY AND ROBERT T. CALEGOUN, d/b/a MAGIC VALLEY REFRIGERATED EXPRESS, 1400 White Rock Road, McAllen, Tex. 78501. Applicant's representative: M. Ward Bailey, 2412 Continental Life Bldg., Fort Worth, Tex. 76102. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: (1) canned citrus juice, from the facilities of Texas Citrus Exchange located at Harlingen and Mission, Tex., to points in New Mexico, Arizona, California, Indiana, Michigan, and the ports of entry on the Pacific Coast.
the International boundary line between the United States and Canada; located at Detroit, Mich., Pembina and Portal, N. Dak., for furtherance into the Canadian provinces of Saskatchewan, Manitoba and Ontario; and (2) Frozen concentrated citrus products, in containers, in mixed loads with canned-oleate juice, from the facilities of Texas Citrus Exchange located at Harlingen and Mission, Tex., and from the storage facilities of Texas Citrus Exchange at Brownsville, and McAllen, Tex., to points in Oklahoma, Missouri, Kansas, Illinois, Nebraska, Iowa, South Dakota, Minnesota, Wisconsin, North Dakota, Colorado, New Mexico, Arizona, California, Indiana, Michigan, and the ports of entry on the International boundary line between the United States and Canada, located at Detroit, Mich., Pembina and Portal, N. Dak., for furtherance into the Canadian provinces of Saskatchewan, Manitoba and Ontario, under a continuing contract or contracts, in (1) and (2) above with Texas Citrus Exchange.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Dallas or San Antonio, Tex.

No. MC 136077 (Sub-No. 7), filed May 23, 1977. Applicant: REBER CORPORATION, 2216 Old Arch Road, Norristown, Pa. 19401. Applicant's representative: Roland M. Hoffer, 100 East 12th Street, The Bldg., 100 S. Broad St., Philadelphia, Pa. 19110. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Malt beverages, from Detroit, Mich., to points in Alabama, Delaware, Georgia, Maryland, North Carolina, South Carolina, West Virginia, and the District of Columbia.

Note.—Applicant holds contract carrier authority in Md. No. 126963, Sub 2, and sub thereunder, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 136080 (Sub-No. 20), filed May 31, 1977. Applicant: WORSTER-MICHI- GAN, INC., R.D. No. 1, Clay Road, North Liberty, Michigan. Applicant's representative: Joseph F. MacKrell, 23 West Tenth Street, Erie, Pennsylvania 16501. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Frozen foodstuffs, from Traverse City, Michigan to points in Missouri and Kansas.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Columbus, Ohio.

No. MC 136094 (Sub-No. 20), filed May 31, 1977. Applicant: HILL, W. W., 50158, East 8th Street, Des Moines, Iowa. Applicant's representative: Charles E. Cragar, 1329 Pennsylvania Avenue, Post Office Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Malt beverages, from Detroit, Mich., to points in Alabama, Delaware, Georgia, Maryland, North Carolina, South Carolina, West Virginia, and the District of Columbia.

No. MC 136096 (Sub-No. 1), filed May 17, 1977. Applicant: ENDICOTT TRUCKING CO., A Corporation, P.O. Box 705, Columbus, Ohio 43216. Applicant's representative: F. E. Dubin, Suite 200, 220 West Bridge Street, P.O. Box 97, Dubuque, Iowa 52002. Applicant's representative: William L. Fairbank, 100 Financial Center, Des Moines, Iowa 50309. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Dry fertilizer and dry fertilizer materials, in bulk, from Pekin, Ill. to points in Iowa, Minnesota, Missouri and Wisconsin.

Note.—If a hearing is deemed necessary, applicant requests the hearing be held at St. Paul, Minn.

No. MC 136826 (Sub-No. 5), filed May 26, 1977. Applicant: HICKS TRUCKING, INC., A Corporation, P.O. Box 68, Stephens City, Va. 22665. Applicant's representative: Edward N. Button, 1329 Pennsylvania Avenue, Post Office Box 1417, Hagerstown, Md. 21740. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (A) Slag, except in bulk: (1) From Strasburg, Va. to Gore, Va.; (2) From Gore, Va. to Coatesville, Pa.; and (3) From Coatesville, Pa. to Chelsea, Mich.; and (4) From Gore, Va. to Chelsea, Mich.; and (B) powdered clay, except in bulk, from Whitulo, Tenn., to Chelsea, Mich.

Note.—Applicant holds contract carrier authority in No. MC-136826, Sub 2, and sub thereunder, therefore dual operations may be involved. If a hearing is deemed necessary, applicant requests it be held at Washington, D.C.

No. MC 136805 (Sub-No. 1), filed May 21, 1977. Applicant: BAKER TRUCK SERVICE, INC., P.O. Box 535, Lewiston, Idaho 83501. Applicant's representative: George R. Labissoniere, 1100 Norton Building, Seattle, Wash. 98104. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Fertilizer, from the plant/ site of Boise-Cascade located at or near La Grande, Ore., on the one hand, and on the other, Portland, Ore.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Spokane, Wash.

No. MC 139495 (Sub-No. 239), filed May 31, 1977. Applicant: NATIONAL CARRIERS, INC., 1501 East 6th Street, Rockville, Ind. 47665. Applicant's representative: Herbert Alan Dubin, Suite 1030, 1819 H Street NW., Washington, D.C. 20006. Authority sought to operate as a common carrier,
NOTICES

by motor vehicle, over irregular routes, transporting: (1) Cigars from Dothan and Selma, Ala., to Fort Worth, Dallas, Fort Worth, San Antonio, El Paso, Brownsville, McAllen, Brownsville, Edinburg, McAllen, Corpus Christi, Laredo, Brownsville, Laredo, San Antonio, and Houston, Texas, in bulk, under a continued contract or contracts with the above shippers. (2) Oranges, apples, and potatoes, from key West, Fla., to Jacksonville, Fla., and to Jacksonville, Fla., from Phoenix, Ariz., to Phoenix, Ariz., and to Houston, Tex., in bulk, under a continued contract or contracts with the above shippers. (3) Oranges, apples, and potatoes, from key West, Fla., to Jacksonville, Fla., and to Jacksonville, Fla., from Phoenix, Ariz., to Phoenix, Ariz., and to Houston, Tex., in bulk, under a continued contract or contracts with the above shippers.

No. MC 139923 (Sub-No. 33), filed May 31, 1977. Applicant: MILLER TRUCKING CO., INC., P.O. Drawer D, Stroud, Okla. 74079. Applicant's representative: Jack E. Bond, 110 W. Toulouse Avenue, Park Ridge, Ill. 60656. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cranberry products, and nilehine and tobacco leaves (except commodities in bulk), from the pallets and warehouse facilities of or utilized by Ocean Spray Cranberries, Inc., located at or near Kenosha, Wis. and North Chicago, III., to Kansas City, Mo., and points in Kansas, Oklahoma, and Texas, surrendered the transportation of traffic originating at the named origins and destined to the named destinations.

Note.—Applicant holds contract carrier authority in No. MC 139926 (Sub-No. 2), therefore, dual operations may be involved. If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C.


Note.—A hearing is deemed necessary. The applicant requests that it be held at Columbus, Ohio, D.C.

No. MC 140216 (Sub-No. 3), filed May 28, 1977. Applicant: JOHN E. WAY, Jr., d.b.a. WAY MESSENGER SERVICE, 205 East King Street, Lancaster, Pennsylvania 17602. Applicant's representative: John M. Musselman, P.O. Box 1146, 410 North Third Street, Harrisburg, Pennsylvania 17108. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Printed matter, (1) Between Lancaster, Pa., on the one hand, and, on the other, Baltimore, Md., and Washington, D.C., over, other than irregular routes, transporting: General commodities (except those of unusual value, Classes A and B explosives, commodities in bulk, and those requiring special equipment, except for those of unusual value, Classes A and B explosives, commodities in bulk, and those requiring special equipment), which are within the time moving on bills of lading of freight forwarders under part IV of the Interstate Commerce Act, (1) from Atlanta, GA; Charlotte, NC; Greensboro, NC; Greensville, S.C.; Lynchburg, VA; Norfolk, VA and Nashville, TN, to Memphis, TN and points in Arizona, California, Washington and Oregon and, (2) from Memphis, TN to points in Arizona, California, Washington and Oregon.

Note.—Applicant holds contract carrier authority in No. MC 139926 (Sub-No. 2) and subthereunder, therefore dual operations may be involved. Common control may be involved. If a hearing is deemed necessary, the applicant requests it be held at Washington, D.C. or Memphis, Tenn.

No. MC 141124 (Sub-No. 4), filed May 26, 1977. Applicant: EVANGELIST COMMERCIAL CORPORATION, P.O. Box 1703, Wilmington, Delaware 19899. Applicant's representative: Boyd B. Ferris, 50 West Broad Street, Columbus, Ohio 43215. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Paper and paper products, from Ludlow and Covington, Kentucky to points in Pennsylvania, Maryland, Delaware, New Jersey, New York, Connecticut, Massachusetts, Rhode Island, New Hampshire, Vermont, Virginia, Maine, and the District of Columbia and (2) rejected and returned shipments and commodities used in the manufacture of paper and paper products, from points in Pennsylvania, Maryland, Delaware, New Jersey, New York, Connecticut, Massachusetts, Rhode Island, New Hampshire, Vermont, Virginia, Maine, and the District of Columbia to Ludlow and Covington, Kentucky.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Columbus, Ohio.

No. MC 141124 (Sub-No. 5), filed May 26, 1977. Applicant: EVANGELIST COMMERCIAL CORPORATION, P.O. Box 1703, Wilmington, Del. 19899. Applicant's representative: Boyd B. Ferris, 50 West Broad Street, Columbus, Ohio 43215. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Paper and paper products, from Ludlow and Covington, Kentucky to points in Pennsylvania, Maryland, Delaware, New Jersey, New York, Connecticut, Massachusetts, Rhode Island, New Hampshire, Vermont, Virginia, Maine, and the District of Columbia and (2) rejected and returned shipments and commodities used in the manufacture of paper and paper products, from points in Pennsylvania, Maryland, Delaware, New Jersey, New York, Connecticut, Massachusetts, Rhode Island, New Hampshire, Vermont, Virginia, Maine, and the District of Columbia to Ludlow and Covington, Kentucky.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Columbus, Ohio.

No. MC 141072 (Sub-No. 3), filed May 26, 1977. Applicant: ARMOND L. HART, doing business as PETE HART TRUCKING, 3328 North Granfield Avenue, Fresno, Calif. 93711. Applicant's representative: Edward L. Awiak, 2409 Merced Street, Suite 3, Fresno, Calif. 93721. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Onion and garlic planting and harvesting machines, transported on lowbed trailers specially built to accommodate shipper's equipment, between points in California, and Nevada, under a continuing contract or contracts with Gilroy Foods, Inc.

Note.—If a hearing is deemed necessary, the applicant requests it be held at Fresno, Calif.
operate as a common carrier by motor vehicle, over irregular routes transporting: Wrecker, de-alarms, and other equipment, by use of wrecker equipment, between New Orleans, La., and points in St. John the Baptist Parish, La., on the one hand, and, on the other, points in Alabama, Arkansas, Mississippi, Tennessee, and Texas.

Note.—If a hearing is deemed necessary, the applicant requests it be held at New Orleans, La.

No. MC 142857 (Sub-No. 2), filed May 21, 1977. Applicant: MCC TRANSPORTATION COMPANY, INC., 1311 West Seventh Street, Little Rock, Arkansas 72201. Applicant's representative: Eugene T. Lipfert, Suite 1000, 1660 L Street NW, Washington, D.C. 20036. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: (1) Wines, liquors, and mixtures, in bulk, from and to wholesale distributors of wine and liquors, in containers, from ports in the New York City Commercial Zone, to the facilities of Banfi Products, Inc., located at Farmingdale, N.Y., (2) wines and liquors in vehicles equipped with mechanical refrigeration, from wineries at San Jose, Rippon, and Modesto, Calif., to the facilities of Banfi Products, Inc., located at Farmingdale, N.Y., to wholesale distributors, of wine and liquors located at points in the United States including Alaska, but excluding Hawaii with unlimited intermediate stop-offs; and (3) wines in vehicles not containing wine, from New York, N.Y. or Washington, D.C., under a continuing contract or contracts with Banfi Products, Inc., Corp., located at Farmingdale, N.Y.

Note.—Common control may be involved. In the event a hearing is deemed necessary, applicant requests it be held at New York, N.Y. or Washington, D.C.

No. MC 143241 (Sub-No. 2), filed May 27, 1977. Applicant: SUBURBAN TRUCKING, INC., 500 Hazle Avenue, Wilkes-Barre, Penna. 18702. Applicant's representative: John W. Frame, Box 625, 2207 Old Gettysburg Road, Camp Hill, Penna. 17011. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Such merchandise as is dealt in by retail department stores (except commodities in bulk); and (2) Wines, liquors, in packages, from and to wholesale distributors of wine and vehicle, over irregular routes, transporting: (1) Such merchandise as is dealt in by retail department stores (except commodities in bulk); and (2) Wines, liquors, in packages, from and to wholesale distributors of wine and

Federal Register, Vol. 42, No. 131—Friday, July 8, 1977
NOTICES

No. MC 47786 (Sub-No. 0), filed April 27, 1977. Applicant: ROSSMEYER & WEBER, INC., doing business as RAY- TIAN VALLEY BUS SERVICE, P.O. Box 1069, York, N.Y. 10018. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting passengers and their baggage in the same vehicle with passengers from New York to Vermont and Maine and, return, in charter operations.

No. MC 51016 (Sub-No. 6), filed May 25, 1977. Applicant: PETER PAN BUS LINES, INC., 1776 Main Street, Springfield, Mass. 01103. Applicant's representative: Frank Daniels, 15 Court Sq., Boston, Mass. Authority sought to join this authority with its authority authorizing charter operations from New York to New Hampshire, Maine, Rhode Island, Connecticut, New York, New Jersey, Delaware, Pennsylvania, Ohio, Nebraska, Maryland, the District of Columbia, and return. If a hearing is deemed necessary, it shall be held at New York, New York.

No. MC 99581 (Sub-No. 4) (Correction), filed May 6, 1977, published in the Federal Register issue of June 16, 1977, republished as corrected this issue. Applicant: HORACE SIMMONS, doing business as ACA, V. A. 3009, New York, N.Y. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting passengers and baggage of passengers in the same vehicle with passengers, in special and charter operations, from and to the following points or areas: between points in Contra Costa County, and those points in Alameda County on, north and east of, the following highways, including all points within 3 miles of said highways: Interstate Highway 680 between the Alameda-Contra Costa County Boundary, and junction with State Highway 84; State Highway 84, between Junction with Interstate Highway 680 and junction with Tesla Road; Tesla Road, between junction with State Highway 84 and the Alameda-San Joaquin County Boundary Line; and Dublin and Livermore, Calif., on the one hand, and, on the other, points in the United States, including Alaska (except Hawaii).
NOTICE

The purpose of this republication is to amend the territorial description in this proceeding. If a hearing is deemed necessary, applicant requests it be held at San Francisco, Calif.

No. MC 143333, filed May 21, 1977. Applicant: BERRY TRANSPORTATION CO., INC., Walnut Ave., No. Hampton, N.H. 03862. Applicant’s representative: Shawn G. Bridgman (same address as applicant). Authority sought to operate as a common carrier by motor vehicle, over irregular routes, in the transportation of passengers and baggage in the same vehicle with passengers in charter operations, beginning and ending at points on and east of Route 125 located in Rockingham and Strafford Counties, New Hampshire and extending to points in Connecticut, District of Columbia, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont.

No. MC 143335, filed May 26, 1977. Applicant: CONCORD COACH LINES LTD., 4705 50th St., Lloydsminster, Saskatchew an, Canada S9V 0M7. Applicant’s representative: Ronald Carlyle (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Passengers and their baggage in the same vehicle with passengers in charter operations, beginning and ending at all ports of entry on the International Boundary line between the United States and Canada, and extending to points in the United States, including Alaska, but excluding Hawaii.

No. MC-P-13216, Correction (CALIFORNIA AND WESTERN STATES AMMONIA TRANSPORT, INC., d/b/a CALIFORNIA AMMONIA TRANSPORT, INC.—Purchase (portion)—Allia Transportation Company, published in the May 28, 1977 issue of the Federal Register on pages 27104 and 27105. Previous notice excluded a portion of the operating authority to be transferred when Allia Transportation Company, a common carrier by motor vehicle, over irregular routes, in the transportation of passengers and baggage in the same vehicle with passengers in charter operations, beginning and ending at all points on and east of Route 125 located in Rockingham and Strafford Counties, New Hampshire and extending to points in Connecticut, District of Columbia, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont.

No. MC-P-13218, Authority sought for purchase by PENN EMPIRE TRANSPORT, INC., P.O. Box 517, Livingston Avenue, Jamestown, N.Y. 14701, of a portion of the operating rights of James E. Griffin & Sons, Inc. 276 Circuit Street, West Hanover, MA 02339, and for acquisition by E. Virginia Beckstrom, RD No. 1, Ashville, NY 14710, W. M. Beckstrom, Orchard Street, in Arizona; Donald Sundell, Knowlton Avenue, Pittsburgh, PA., of control of such rights through the purchase. Applicant’s attorney: Frederick T. O’Sullivan, P.O. Box 2184, Peabody, MA 01960. Applicants sought to be purchased: Household goods as defined by the Commission, furniture, pianos and baggage, as a common carrier over irregular routes between points in Massachusetts; New furniture, from Concord and Acton, Mass., to points in Arizona and off-route points in Arizona within 50 miles of the above-specified route, restricted to delivery only; From the above-specified origin points over irregular routes to junction U.S. Highway 89, thence over U.S. Highway 89 to the boundary of the United States and Mexico. Serving no intermediate points; From the above-specified origin points over irregular routes to junction U.S. Highway 101 to the boundary of the United States and Mexico. Serving no intermediate points; Return, with no transportation for compensation except as otherwise authorized, over above-specified regular routes to junction irregular routes, and thence over irregular routes, to the above-specified origin points.

Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Passengers and their baggage in the same vehicle with passengers in charter operations, beginning and ending at all points on and east of Route 125 located in Rockingham and Strafford Counties, New Hampshire and extending to points in Connecticut, District of Columbia, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont.
NOTICES

Allegany, Broome, Cattaraugus, Chautauqua, Erie, Genesee, Chemung, Livingston, Niagara, Orleans, Steuben, Tioga, and Wyoming Counties, N.Y., with no transportation for compensation on return as otherwise vendered is authorized to operate as a common carrier in New York, District of Columbia, Maryland, West Virginia, Pennsylvania, New Jersey, New York, Connecticut, Rhode Island and Washington, D.C. Application has not been filed for temporary authority under section 210a(b).

No. MC-P-13324. Authority sought for purchase by FRITZ TRUCKING, INC., East Highw. 7, Clara City, MN., 56222, of the operating rights of Multi-County Trucking, Inc., 517 Tenth Street SW., P.O. Box 903, Watertown, SD, 57201, and for acquisition by Vernon O. Fritz, Clara City, MN., 56222, of such rights in Brown County, S.D., except Aberdeen, points in Day County, S.D., except Watertown and points within 30 miles thereof, and points in Clark and Fallin Counties, D.D., except animal and poultry feed (excl. liquid molasses), from Minneapolis, Minn. to points in Day, Roberts, Marshall, Grant, Spink, Deuel, Codington, Brookings, Kingsbury, Beadle, Hand, Hyde, Faulk, Edmunds, McPherson, Campbell, Walworth, Potter, Sully, Hughes, Stanley, Haxton, Ziebach, Corson, Perkins, Meade, and Butte Counties, SD. Vandee is authorized to operate as a contract carrier in Minnesota, Idaho, Iowa, Montana, Nebraska, North Dakota, Washington, Wisconsin, Wyoming, Illinois, Colorado, and Utah, and as a common carrier in Minnesota, North Dakota, and South Dakota. Application has not been filed for temporary authority under section 210a(b).

No. MC-P-13325. Authority sought for purchase by ARBO MAXFLOWER TRANSIT COMPANY, INC., P.O. Box 107B, Indianapolis, IN., 46208, of a portion of the operating rights of Warners Motor Express, Inc., West Country Club Road, Red Lion, PA, 17356, and for acquisition by Mayflower Corporation, a public corporation, P.O. Box 107B, Indianapolis, IN., 46208, of control of such rights through the purchase. Applicant's attorneys: James L. Beattie, 125 E. Washington Street, Suite One Thousand, Indianapolis, IN, 46204, and Norman T. Bow, 43 North Duke Street, York, PA, 17401. Operating rights sought to be transferred: New furniture, as a common carrier over irregular routes between Red Lion, PA, on the one hand, and, on the other, Camden, N.J., and Baltimore, Md.; new furniture, from Red Lion and Stewartstown, PA, to Washington, D.C., Baltimore, Md., Columbus, Cincinnati, Cleveland, and Pickerington, Ohio, Grand Rapids, Michigan, and to points in Massachusetts, Connecticut, New Jersey, New York, New Jersey, and Rhode Island; and from Railroad, PA., to points in Illinois, Indiana, Ohio, and West Virginia, points in Virginia (except those within 15 miles of Washington, D.C.), and points in Michigan (except Grand Rapids); from Helton, Pa., to points in Pennsylvania, to points in Maryland, to points in Pennsylvania, to points in Connecticut, Massachusetts, New Jersey, New York, and Ohio. Also, delivery of furniture, as a common carrier in all 50 States. Application has not been filed for temporary authority.

No. MC-P-13326. Authority sought for purchase by GATEWAY TRANSPORTATION CO., Inc., 455 Park Plaza Drive, La Crosse, a portion of the operating rights of Atkinson Freight Lines, Inc., P.O. Box 520, Blanche Road, Cornwells Heights, PA, 19020, and for acquisition by estate of W. Leo Murphy, 1st Wisconsin Trust Co, Milwaukee, WI, Eugene W. Murphy, 300 South Ocean Blvd., Palm Beach, FL., John A. Murphy, 455 Park Plaza Dr., La Crosse, WI, 54601, and Michael P. Murphy, 1501 S. Faraday Avenue, Chicago Ridge, IL, 60415, of control of such rights through the purchase. Applicant's attorneys: Maxwell A. Howell, 1511 S. Fifth Ave., Washington, D.C. 20005, and F. Neil Aschemeyer, 455 Park Plaza Drive, La Crosse, WI, 54601, with copy to Joseph B. Atkinson, Jr., President, P.O. Box 520, Blanche Road, Cornwells Heights, PA, 19020. Operating rights sought to be transferred: General commodities, with exceptions as a common carrier over irregular routes between Sewell, N.J., and points in Gloucester and Camden Counties, N.J., on the one hand, and, on the other, Philadelphia, Pa.; new furniture in Pennsylvania, to points in Virginia, West Virginia, and Ohio; new and used furniture, between Wilkes-Barre, Pa., on the one hand, and, on the other, Washington, D.C., and Pennsylvania; new furniture, between Pennsylvania, and New York, from Pennsylvania, to points in Delaware, North Carolina, South Carolina, Georgia, and Florida, from points in Virginia, to points in Delaware, North Carolina, South Carolina, Georgia, and Florida, from points in New York, to points in North Carolina, South Carolina, Georgia, and Florida, from points in New York, to points in Pennsylvania, to points in Maryland, to points in Maine, New Hampshire, New York, Delaware, Massachusetts, Connecticut, New Jersey, North Carolina, South Carolina, Georgia, and Florida, from points in New York, to points in Colorado, Pennsylvania, to points in Connecticut, Massachusetts, New Jersey, New York, and Ohio. Also, delivery of furniture, as a common carrier in all 50 States. Application has not been filed for temporary authority.

NOTICES

35265


No. MC-F-13260. Authority sought for control and merger by BECKER CORPORATION, P.O. Box 1585, El Dorado, KS, 67042, of C. E. Reynolds Transport, Inc., P.O. Box A, Joplin, MO, 64801, and for acquisition by Frank J. Becker P.O. Box 1585, El Dorado, KS, 67042, of control of such rights through the transaction. Application filed by Mr. J. Brown 223 Ciudad Bldg, Oklahoma City, OK, 73112.

The operating rights sought to be controlled and merged are contained of public convenience and necessity under No. MC-114890 and subs authorizing the transportation of Anhydrous ammonia, nitrogen fertilizer solutions, aqua ammonia, methanol, and anti-freeze preparations, in bulk, in tank vehicles, nitrogen fertilizer solutions, in bulk, in tank vehicles, nitric acid, in bulk, in tank vehicles, phosphoric acid, in bulk, in stainless steel tank vehicles, Sulphuric and phosphoric acid, in bulk in tank vehicles, Sulphuric and phosphoric acid, in bulk in tank vehicles, refined petroleum products, in bulk, lubricating oil, in containers petroleum products, in truckload lots, petroleum products, in bulk, in tank vehicles, nitric acid, in bulk, in tank vehicles, sulphuric acid, in bulk, in tank vehicles, and numerous other specified commodities, as a common carrier over irregular routes, from, to, and between unspecified points in Kansas, Missouri, Oklahoma, Texas, Tennessee, Alabama, Florida, Illinois Indiana, Kentucky, Louisiana Mississippi, Nebraska, Iowa, Nevada, Colorado, Wisconsin, Minnesota, Mississippi, Arkansas, New Mexico, Wisconsin, Montana, Michigan, and Ohio, with certain restrictions, as more specifically described in Docket No. MC-114890 and subs thereunder. This notice does not purport to be a complete description of all of the operating rights of the carrier involved. The foregoing summary is believed to be sufficient and the purpose of this notice is to give notice regarding the nature and extent of this carrier's operating rights, without stating, in full, the entirety, thereof. Vendee is authorized to operate as a common carrier in the States of Kansas, Nebraska, Oklahoma, Texas, New Mexico, Colorado, Iowa, South Dakota, North Dakota, Montana, Idaho, Minnesota, Wisconsin, Illinois, Missouri, Arkansas, and Louisiana. Application has been filed for temporary authority under section 210(a).

No. MC-F-13261. Authority sought for purchase by THE MICKOW CORP., 7510 B St., El Dorado, KS, 67042, of the operating rights of Romans Drywall Express, Inc., R.R. 1, Yutan, NB and for acquisition by Double-D Systems Corporation, P.O. Box 1714, Des Moines, IA, of Romans Drywall Express. Vendee is authorized to operate as a common carrier in Colorado, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, Nevada, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Wisconsin and Wyoming. Application has been filed for temporary authority under section 210(a).

No. MC-F-13265. Authority sought for purchase by BENTON COUNTY COMMUNITY TRANSPORTATION, Box 155, Berryville, AR, 72616, of the operating rights of John B. Burch, d.b.a. Benton County Community Transportation, Box 110, Gentry, AR, 72734, of control of such rights through the purchase. Application by B. Burch, d.b.a. Benton County Community Transportation.

No. MC-F-13268. Authority sought for purchase by BEAUFORT TRANSFER COMPANY, Box 151, Gerald, MO, 63037, of the operating rights of John Kiesler, d.b.a. Beaufort Transfer Co., Box 151, Gerald, MO, 63037, of acquisition by Olvin Flottmann, P.O. Box 151, Gerald, MO, 63037, of control of such rights through the purchase. Applicants' attorney: Ernest A. Brooks II, 1301 Ambassador Building, St. Louis, MO, 63101.

No. MC-F-13269. Authority sought for purchase by EAST TEXAS FREIGHT SYSTEM, 2355 Stemmons Freeway, Dallas, TX, 75207, of a portion of the operating rights of Hemingway Transport, Inc., 4900 S. Lamar, Austin, TX, 78744, and for acquisition by H. R. Bright, individually, and as executor and trustee of the estate of Mary Frances Smith Bright, deceased, of the operating rights of Hemingway Transport, Inc., 4900 S. Lamar, Austin, TX, 78744, of control of such rights through the purchase. Applicants' attorneys: Leroy Hallman, 4355 East National Bank Blvd., Dallas, TX, 75202, Ray Chesney, East Texas Motor Freight Lines, Inc., 2355 Stemmons Freeway, Dallas, TX, 75207, and David G. Macdonald, 1000 20th St. N.W., Washington, D.C., 20009. Operating rights sought to be transferred: General commodities, with exceptions as a common carrier over irregular routes between Iowa, Missouri, and Illinois.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES


FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

NOTICES

Atlantic Richfield Company, 150 South Flower Street, Los Angeles, California 90071, and the Anacostia Company, 121st Avenue of the Americas, New York, New York 10020, by its attorneys, hereby give notice that on the 17th day of June, 1977, they filed with the Interstate Commerce Commission at Washington, D.C., an application under Section 5(2) of the Interstate Commerce Act for an order approving and authorizing the acquisition of the Atlantic Richfield Company and the Anacostia Company to acquire control of the Butte, Anaconda & Pacific Railway Company and the Tooele Valley Railway Company, which application is assigned Finance Docket No. 28480.

The nature of the proposed transaction is for the acquisition of control of Butte, Anaconda & Pacific Railway Company and Tooele Valley Railway Company, carriers operating under Part I of the Interstate Commerce Act, by the Atlantic Richfield Company and the Anacosta Company, which are not carriers.

but the application is assigned Finance Docket No. 28480.

The nature of the proposed transaction is for the acquisition of control of Butte, Anaconda & Pacific Railway Company and Tooele Valley Railway Company, carriers operating under Part I of the Interstate Commerce Act, by the Atlantic Richfield Company and the Anacosta Company, which are not carriers.

but the application is assigned Finance Docket No. 28480.

The nature of the proposed transaction is for the acquisition of control of Butte, Anaconda & Pacific Railway Company and Tooele Valley Railway Company, carriers operating under Part I of the Interstate Commerce Act, by the Atlantic Richfield Company and the Anacosta Company, which are not carriers.

but the application is assigned Finance Docket No. 28480.
DIXON LINES, INC., Eastman Road, Post Office Box 385, Elizabethtown, Tenn. 37022, Applicant: Titus D. MAIN, Suite 1010, 7101 Wisconsin Avenue, Washington, D.C. 20014. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: General commodities (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between points in York County, S.C.; and between points in York County, Ohio, on the one hand, and, on the other, points in South Carolina.

Note—Common control may be involved. This application is directly related to the application simultaneously filed in docket No. MC 47-12266. By this application, Mason and Dixon seeks to convert the certificate of registration issued City Transfer & Storage Co. in MC 132105 (Sub-No. 1) to one of public convenience and necessity. If a hearing is deemed necessary, applicant requests that it be held at Columbia, S.C. Notice of the filing of the application does not yet as MC P-13266 appears in a prior section of this FEDERAL REGISTER issue.

No. MC 121420 (Sub-No. 8), filed June 13, 1977. Applicant: DART TRUCKING CO., INC., 61 Railroad Street, F.D. Box 695, Chillicothe, Ohio, 45601, Applicant's representative: Paul F. Beery, Paul F. Beery Co., L.P.A., 275 East State Street, Columbus, Ohio 43215. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) General commodities, between Atwater, Ohio, on the one hand, and, on the other, points in Ohio; (2) coal, building supplies, farm commodities, lumber, logs, and sawmill equipment, between Portage County, Ohio, on the one hand, and, on the other, points in Ohio; (3) lumber, logs and sawmill equipment, between Columbiana, Mahoning, Trumbull, Stark, and Summit Counties, Ohio, on the one hand, and, on the other, points in Ohio; (4) such commodities in bulk, in dump vehicles, (a) from Portage County, Ohio, gateways), (b) from points in Ohio, Pennsylvania, and West Virginia within 50 miles of Toronto, Ohio, to points in Pennsylvania and West Virginia, by motor vehicle, other than such commodities in bulk, in dump vehicles, (b) from points in Ohio, Pennsylvania, and West Virginia within 50 miles of Toronto, Ohio, to points in Pennsylvania and West Virginia, by motor vehicle, other than such commodities in bulk, in dump vehicles (c) from Portage County, Ohio, to points in Pennsylvania and West Virginia, by motor vehicle, other than such commodities in bulk, in dump vehicles (d) points in Ohio, Pennsylvania, and West Virginia within 50 miles of Toronto, Ohio, to points in Ohio, Pennsylvania, and West Virginia, by motor vehicle, other than such commodities in bulk, in dump vehicles with the Commission or on or before August 8, 1977. Such protests shall comply with Special Rules 247(d) of the Commission's General Rules of Practice (49 CFR 1.140.247) and include a concise statement of protestant's interest in the proceeding and copies of its conflicting authorities. Verification of the requested relief shall not be tendered at this time. A copy of the protest shall be served concurrently upon applicant's representative, or applicant if no representative.

Each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

No. MC 59583 (Sub-No. 163), filed June 14, 1977. Applicant: THE MASON AND
in the lower peninsula of Michigan, restricted against the transportation of traffic moving to Canada, (c) from points in Mercer County, Pa.; and points in Ashtabula, Mahoning, Trumbull, Columbiana, and Conneaut Counties, Ohio, to points in Pennsylvania (except points in Butler, Crawford, Venango, Armstrong, Indiana, Westmoreland, Washington, Greene, Fayette, Somerset, Mercer, Lawrence, Beaver, Clarion, and Allegheny Counties), (e) from points in Ohio, Pennsylvania, and West Virginia within 5 miles of Toronto, Ohio, to points in Pennsylvania (except points in Butler, Crawford, Venango, Armstrong, Indiana, Westmoreland, Washington, Greene, Fayette, Somerset, Mercer, Lawrence, Beaver, Clarion, and Allegheny Counties) (elimination in (9) of Ohio gateways);

(10) Coal, builders supplies, farm supplies, farm commodities, lumber and logs, as are used in the construction of trucks, (a) between points in Ohio, on the one hand, and, on the other, points in Ohio, Pennsylvania, and West Virginia, within 50 miles of Toronto, Ohio, including (a) and (b) between points in Ohio, on the one hand, and, on the other points in Mercer County, and points in Ashtabula, Trumbull, Mahoning, Columbiana, and Portage Counties, Ohio (elimination in (10) of Alvahater, Ohio gateway).

Note.—The purpose of parts (1), (2), and (3) is to convert a certificate of registration to a certificate of public convenience and necessity. The purpose of parts (4) through (10) is to eliminate gateways in Ohio and Mercer County, Pa., pursuant to Ex Parte 66 (Sub-No. 8), Gateway Elimination, 119 M.C.C. 530 (1974). If a hearing is deemed necessary, applicant requests it be held at Columbus, Ohio. This application is directly related to a finance matter in MC-F-32588 which was noticed in the Federal Register issue of June 30, 1977.

Motor Carrier Alternate Route Deviations

The following letter-notices to operate over deviation routes for operating convenience only have been filed with the Commission under the Deviation Rules—Motor Carrier of Property (49 CFR 1842.4(c) (11)).

Protests against the use of any proposed deviation route herein described may be filed with the Commission in the manner and form provided in such rules at any time, but will not operate to stay commencement of the proposed operations unless filed within 30 days from the date of this Federal Register notice.

Each application states that there will be no significant effect on the quality of the human environment resulting from approval of its request.

Motors Carriers of Property

No. MC 3054 (Deviation No. 179), TUCKER FREIGHT LINES, INC., P.O. Box 3144, South Bend, Ind. 46619, filed June 22, 1977. Carrier proposes to operate a common carrier, by motor vehicle, of general commodities, except certain exceptions, over a deviation route as follows: From Michigan City, Ind., over U.S. Highway 421 to junction U.S. Highway 331, then over U.S. Highway 231 to junction Interstate Highway 74, then over Interstate Highway 74 to junction Interstate Highway 80, then over Interstate Highway 61 to junction U.S. Highway 80 and Interstate Highway 20 By-Pass, and return over the same route.

Motor Carrier Intrastate Applications

The following application (a) for motor carrier authority to operate in intrastate commerce seek concurrent motor carrier authorization in interstate or foreign commerce within the limits of the intrastate authority sought, pursuant to Section 206(a) (6) of the Interstate Commerce Act. These applications are governed by Special Rule 235 of the Commission's General Rules of Practice (49 CFR 1100.245), which provides among other things, that protests and requests for information concerning the time and place of State Commission hearings or other proceedings, any subsequent changes therein, and any other related matters shall be directed to the State Commission with which the application is filed and shall be addressed to or filed with the Interstate Commerce Commission.

California Docket No. A 57339, amendment filed June 3, 1977. Applicant: MERRILL E. WOLKINS, doing business as California Mail Delivery Service, P.O. Box 77132, San Francisco, Calif. 94177. Applicant's representative: Raymond A. Greene, Jr., 100 Pine St., Suite 2550, San Francisco, Calif. 94111. Certificate of public convenience and necessity sought for the operation of certain general commodities, as follows: (A) between all points in the San Francisco Territory as described in Note A (B) between all points on and within the following routes: (1) U.S. Highway 401, between San Francisco and Sauanalo, inclusive; (2) Interstate Highway 80, between San Pablo and Crockett, inclusive; (3) unnumbered road and route between Crockett and Martinez, inclusive; (4) unnumbered road and route between Martinez and Pittsburg, inclusive; (5) unnumbered road and route between Pittsburg and Antioch, inclusive; (6) State Highway 24 between Antioch and the Willows Road intersection, inclusive; (7) Willows Road between the intersection of Interstate Highway 4 and the intersection of Interstate Highway 80, inclusive; (8) State Highway 4 between its intersection with Willows Road and its intersection with Fort Chicago Highway, inclusive; (9) Monument Boulevard between its intersection with State Highway 24 and its intersection with Willows Road, inclusive; (10) State Highway 4 between its intersection with Fort Chicago Highway and its intersection with State Highway 24, inclusive; (11) State Highway 24 between its intersection with State Highway 4 and its intersection with Interstate Highway 880, inclusive; (12) Interstate Highway 880 between its intersection with State Highway 24 and its intersection with Interstate Highway 4.
580 at Dublin; (13) Interstate 680 between its intersection with Interstate Highway 880 at Dublin and its intersection with Bernal Ave, inclusive; (14) Bernal Avenue between its intersection with Interstate Highway 680 and the City of Pleasanton; (15) Interstate Highway 880 between its intersection with Interstate Highway 880 at Dublin and its intersection with State Highway 236 at Mission San Jose. (16) State Highway 236 between its intersection with Interstate Highway 880 and its intersection with State Highway 101; (17) State Highway 101 between its intersection with Interstate Highway 880 at Dublin and its intersection with State Highway 4 at Stockton and its intersection with State Highway 88, inclusive; (18) State Highway 88 between its intersection with Interstate Highway 5 and its intersection with State Highways 99 and 50, inclusive; (19) State Highway 99 between Vacaville and its intersection with Interstate Highway 5, inclusive; (20) Interstate Highway 5 between its intersection with State Highway 4 at Stockton and its intersection with State Highway 99, inclusive; (21) State Highway 120 between its intersection with Interstate Highway 5 and its intersection with State Highway 99, inclusive; (22) State Highway 99 between Sacramento and Tulare, inclusive; (23) State Highway 162 between its intersection with interstate Highway 5 and its intersection with State Highway 99, inclusive; (24) State Highway 33 between its intersection with State Highway 152 at the Dos Palos Wye and its intersection with Interstate Highway 5, via Firebaugh, inclusive; (25) State Highway 180 between its intersection with Interstate Highway 5 and its intersection with State Highway 99, inclusive; (26) State Highway 49 between its intersection with State Highway 152 at the Dos Palos Wye and Interstate Highway 5, via Firebaugh, exclusive; (27) State Highway 140 between its intersection with Interstate Highway 5 and State Highway 99, inclusive; (28) U.S. Highway 101 between its intersection with Interstate Highway 5 and State Highway 99, inclusive; (29) U.S. Highway 101 between its intersection with State Highway 1 at Santa Cruz, exclusive; (30) State Highway 1 between its intersection with State Highway 1 at Santa Cruz and its intersection with State Highway 68 at Monterey; (31) State Highway 68 between its intersection with State Highway 1 at Castroville and its intersection with State Highway 1 at Water-
Los Angeles Basin Territory includes Drive; southwesterly along La Cadena Drive to Iowa Ave.; southerly along Iowa Ave.; to U.S. Highway No. 60; southwesterly along U.S. Highways Nos. 60 and 395 to the county road approximately one mile north of Perris; easterly along said county road via Nuevo and Lakeview to the corporate boundary of the City of San Jacinto; easterly, southerly and westerly along said corporate boundary to San Jacinto Ave.; southerly along San Jacinto Ave.; to State Highway No. 74.

Westerly along State Highway No. 74. to the corporate boundary of the City of Hemet; southerly, westerly and northerly along said corporate boundary to McClay Ave.; southerly along McClay Ave.; through and including the unincorporated community of Winchester to Benton Road; westerly along Benton Road to the county road intersecting U.S. Highway No. 395, 2.1 miles north of the unincorporated community of Temecula; southerly along said county road to U.S. Highway No. 395; southeasterly along U.S. Highway No. 395 to the Riverside County-San Diego County boundary line, westerly along boundary line to the Orange County-San Diego County boundary line; southerly along said boundary line to the Pacific Ocean to point of beginning. Intrastate, interstate and foreign commerce authority sought.

By the Commission.

H. G. HOMME, JR.,
Acting Secretary.


Hearing.—Date, time and place not yet fixed. Requests for procedural information should be addressed to the Florida Public Service Commission, 700 South Adams Street, Tallahassee, Fla. 32304 and should not be directed to the Interstate Commerce Commission.

By the Commission.

H. G. HOMME, JR.,
Acting Secretary.

[FR Doc. 77-15954 Filed 7-7-77; 8:45 am]
## CONTENTS

<table>
<thead>
<tr>
<th>Item</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Civil Rights Commission</td>
<td>1</td>
</tr>
<tr>
<td>2. Equal Employment Opportunity Commission</td>
<td>2</td>
</tr>
<tr>
<td>3. Federal Election Commission</td>
<td>3</td>
</tr>
<tr>
<td>4. Federal Maritime Commission</td>
<td>4</td>
</tr>
<tr>
<td>5. Securities and Exchange Commission</td>
<td>5</td>
</tr>
</tbody>
</table>

### 1

**AGENCY HOLDING THE MEETING:**

Commission on Civil Rights.

**FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:** 42 FR 34403, July 5, 1977.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING:** July 6, 1977, 7-10 p.m.

**CHANGES IN THE MEETING:** Time of meeting is changed to 4-10 p.m.

**CONTACT PERSON FOR FURTHER INFORMATION:**

Barbara Brooks, Public Affairs Unit (202-254-6697).

**[S-833-77 Filed 7-6-77;10:02 am]**

### 2

**AGENCY HOLDING THE MEETING:**


**TIME AND DATE:** 9:30 a.m. (eastern time), Tuesday, July 12, 1977.

**PLACE:** Chairman's Conference Room, No. 5240, on the fifth floor of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

**STATUS:** Parts of the meeting will be open to the public. The rest of the meeting will be closed to the public.

**MATTERS TO BE CONSIDERED:**

1. Freedom of Information Act Appeal No. 77-FEFOIA-97. Request by an attorney representing an employer charged with discrimination, for an affidavit submitted to the Commission by the party filing the charge of discrimination.
2. New seniority systems. Recommendations concerning the appropriate interpretation of recent U.S. Supreme Court decisions defining the application of title VII to "bene fide" seniority systems.

**PORTIONS CLOSED TO THE PUBLIC:**

1. Litigation authorization; general counsel recommended that matters closed to the public under 5 U.S.C. 552b(c) of the Commission's regulations (42 FR 13890, March 14, 1977).
2. Audit Report No. EEO-77-460-20-015 of EEOC Financial Services Division for fiscal year 1975; resolution of Anti-Deficiency Act questions. The Commission will consider an opinion and recommendation submitted by the General Counsel.

### 3

**AGENCY HOLDING THE MEETING:**

Federal Election Commission.

**DATE AND TIME:** Wednesday, July 13, 1977, at 10 a.m.

**PLACE:** 1225 K Street NW., Washington, D.C.

**STATUS:** This meeting will be closed to the public.

**MATTERS TO BE CONSIDERED:**

1. Agreement No. 10281; the U.S. South Atlantic/Guianas, Portuguese, Moroccan, and Mediterranean Rate Agreement, and Agreement No. 134-39; modification of the Gulf/Mediterranean Ports Conference—Creation of new rate agreement and establishment of an agreement to prevent overlap.
4. Agreement No. 10028—Petition for order requiring Sea-Land Service, Inc., to withdraw embargo notice and to carry cargo in accordance with current tariffs (U.S./Puerto Rico Trade).

**ADJACENT MEETING:**

**PREVIOUS ANNOUNCEMENT:** 42 FR 6317, January 18, 1977.

**INFORMATION:**

Barbara Brooks, Public Affairs Unit (202-254-6697).

**[S-830-77 Filed 7-5-77;4:22 pm]**

### 4

**AGENCY HOLDING THE MEETING:**

Federal Maritime Commission.

**TIME AND DATE:** July 13, 1977, at 10 a.m.

**PLACE:** Room 12125, 1100 L Street NW., Washington, D.C. 20573.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

1. Agreement Nos. 8094-15 and 9502-10; Modification of the South and East Africa Conference Agreements—Miscellaneous amendments regarding membership requirements and authorization of Chairman to file amendments.
2. Agreement No. 10281; the U.S. South Atlantic/Guianas, Portuguese, Moroccan, and Mediterranean Rate Agreement, and Agreement No. 134-39; modification of the Gulf/Mediterranean Ports Conference—Creation of new rate agreement and establishment of an agreement to prevent overlap.
3. Agreement No. 9847—Petition for order requiring Sea-Land Service, Inc.—Berthing of Seatrain vessels in San Juan, Puerto Rico.
4. Petition for order requiring Sea-Land Service, Inc., to withdraw embargo notice and to carry cargo in accordance with current tariffs (U.S./Puerto Rico Trade).
8. Sergio E. Vasques (FMC License No. 1685)—Qualification for license as independent ocean freight forwarder.

**CONTACT PERSON FOR MORE INFORMATION:**

Joseph C. Polking, Acting Secretary (202-523-5727).

**[S-831-77 Filed 7-5-77;4:22 pm]**

### 5

**AGENCY HOLDING THE MEETING:**

Securities and Exchange Commission.

**TIME AND DATE:**

Closed meetings will be held on Tuesday, July 12, 1977, at 10 a.m. and immediately following the open meeting on Thursday, July 14, 1977. Open meetings will be held on Tuesday, July 12, 1977, at 2:30 p.m. and on Thursday, July 14, 1977, at 2:30 p.m.

**THE MEETING:**

The Commissioners, their legal assistants, the Secretary to the Commission, and recording secretaries will attend the closed meetings. Certain staff members who are responsible for the calendared matters may be present.

**THE MEETING:**

The General Counsel of the Commission, or his designee, has certified, in his opinion, the items to be considered at the closed meetings may be so considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9), (9A), and (10) and 17 CFR 200.402(a), (4), (8), (9), (9A), and (10).
Chairman Williams and Commissioners Loomis, Pollack, and Evans voted to hold the aforesaid meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, July 12, 1977, will be:

- Formal orders of investigation.
- Institution of injunctive actions.
- Settlement of administrative proceedings.
- Referral of investigative files to Federal, State, or Self-Regulatory authorities.
- Regulatory matters arising from or bearing enforcement implications.
- Other litigation matters.
- Matters relating to issuer registration statements, proxies, tender offers, etc.
- Personnel matters.
- Freedom of Information Act appeal.

The subject matter of the open meeting scheduled for Tuesday, July 12, 1977, at 2:30 p.m. will be:

1. Consideration by the Commission of a recommendation that it issue for public comment (1) a revised version of proposed Rule 206(4)-4 under the Investment Advisers Act of 1940, which would require investment advisers to deliver to their clients and prospective clients certain information about the adviser, (2) a revised and expanded Form ADV, the investment adviser registration form, and (3) a proposed form to be filed annually by investment advisers disclosing whether the adviser is still in business.

The subject matter of the open meeting scheduled for Thursday, July 14, 1977, at 2:30 p.m. will be:

1. Oral argument in support of American Bakers Company's application pursuant to section 6(c) of the Investment Company Act of 1940 for an exemption from provisions of section 17(a)(2) of the Act.

The subject matter of the closed meeting scheduled for Thursday, July 14, 1977 immediately following the 2:30 p.m. open meeting will be:

- Post-oral argument discussion.

FOR FURTHER INFORMATION CONTACT:

Lawrence A. Horn (202-755-1563) or Edward A. Scallet (202-376-6025).

JULY 5, 1977.

[S-532-77 Filed 7-5-77 4:22 p.m.]
DEPARTMENT OF STATE

FISHERY CONSERVATION AND MANAGEMENT ACT OF 1976

Applications for Permits To Fish Off the Coasts of the United States
Notices

Department of State

[Federal Register No. 553]

Fishery Conservation and Management Act of 1976

Applications for Permits to Fish Off the Coasts of the United States

The Fishery Conservation and Management Act of 1976 (P.L. 94-265) (the "Act") provides that no fishing shall be conducted by foreign fishing vessels in the Fishery Conservation Zone of the United States after February 28, 1977, except in accordance with a valid and applicable permit issued pursuant to Section 204 of the Act.

The Act also requires that all applications for such permits be published in the Federal Register.

Applications for fishing during 1977 have been received from the Government of Italy, and are published herewith.

Dated: July 1, 1977.

Albert L. Zucca,
Director,
Office of Fisheries Affairs.

Fishing Vessel Identification Form (Foreign)

<table>
<thead>
<tr>
<th>Permit Period</th>
<th>Application No.</th>
<th>For Use of Issuing Office</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>EC/77-71-0009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Vessel</th>
<th>Gabriele C</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
<td>Italy</td>
</tr>
</tbody>
</table>

1. Name of Vessel: Gabriele C
2. Vessel No.: Hull No. (if any) Registration No. 905
3. Name and Address of Owner:
   Name: Felice Cefalu
   Address: Via Onorato, 4, 90139 Palermo
4. Homeport and State of Registry: Palermo
5. Type of Vessel: Stern Trawler
6. Tonnage (Gross): 1325.98 (Net): 651.24
12. Propulsion: Diesel (X), Steam ( ), Diesel/Electric ( ), Other (Specify)
13. Date Built: 1971
14. Number and Nationality of Personnel: 32 Persons, Italy
   Officers: 10 Crew: 22 Other: (Specify)
15. Communications: VHF-FM (X), AM/SSB, Voice (X), Telegraphy ( ), Other (Specify)
   International Radio Call Sign: KUUV
   Radio Frequencies Monitored: 24.77
   Other Working Frequencies
   Schedule

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
16. **Navigation Equipment:** Loran C (X), Loran A ( ), Omega ( ), Bressa ( ), Havis ( ), Radar (X), Fathometer (X), Other

17. **Cargo Capacity (MT):**

<table>
<thead>
<tr>
<th>Item</th>
<th>Number</th>
<th>Tons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salted Fish</td>
<td></td>
<td>600</td>
</tr>
<tr>
<td>Frozen Fish</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>Fish Meal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

18. **Cargo Space Number:**

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

19. **Processing Equipment (Indicate daily capacity, MT):**

<table>
<thead>
<tr>
<th>Gear to be Used (Catch, MT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catch (MT)</td>
</tr>
<tr>
<td>500</td>
</tr>
</tbody>
</table>

20. **Fishing Areas for which Permit is Requested:**

<table>
<thead>
<tr>
<th>Ocean Area</th>
<th>Period</th>
<th>Species Contemplated</th>
<th>Gear to be Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlantic</td>
<td>(5 and 6)</td>
<td>Squid, Butterfish, Mackerel, Other fish</td>
<td>Bottom and mid-water trawl</td>
</tr>
</tbody>
</table>

21. **Name and Address of Agent appointed to receive any legal process issued in the United States:**

- **International Trading and Shipping Agency**
- **25 Broadway**
- **New York, New York**

---

**FISHING VESSEL IDENTIFICATION FORM (FOREIGN)**

<table>
<thead>
<tr>
<th>Permit Period Applied For:</th>
<th>Application No.</th>
<th>State:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ITALY</td>
</tr>
</tbody>
</table>

1. **Name of Vessel:** AMORUSO BASTO

2. **Vessel No.: Hull No.:** Registration No. 170

3. **Name and Address of Owner:** Name and Address of Charterer

- **Name:** Amoruso Michele & Figli
- **Address:** Molo Pizzoli 70123
- **Cable Address:** Amoroslapari

4. **Homeport and State of Registry:** BARI

5. **Type of Vessel:** Stern Trawler

6. **Tonnage (Gross):** 833.89 (Net) 369

7. **Length:** 62.73 ft, **Breadth:** 10.42 ft, **Draft:** 3.24 ft

8. **Horsepower:** 2000 shp, **Maximum Speed:** 13 kt

9. **Propulsion:** Diesel (X), Steam ( ), Diesel/Electric ( ), Other

10. **Date Built:** 1970

11. **Number and Nationality of Personnel:** 30 persons, Italy

- **Officers:** 10
- **Crew:** 20
- **Other:** (Specify)

12. **Communications:** VHF-FM (X), AM/SSB, Voice (X), Telegraphy ( ), Other

- **International Radio Call Sign:** F.R.G.
- **Radio Frequencies Monitored:** 2162
- **Other Working Frequencies Schedule:**

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**NOTICES**
16. Navigation Equipment: Loran C (X), Loran A ( ), Omega ( ),
Decca (X), Navsat ( ), Radar (X), Fathometer (X),
Other ________________________________

17. Cargo Capacity (HT)  18. Cargo Space
   Number       Name
   500 tons
Salted Fish ___________ Freezer
Fresh Fish ___________ Dry Hold
Frozen Fish 500 _______ Tanks
Fish Meal ___________ Other
Other __________________

19. Processing Equipment (Indicate daily capacity, HT)

20. Fisheries for which Permit is Requested:
   Ocean Area  Period  Species Contemplated  Gear to be Used  Catch (HT)
   (From-To)
Atlantic (5 and 6) 1977  Squids, Mackerel, Other Finfish 400 Bottom and mid-
                   (and 6)                    water trawls

21. Name and Address of Agent appointed to receive any legal
   process issued in the United States:

   International Trading and Shipping Agency
   25 Broadway
   New York, New York

[FR Doc.77-19392 Filed 7-7-77; 8:45 am]
EN viRONMENtiAL PROTECTION AGENCY

AIR QUALITY

Recommended Policy on Control of Volatile Organic Compounds
ENVIRONMENTAL PROTECTION AGENCY

AIR QUALITY

Recommended Policy on Control of Volatile Organic Compounds

PURPOSE

The purpose of this notice is to recommend a policy for States to follow on the control of volatile organic compounds (VOC), which are present in the formation of photochemical oxidants (smog). This notice does not place any requirements on States; State Implementation Plans (SIP) provisions which offer reasonable alternatives to this policy will be acceptable. However, this policy will be followed by EPA whenever it is required to draft State Implementation Plans for the control of photochemical oxidants.

BACKGROUND

Photochemical oxidants result from sunlight acting on volatile organic compounds (VOC) and oxides of nitrogen. Some VOC, by their nature, start to form oxidant after a short period of irradiation in the atmosphere. Other VOC may undergo irradiation for a longer period before they yield measurable oxidant.

In its guidance to States for the preparation, adoption, and submittal of State Implementation Plans published in 1971, the Environmental Protection Agency emphasized reduction of total organic compound emissions, rather than substitution. (See 40 CFR Part 51, Appendix B.) However, in Appendix B, EPA stated that substitution of one compound for another might be used where it would result in a clearly evident decrease in reactivity and thus tend to reduce photochemical oxidant formation. Subsequently, many State Implementation Plans were promulgated with solvent-substitution provisions similar to Rule 66 of the Los Angeles County Air Pollution Control District. These regulations allowed exemptions for many organic solvents which have now been shown to generate significant photochemical oxidant. On January 29, 1976, EPA published its “Policy Statement on Use of the Concept of Photochemical Reactivity of Organic Compounds in State Implementation Plans for Oxidant Control.” The notice of availability of this document appeared in the Federal Register on February 5, 1976 (41 FR 5559).

The 1976 policy statement emphasized that the reactivity concept was useful as an interim measure only, and would not be considered a substitute or compensation for purposes of estimating attainment of the ambient air quality standard for oxidants. The document also included the following statement:

Although the substitution portions of Rule 66 and similar rules were considered a workable and acceptable program at the present time, better substitution regulations can be developed, based on current knowledge of reactivity and industrial capability. EPA in collaboration with State and industry representatives will formulate in 1976 an improved rule for national use.

SUMMARY

Analysis of available data and information show that very few volatile organic compounds are of sufficiently photochemical reactivity that they can be ignored in oxidant control programs. For this reason, EPA's recommended policy reiterates the need for positive control techniques. There is also the reduction of volatile organic compounds in surface coatings, process changes, and the use of control equipment rather than the substitution of compounds of low (slow) reactivity in the place of more highly (fast) reactive compounds. There are three reasons for this. First, many of the VOC that previously have been designated as having low reactivity are now known to be moderately or highly reactive in urban atmospheres. Second, even compounds that are presently known to be low in reactivity can form appreciable amounts of oxidant under midday stagnation conditions such as occur during summer in many communities. Therefore, the compounds of low or negligible reactivity may have other deleterious effects.

Of the small number of VOC which have, only negligible photochemical reactivity, several (methane, acetonitrile, chloroform, carbon tetrachloride, ethylene dichloride, ethylene dibromide, and methylene chloride) have been identified or implicated as being carcinogenic, mutagenic and teratogenic. An additional compound, benzaldehyde, while producing no appreciable ozone, nevertheless, forms a strong eye irritant under irradiation. In view of these circumstances, it would be inappropriate for EPA to encourage or support increased utilization of these compounds. Therefore, they are not recommended for exclusion from control. Only the four compounds listed in Table 1 are recommended for exclusion from SIP regulations and, therefore, it is not necessary that they be in vented or controlled for determining reductions required to meet oxidant NAAQS, these VOC should not be included in the base line nor should reductions in their emissions be credited toward achievement of the NAAQS.

It is recognized that the two halogenated compounds listed in Table 1 (methyl chloroform and Freon 113) may cause deterioration of the earth's ultra-violet radiation barrier and, therefore, are nearly unreactive in the lower atmosphere and all contain appreciable fractions of chlorine. The Agency has reached conclusions on the effects of only the fully halogenated chlorofluorocarbons. The Agency on May 13, 1977 (42 FR 24842), proposed rules under the Toxic Substances Control Act (TSCA) to prohibit the nonessential use of fully halogenated chlorofluorocarbons as aerosol propellants. The restrictions were applied to all members of this class, including Freon 113, since they are potential substitutes for Freon 11, Freon 12, Freon 114, and Freon 115, which are currently used as aerosol propellants. The Agency is planning to investigate control systems and substitutes for nonpropellant uses under TSCA, as announced on May 13. Methyl chloroform is not a fully halogenated chlorofluorocarbons. Rather, it is among the chlorine-containing compounds for which the Agency has not completed its analysis; EPA has not yet concluded whether it is or is not a threat to the stratospheric ozone. Therefore, it has been placed on this list as an acceptable exempt compound. As new information becomes available on these compounds, EPA will reconsider the recommendation.

The volatile organic compounds listed in Table 2, while more photochemically reactive than those in Table 1, nevertheless do not contribute large quantities of oxidant under many atmospheric conditions.

Table 1—Volatile Organic Compounds of Negligible Photochemical Reactivity That Should Be Exempt From Regulation Under State Implementation Plans

<table>
<thead>
<tr>
<th>Compound</th>
<th>Reason for Exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methane</td>
<td></td>
</tr>
<tr>
<td>Ethane</td>
<td></td>
</tr>
<tr>
<td>1,1-Dichloroethylene</td>
<td></td>
</tr>
<tr>
<td>2,2-Dichlorotrifluoromethane</td>
<td></td>
</tr>
<tr>
<td>Trichlorofluoromethane</td>
<td></td>
</tr>
</tbody>
</table>

These compounds have been implicated as having deleterious effects on stratospheric ozone and, therefore, may be subject to TSCA controls.

Table 2—Volatile Organic Compounds of Low Photochemical Reactivity

<table>
<thead>
<tr>
<th>Compound</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propene</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td></td>
</tr>
<tr>
<td>1-Methyl Ketone</td>
<td></td>
</tr>
<tr>
<td>Methanol</td>
<td></td>
</tr>
<tr>
<td>Isopropyl Alcohol</td>
<td></td>
</tr>
<tr>
<td>Methyl N-butylate</td>
<td></td>
</tr>
<tr>
<td>Tertiary Butyl Alcohol</td>
<td></td>
</tr>
<tr>
<td>Methyl Acetate</td>
<td></td>
</tr>
<tr>
<td>Ethyl Acetate</td>
<td></td>
</tr>
<tr>
<td>Ethyl Amines</td>
<td></td>
</tr>
<tr>
<td>Acroleine</td>
<td></td>
</tr>
<tr>
<td>N,N-Dimethyl formamide</td>
<td></td>
</tr>
</tbody>
</table>

Only during midday stagnations do VOC yield significant oxidants. Therefore, if resources are limited or if the sources are located in areas where prolonged atmospheric stagnations are uncommon, priority should be given to controlling more reactive VOC and Table 2 organics later. Table 2 VOC are to be included in base line emission inventories and reductions in them will be credited toward achievement of the NAAQS. Reasonably available control technology should be applied to significant sources of Table 2 VOC where necessary to attain the NAAQS for oxidants. New sources of these compounds will also be subject to new source review requirements.

Perchloroethylene, the principal solvent employed in the dry cleaning industry, is also of low reactivity, comparable to VOC listed in Table 2. It was not included in Table 2 because of reported adverse health effects. Uses, environmental distribution, and effects of perchloroethylene currently are being studied intensively by occupational health authorities; perchloroethylene is currently being studied in investigations that have major impact on...
industrial users. In designing control regulations for perchloroethylene sources, particularly dry cleaners, consideration should be given to these findings as well as industry requirements and the cost of applying controls. Available control technology is highly cost effective for large perchloroethylene-dry cleaning operations. However, for coin-operated and small dry cleaners, the sampling equipment would represent a heavy economic burden.

As part of its continuing program, EPA will review new information relative to the photochemical reactivity, toxicity, or effects on stratospheric ozone of volatile organic compounds. Where appropriate, additions or deletions will be made to the lists of VOC in Tables 1 and 2.

Discussion

Most air pollution control regulations applicable to stationary sources of VOC in the United States are patterned after Rule 66 of the Los Angeles County Air Pollution Control District (presently Regulation 442 of the Southern California Air Pollution Control District). Rule 66 and similar regulations incorporate two basic strategies to reduce ambient oxidant levels, i.e., positive VOC reduction and solvent substitution based on photochemical reactivity. Positive reduction schemes such as incineration, absorption, and the use of low-solvent coatings are acknowledged means of reducing ambient oxidant levels; they should be retained in future VOC control programs. In contrast, the utility of solvent substitution strategies has been questioned as more information on photochemical reactivity has emerged.

EPA acknowledged the shortcomings of solvent substitution based on Rule 66 reactivity criteria in a 1976 policy statement (41 FR 5359). Findings were cited which indicated that VOC's eventually re-act in the atmosphere to form some oxidant. Concurrently, EPA initiated an investigation to consider implications of revising the solvent substitution aspects of Rule 66. Three separate forms were conducted with representatives of State and local air pollution control agencies, university professors, and industrial representatives with knowledge and expertise in the fields of atmospheric chemistry and industrial solvent applications. In addition, numerous discussions were held with acknowledged experts in the field. Topics of particular concern were:

- Whether Rule 66 substitution criteria could be revised with available reactivity data and yet be compatible with industrial processes and with product requirements.
- Whether some compounds are of sufficiently low reactivity that they are not oxidant precursors and can be exempted from control under State Implementation Plans.
- Whether the imposition of reactivity restrictions in addition to positive emission reductions will delay the development of implementation of promising technologies, particularly the use of water-borne and high-solids surface coatings.

Investigation showed that:

1. Solvent substitution based on Rule 66 has been directionally correct in the aggregate and probably effects some reductions. However, because of the relatively high reactivity of most of the substituted solvents, the reduction is small compared to that which can be accomplished with dichloroethylene, 1,1,1-trichloroethane, and trichloroethylene. Revisions of Rule 66 consistent with current knowledge of reactivity would eliminate the solvent substitution option for most sources in which substitution is employed. Many of the organic solvents which have been categorized as having low photochemical reactivity are, in fact, moderately or highly reactive; they yield significant oxidant when subjected to irradiation in smog chambers designed to simulate the urban atmosphere.

2. A few VOC yield only negligible oxide when irradiated in smog chambers under both urban and rural conditions. Experiments conducted to date indicate that only methanol and ethane, a group of halogenated paraffins, and three other classes of compounds—acetone, methyl ethyl ketone, perchloroethylene, and acetonitrile—can be so classified. These compounds react very slowly yielding little ozone during the first few days following their release to the atmosphere. Under these circumstances, none of the listed compounds contribute significant oxidant even during extended irradiation under multiday stagnation conditions.

3. Besides focusing on VOC of negligible reactivity, smog chamber studies show that a few additional VOC generate oxidant at a moderate low rate. Under favorable atmospheric conditions, these VOC releases may not form oxidant until they have been transported substantial distances and become greatly diluted. However, under conditions such as occur during summer in many areas of the middle and eastern United States, there is the potential for these organics to undergo appreciable conversion to oxidant. The more important VOC in this category are acetone, methyl ethyl ketone, perchloroethylene, methanol, isopropanol, and propane. All except the latter are industrial solvents. The latter, a gas under normal conditions, is associated principally with crude oil and liquefied petroleum gas operations.

4. The vast number of volatile organic compounds—particularly nonhalogenated VOC—yield appreciable ozone when irradiated in the presence of oxides of nitrogen. While their reactivity varies in their rates of ozone formation, all are significantly more reactive than VOC listed in Table 2. Quickly reactive VOC include almost all aliphatic and aromatic solvents, alcohols, ketones, glycols, and ethers.

5. Low photochemical reactivity is not synonymous with low biological activity. Some of the nonhalogenated, weaker reactive compounds have adverse effects on human health. Benzene, acetonitrile, carbon tetrachloride, chloroform, perchloroethylene, ethylene dichloride, ethylene chloride, methylene chloride, and chloroform have been implicated as being carcinogens, teratogens, or mutagens. In addition, benzaldehyde, which produces no appreciable ozone, nevertheless forms a strong eye irritant under irradiation. While their use might reduce ambient oxidant levels, it would be unwise to encourage their uncontrolled release. Additional attention should be given to these findings as well as to some oxidant formation.

Most of the related health information available at this time concerns acute toxicity. Threshold limit values (TLVs) have been developed for many of these organics. They are appropriate for the healthy, adult work force exposed eight hours a day, five days a week. Experts suggest that more stringent levels should be established for the general population. Hazards represented by chronic and subchronic exposure are much more difficult to quantify than acute toxicity. Additional health effects of the VOC's listed above are generally recognized although not completely quantified. Chlorinated solvents currently are under intensive study.

6. Some VOC are of such low photochemical reactivity that they persist in the atmosphere for several years, eventually migrating to the stratosphere where they are suspected of reacting and destroying the ozone layer.

The potential for severe damage to the stratospheric ozone is the principal absorber of ultraviolet (UV) light; the depletion could lead to an increase in UV penetration with a resultant worldwide increase in skin cancer. The only in-depth analysis of this potential problem has focused on the chlorofluoromethanes (CFM), Freon 11 and Freon 12, because of their known stability and widespread use in aerosol and propellant containers. A report of the National Academy of Sciences concerning environmental effects of CFM's concluded that:

- Selective regulation of CFM uses and releases is almost certain to be necessary at some time and to some extent of completeness.

In response to the report of the National Academy of Sciences and other studies, EPA on May 13, 1977 (42 FR 24542), proposed rules to prohibit nonessential use of fully halogenated chlorofluorocarbons as aerosol propellants. The restrictions were applied to all members of this class including Freon 115 since they are potential substitutes for Freon 11, Freon 12, Freon 114, and Freon 115 which are currently used as aerosol propellants.

Other stable halogenated solvents which are released in volumes comparable to the chlorofluorocarbons are suspected of depleting the earth's UV shield. Of major concern is the wide-
spread substitution of methyl chloroform (1,1,1 trichloroethane) for the photochemically reactive degreasing solvent trichloroethylene. Such substitution under Rule 66 generation regulations has already influenced industrial degreasing operations to the extent that methyl chloroform production has surpassed that of trichloroethylene in the United States. Any regulation in the area will have a marked effect on the production and atmospheric emissions of both solvents. Endorsing methyl chloroform substitution would increase emissions, particularly in industrial States that have not, heretofore, implemented Rule 66. On the other hand, disallowing methyl chloroform as a substitute or banning it altogether would significantly increase emissions of trichloroethylene even if degreasers were controlled to the limits of available technology. Presently, technology is only able to reduce emissions by approximately 50 percent. In metropolitan areas which have already implemented Rule 66, a return to trichloroethylene would have an adverse effect on ambient oxidant levels. In addition to being highly reactive, trichloroethylene has been implicated as a carcinogen.

Alternatives to the above-cited choices would be (1) development and application of highly efficient degreaser control systems and (2) replacement with an intermediate solvent which is neither reactive nor detrimental to the upper atmosphere. Major revisions would be needed to degreaser designs to improve vapor capture above the current best level. Anticipated design changes could add materially to degreaser costs. No alternative solvent is clearly acceptable from the standpoints of photochemical oxidant and stratospheric ozone depletion. Neither methylene chloride nor trichlorotrifluoroethane are reactive, but, like methyl chloroform, are suspected of causing damage to the stratospheric ozone layer. In addition, methylene chloride is a suspect mutagen. Perchloroethylene, the principal dry cleaning solvent, does not present a hazard to the stratosphere but has been implicated as being a carcinogen and also reacts slowly in the atmosphere to form oxidant.

7. Organic solvents of low or negligible photochemical reactivity have only limited use in many industries. Most are chlorinated organics that find principal applications as cleaners for metals and fabrics. A few nonhalogenated VOC such as acetone, methyl ethyl ketone, and isopropanol are of low reactivity but these can't possibly satisfy all the myriad needs of the paint, plastics, pharmaceutical, or many other industries. While users of reactive VOC usually can employ effective control equipment to recover or destroy VOC emissions, they seldom have the option of applying reactivity considerations in choosing solvents. Applying reactivity restrictions to the surface coating industry would be especially disadvantageous since it would greatly inhibit the development of low-solvent coatings; essentially all of the organic solvents used to constitute high-solids coatings and water-borne coatings are, in fact, highly reactive.

8. It is recognized that smog chamber studies conducted to date are incomplete because many organic compounds have not been examined and it has been impossible to duplicate all atmospheric situations. For example, there has been only limited examination of oxidant formation under relatively high ratios of VOC to NO (30:1 and greater), comparable to rural conditions. Any policy on photochemical reactivity necessarily has to be open to revision as new information is developed which may show specific organic compounds to be more or less photochemically reactive than indicated by current data.

Dated: June 29, 1977.

Edward F. Toerek, Acting Assistant Administrator for Air and Waste Management.

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DEPARTMENT OF LABOR

Office of the Secretary

COMPREHENSIVE MANPOWER PROGRAMS AND GRANTS TO AREAS OF HIGH UNEMPLOYMENT

Proposed Rulemaking
DEPARTMENT OF LABOR
Office of the Secretary
[29 CFR Parts 94, 95, 96, 98]

PROPOSED RULES

COMPREHENSIVE MANPOWER PROGRAMS AND GRANTS TO AREAS OF HIGH UNEMPLOYMENT

Proposed Rulemaking

AGENCY: Employment and Training Administration, Labor

ACTION: Proposed rules.

SUMMARY: This document proposes to amend the Comprehensive Employment and Training Act of 1973 (CETA) regulations. The changes are being proposed in order to reflect the experience gained during the first 3 years of implementation, clarify existing policies, and provide for new approaches to the grant process.

DATES: Comments are due by August 8, 1977.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Summary of Proposed Changes

A new paragraph (a) in §94.4, Definitions, would permit prime sponsors to utilize the higher of the poverty levels or 70 percent of the lower living standard income level in determining whether a person is economically disadvantaged, and to annualize the family income of the applicant.

A new grant procedure is being proposed which would substantially simplify the grant process, in reading all the changes in conjunction with unrevised portions of Parts 95, 96, and 98, whenever the terms “Comprehensive Manpower Plan” or “plan” appear in the unrevised portions, the terms “grant application” or “grant,” as appropriate, shall be substituted; except that in §§95.17(b)(7), 96.13, 96.24(e)(2), 98.6(f)(3), 98.6(b)(1), 98.6(c), 98.37(g), 98.30(a), 98.32(b) in the last line, and 98.32(b)(1), the term “Annual Plan” shall be substituted for the terms “plan” and “grant.”

Accordingly, 29 CFR Parts 94, 95, 96, and 98 are proposed to be amended as follows:

PART 94—GENERAL PROVISIONS FOR PROGRAMS UNDER THE COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

§94.4 Definitions.

(a) “Economically disadvantaged” shall mean a person who is a member of a family which:

(1) Receives cash welfare payments, or

(2) Has a total family income which, in relation to family size, does not exceed the poverty level determined in accordance with criteria established by OMB.

PART 95—PROGRAMS UNDER TITLE I OF THE COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

§95.3 Eligibility for funds.

(a) * * *

(4) (i) Any unit of general local government, or any combination of such units, without regard to population, which, in exceptional circumstances, is determined by the Secretary, after giving serious consideration to comments from the prime sponsor otherwise responsible for the area and the Governor, to serve a substantial portion (e.g., 75 percent) of
PROPOSED RULES

§ 95.13 Planning process; advisory councils.
(a) Planning process.
(b) Advisory councils.

§ 95.14 Content and description of grant application.
(a) General. This section describes the grant application which designated prime sponsors shall use to apply for funds under title I. The application shall consist of two documents, the Prime Sponsor Agreement (PXA) and the Annual Plan (AP). Detailed instructions for completing the application, which is described in summary form below, are contained in the Forms Preparation Handbook.
(b) Prime Sponsor Agreement. A designated prime sponsor applying for assistance for the first time shall submit to the RA a signed copy of the PxA. A designated prime sponsor which has already entered into a PSA in a previous year shall submit to the RA with its Annual Plan, a certification that the effective operation and coordination of the PxA remain the same or that it is revised as described in attachments to the certification. The initial submission and subsequent certification of the PxA which must be in the forms and publication procedures of § 95.15 (c), (d), and (e) of this part. The PxA shall consist of the Signatory Page, the Narrative Description of General Information, Assurances and Certifications, and, for consortiums, the approved consortium agreement.
(c) Narrative description of general information. The Narrative Description of General Information shall include a detailed statement on the following items:

(i) Program purpose.
(ii) Geographic description and economic conditions of area to be served. A brief description of the geographic area to be served and the economic conditions of the area.

(iii) Approach. (A) A description of the recruitment and selection methods to be used.

(iv) Delivery agents. (A) An explanation of the methods and criteria to be used in the selection of deliverers of service.

(v) A list of the manpower-related services and facilities which are available from Federal, State, and local agencies and an indication of which have been determined to have demonstrated effectiveness in providing manpower services.

(C) A description of priority given to area skill centers.

(D) A description of efforts to utilize apprenticeships and other on-the-job training opportunities available under Section 1767 of Title 38, United States Code.

(E) Prime sponsor planning. (A) A description of the role and procedures of the planning council.

(B) A description of the staff support of the council.

(C) A list of the sectors represented on the council.

(D) A description of the participation of community-based organizations and groups in the program plan.

(E) Management and administrative plan.—(A) Organizational structure. A description of the prime sponsor's organizational structure.

(B) Administrative controls. A description of the internal administrative controls including:

(1) Monitoring system;

(2) Evaluation system;
(1) Personnel or merit system (including the prime sponsor's plan for obtaining an acceptable personnel system as required in § 98.14(b));

(2) Accounting system;

(3) Fiscal and accountability tracking system(s);

(4) Allowance payments system. A description of the details of the allowance payments system, including waiver provisions.

(D) Grievance procedures. A description of the procedures for resolving any complaints of CETA participants, contractors, subgrantees and other parties prior to the Department's hearing process.

(E) Equal employment opportunity. A description of the mechanisms which will be used to assure nondiscrimination and equal employment opportunities.

(vi) Public service employment program. (A) A description of actions to insure compliance with personnel procedures and collective bargaining agreements for jobs, in other than the entry level.

(B) A description of the training for supervisory personnel.

(C) A description of efforts to remove artificial barriers.

(D) A description of the specific steps to be undertaken to provide consultation to special veterans, disabled veterans, those veterans who have received other than a dishonorable discharge within four years prior to application, and welfare recipients.

(E) A description of the emphasis which will be placed on the development of jobs for veterans which will utilize skills acquired through their military experience.

(v) Additional assurance for Title II programs:

(A) Hiring of residents of areas of substantial unemployment for all jobs created under Title II and providing services to benefit residents of such areas.

(B) Selection of other than necessary technical supervisory and administrative personnel from the unemployed and underemployed population.

(vi) Additional assurance for Title VI programs:

(A) Only persons residing in the area served by the eligible applicant under Title VI of the Act will be hired to fill jobs created under the Act and that the public services provided by such jobs shall, to the extent feasible, be designed to benefit the residents of such areas except that funds allocated under Title VI of the Act (section 603(a)(2)(B)), to an area eligible for assistance under Title II of the Act shall only be used to provide project and program opportunities to persons residing in those areas of substantial unemployment as defined in section 204(c). (Sec. 98a(a)(2)).

(B) To the extent possible, administrative staff shall be drawn from unemployed and underemployed persons. (Section 205(c)(2)).

(C) On a date set by the Secretary, an Annual Plan for Title I must be submitted by designated prime sponsors in order to obtain funds under Title I. The Annual Plan shall consist of the following:

(1) Application for Federal assistance. The Application for Federal Assistance shall identify the designated prime sponsor and the amount of funds requested and provide information concerning the area to be served and the number of people expected to benefit from the program. Statement 412 contained in FMC 74-7 shall be used.

(2) Annual narrative description of program. The Annual Narrative Description of Program shall contain a detailed statement of the following items:

(i) Objectives and needs for assistance. (A) A breakdown of the unemployed population in terms of age, race and sex; identification of the significant segments to be served; and justification where services to the significant segments results in a plan of service which varies by more than 15 percentage points from the demographic characteristics of the unemployed population.

(ii) Results and benefits expected. (A) A statement of the specific participant goals the prime sponsor intends to accomplish.

(iii) A statement of other goals.

(B) Approach.—(A) Program activities and services. (1) A description of the activities and services to be provided.

(2) A description of the participant flow and the relationship among the activities to be provided.

(3) A description of programs, if any, designed for persons of limited English-speaking ability.

(B) Delivery agents. (1) A list of deliverers, and the services to be provided by each.

(2) A description of the linkage established.

(3) An explanation for non-use or duplication of existing services and facilities including programs of demonstrated effectiveness listed in § 951.4(b) (iv) (B).

(C) Program planning summary (PPS) and budget information summary (BIS). (1) An explanation of how the PPS reflects the goals, objectives, and activity description provided above.

(2) An explanation of how costs were determined for the BIS.

(D) Property. A list of any items of capital equipment which individually cost more than $1,000 including quantity and prices.

(iv) Public service employment program. (A) For those Title II applicants whose geographic area differs from the Title I area described in the PPS, a description of the Title II area.

(B) Analysis of public service needs. A description of the unmet public service needs.

(C) Approach. A description by employing agency of the types of jobs to be funded including: (1) An explanation of how these jobs relate to the public service needs identified in paragraph (a) (2) (iv) (B) of this section.

(2) A description of determination of rates of compensation when they differ from what is normally paid by the employer.

(3) A description of the education, training, and supportive services to participants.

(4) A maintenance of effort verification.

(5) A description of plans to improve and expand employment and advancement opportunities of the target population.

(6) An explanation of how the public service employment program is integrated with other activities and services.

(7) A narrative explanation for basis of funding and job allocation to each local government and agency.

(3) Program planning summary. The Program Planning Summary requires a prime sponsor to provide a quantitative statement of planned enrollment levels, the participants to be served by each program activity (classroom training, on-the-job training, public service employment, work experience, and other activities) and planned outcomes for program participants. It shall also include an identification of significant segments of the population and the number of individuals in each to be served.

(4) Budget information summary. The Budget Information Summary shall include a quantitative statement of yearly planned expenditures by cost category (administration, allowances, wages, fringe benefits, training, and services), planned quarterly obligations, and planned quarterly expenditures by program activity.

(5) Public service employment occupational summary. The Public Service Employment Occupational Summary shall include a description of proposed public service job opportunities, allowances and wages, including a comparison of such wages for similar unsubsidized jobs in each employing agency. If, at the time of submission of the Annual Plan, final decisions have not yet been made on all jobs to be filled, the Occupational Summary need not be submitted with the Annual Plan. Instead, it shall be submitted to the RA as soon as all jobs are selected but not later than 90 days after the date the Annual Plan is executed.

§ 95.16 Submission of grant application.

(a) Except as indicated in paragraph (b) of this section, each designated prime sponsor shall submit both parts of its grant application to the RA on or before a date set by the Secretary. An Approval Request Letter shall accompany the submission.

(b) Newly designated prime sponsors shall submit the FSA no later than 30 days prior to the submission of the Annual Plan, on or before a date set by the Secretary. An Approval Request Letter shall accompany the submission. A signed
§ 95.18 Application approval.

(a) An application for a grant shall be approved if it meets the requirements of the Act, the regulations promulgated under the Act and other applicable law, and if the RA determines that the prime sponsor has demonstrated maximum efforts to meet the goals of the prior year's annual plan.

(d) In addition to notifying the designated prime sponsor as provided in paragraph (c)(1) of this section, if an Annual Plan is approved, the RA shall provide the prime sponsor with a letter indicating approval.

§ 95.21 Modifications.

(a) Modifications of the prime sponsor agreement. (1) The Signatory Page and the assurances and certifications shall only be modified at the initiation of the RA, after consultation with the prime sponsor, to insure compliance with the regulations.

(2) The narrative description of general information of the PSA. The Narrative Description shall be modified as follows:

(i) RA initiated modifications. RAs may require modification to insure compliance with the regulations, after consultation with the prime sponsor.

(ii) Prime sponsor initiated modifications. (A) When significant changes are planned in the systems and procedures, such as a change in the allowance payment system, prior regional office approval is necessary.

(B) The prime sponsor may make any changes other than those described in (a)(1), (a)(2) (A) and (a)(2) (B) of this section without prior regional office approval, but must notify the RA of these changes in writing before the end of the quarter in which the changes occur. Revised portions of the PSA need not be submitted with the notice.

(3) Format. Modifications pursuant to paragraphs (a)(1), (a)(2) (D), and (a)(2) (E) of this section shall consist of the following:

(i) Approval request letter.

(ii) Revised assurances and certifications or revised narrative description of general information, as appropriate.

(iii) A copy of the newspaper announcement required in paragraph (c) of this section.

(b) Modifications to the annual plan. (1) A modification to the Annual Plan requiring prior Regional Office approval is required under any of the following conditions:

(i) Change in duration of the annual plan;

(ii) Change in annual plan allotment; and

(iii) Substantial change in program design and/or program goals defined as follows:

(A) When the cumulative number of individuals to be served, planned enrollment levels for program activities, planned placement terminations, individuals to be served within significant segments, is to be increased or decreased by 15 percent or more.

(B) For grants of over $100,000 or less, when the cumulative transfer of funds among program activities or cost categories exceeds $50,000 or 15 percent of the total grant budget whichever is greater.

(C) For grants of over $100,000, when the cumulative transfer of funds among program activities or cost categories exceeds $50,000 or 15 percent of the total grant budget whichever is greater.

(2) Annual Plan modifications will not be initiated solely to adjust planned performance to meet actual performance.

(3) A-95 Clearance. (i) Modifications require clearance through the A-95 clearinghouses only under the following conditions:

(A) There is a cumulative increase or decrease in funds equal to or more than 15 percent of the Annual Plan allotment for the current program year and/or;

(B) The Annual Plan is extended for a period of more than 3 calendar months and/or;

(C) The RA directs that A-95 clearance is required for a particular modification.

(ii) (A) When A-95 clearance is required, the prime sponsor, whenever possible, shall provide notification to the appropriate A-95 State and area-wide clearinghouses of its intent to modify its annual plan 60 days prior to submission of the formal modification to the RA.

(iii) The notification of intent should consist of a revised PSA and a brief description of the anticipated modification. If within the 60 days following submission of such notification, the prime sponsor receives no notification from the A-95 clearinghouses that they wish to review the modification, the prime sponsor has fulfilled its obligation under A-95 and may submit its modification to the RA without submitting it to the A-95 clearinghouses as specified in paragraph (b)(3)(ii) (A) of this section.

(B) When a prime sponsor has not provided notification as specified in paragraph (b)(3)(ii) (A) of this section, or when it has provided this notification and the clearinghouses requested to review the completed modification, the prime sponsor shall in all cases submit a copy of its modification to the clearinghouses within 30 days prior to its submission to the RA.

(4) Where no comments have been received from A-95 clearinghouses, or where the clearinghouses have not requested to review the completed modification, the prime sponsor shall so indicate in the appropriate item on the revised Standard Form 424, noting clearinghouses which sent no response after receiving the modification and clearinghouses which did not request to review the completed modification after being notified of the prime sponsor's intent to modify.

(4) A prime sponsor may make any change, consistent with the regulations in this Part and Part 98, in its Program Planning Summary, Budget Information Summary, or narrative description which is not set out in paragraph (b)(1) of this section without prior approval, but must show any such change in the First Program Status and Financial Status Report, as appropriate, submitted to the Department after the change has been made. At the same time this report is submitted, an updated Program Planning Summary, Budget Information Summary, or Annual narrative description, as appropriate, shall also be submitted to the RA. Only those lines and columns or portions of the annual narrative affected by the modification need be submitted. Comments and publication requirements do not apply to changes described in this paragraph (4).

(5) Format. Modifications pursuant to paragraphs (b) (1) and (3) of this section shall consist of the following:

(i) Approval Request Letter;

(ii) Revised PSA (if A-95 clearance is required);

(iii) Revised Program Planning Summary and Budget Information Summary for current and future quarters only; except that a modification not involving a change in the annual plan allotment must be received in the regional office within 30 days of the beginning of the current quarter in order to include changes to the current quarter goals;

(iv) Narrative description of the changes made and certification that the review and comment procedures in paragraphs (b)(4) have been complied with.

(v) A copy of the newspaper announcement required in paragraph (b)(4).

(vi) Revised portions of the program narrative description, if appropriate.

(vii) Revised Program Status Summary, if appropriate.

(6) Incremental Funding. When the Annual Plan allotment is obligated by the RA in increments, each subsequent obligation by the RA requires a new notice.
PROPOSED RULES

§ 95.32 Eligibility for participation in a title I program.

(d) Citizenship shall not be used as a criterion to prevent persons from participating in a program. However, program participation shall be limited to nationals of the United States and aliens who have been accorded the privilege of residence in the United States as lawful permanent residents or are refugees.

§ 95.33 Types of manpower program activities available.

(d) * * *

§ 95.34 Training allowances.

(c) * * *

(2) No allowances shall be paid for participation in any course or program of study (e.g., a B.A. or B.S. degree program) which exceeds 104 weeks. While prime sponsors may pay for the costs of tuition, books, and related training expenses of courses or programs of study exceeding 104 weeks, at no time during participation in such a course shall allowances be paid. (sec. 111(a)).

§ 95.35 Allowances to employers.

(a) (2) Dependents allowances may be reduced pro rata only for absences without good cause. The methodology for making the reduction shall be described in the approved PSA.

(g) * * *

(1) Incentive allowances shall be reduced pro rata only for absences without good cause. The methodology for making the reduction shall be described in the approved PSA.

§ 95.36 Basic responsibilities of prime sponsors.

(a) Providing equitable service to the unemployed population and serving significant segments of the unemployed population in accordance with the requirements of § 95.28.

§ 95.37 OJT programs.

(a) * * *

§ 95.38 Assistance to employers.

(a) * * *

§ 95.39 Employment services.

(a) * * *

§ 95.40 Program evaluation.

(a) * * *

§ 95.41 Program change procedures.

(a) * * *

§ 95.42 Protection of confidentiality.

(a) * * *

§ 95.43 Time limitations.

(a) * * *

§ 95.44 Administration of the program.

(a) * * *
PROPOSED RULES

35323

(6) Incentive allowances shall not be waived.
  
§ 95.35 Wages.

(d) For hours spent in the production of goods or services, the rate of compensation to be paid to trainees by employers, public or private shall be specified in a written agreement entered into by the training or employing facility and the prime sponsor. Where hours spent in production of goods or services are in positions covered by collective bargaining agreements, wages paid to trainees by the employer shall not conflict with the terms of the collective bargaining agreement.

§ 95.38 Cooperative relationships between prime sponsor and other manpower agencies.

(a)(1) Each prime sponsor shall, to the extent feasible, establish cooperative relationships or linkages with other manpower and manpower-related agencies in the area within its jurisdiction, in particular, with agencies operating programs funded through the Department (Section 105(a) (3) (D)). Prime sponsors are encouraged to utilize the free direct placement services offered by State Manpower Services.

§ 95.52 Grant application.

(a)(1) The Governor shall comply with the preapplication and comment and publication requirements specified in 95.11 and § 95.15 (a), (b), (d), (e) and (f). In addition, the Governor shall provide 30 days prior to submission of the grant application for the purposes of commenting thereon:

(i) A summary of the grant application to each prime sponsor in the State to units of local government within the Balance-of-State with a population of at least 25,000; and

(ii) A summary of the grant application to appropriate Indian prime sponsors and to labor organizations representing employees engaged in similar work in the same areas as that for which participants served along with subsidized employment or training; and

(iii) A summary of any programs to be funded within a prime sponsor's area with State Manpower Services funds and State manpower services, to the prime sponsor in whose jurisdiction the programs are to be funded.

(b)(1) Approval Request Letter.

(2) Application for Federal Assistance. Standard Form 424 as prescribed by PSC 74-7 is being used for the application for the special grant.

(3) Special Grant Plan. This plan consists of:

(i) Special Grant-Program Planning Summary. The Special Grant-Program Planning Summary is a multiprogram form providing for statistical entries on numbers of participants served by vocational education projects and State manpower services.

(ii) Special Grant-Budget Information Summary. The Special Grant-Budget Information Summary is a multiprogram form providing for entries on funds planned to be obligated and expended in vocational education projects, State Manpower Services Council and State manpower services.

(iii) Special Grant Program Narrative. The narrative for the special grant will be composed of the three sections. The Program Narrative form contained in the Forms Preparation Handbook requires a detailed statement on the program including the following items:

A Vocational Education Services Program Narrative. (1) An explanation of the method used to allocate funds to prime sponsor areas and the rationale for the method used; (2) An explanation for any nonfinancial agreement which was not reached between a prime sponsor and the Vocational Education Board; (3) A summary of all agreements required in § 95.56 between individual prime sponsors and the State Vocational Education Board; (4) A copy of each such agreement. The summary should follow the procedures established for the development of individual program narratives supporting each nonfinancial agreement. If all of the nonfinancial agreements are not available when the application is submitted, the Governor shall describe the training and services which he expects to be supplied by the State Vocational Education Board to each prime sponsor.

A Nonfinancial agreements received after the grant is made will be forwarded to the RA; and

(5) An explanation of administrative costs which exceed 20 percent.

B State Manpower Services Council Program Narrative. (1) A listing of members of the Council, identifying the group each member represents; (2) Identification of the chairman.

(3) A statement of the procedures which will be followed in reviewing prime sponsor plans and plans of State agencies and making recommendations which will provide more effective overall coordination of manpower services in the State;

(4) A description of the system to be used in monitoring other prime sponsors and State manpower services;

(5) A description of the types of data, materials, and information which will be included in the annual report to the Governor;

(6) If the Governor plans to use part of the funds authorized for the Council under Section 103(d) of the Act (one percent of the allocation) for Section 106 (State services), the specific use of the funds shall also be described, including the amount of funds and objectives to be accomplished.

(7) A breakdown of staff and other council costs. This breakdown should include administration, wages, and fringe benefits.

C State Manpower Services Program Narrative. (1) Explanation of steps taken to assure coordination of State agencies with prime sponsors in implementing the program;

(2) Description of State plan for sharing of manpower resources and facilities for most efficient and economical operation;

(3) Coordination of programs financed under Wagner-Peyser Act to provide assistance to individuals in accordance with policies of this Act;

(4) An explanation of the arrangements made by the State to assist the Secretary in carrying out the Secretary's mandatory listing responsibilities under section 1202(a) of title 38 U.S. Code. Such arrangements shall be explained in the State Comprehensive Manpower Plan and shall relate only to Federal contractors and subcontractors and grantees, subgrantees, or contractors should not be interpreted to include the under-

(5) A description of any arrangements for planning areas (see Part V of Attachment A, OMB Circular A-95) to serve geographical regions within the State;

(6) A description of cooperation and coordination of the manpower and related services to be provided by the State in areas to be served by prime sponsors other than the State, including the exchange of information and coordination of manpower plans;

(7) A description of any of the activities allowable under Section 106(e) of the Act, that the State chooses to provide, detailing those activities to be undertaken and the costs and goals of such activities, including:

(i) A description of allowable services being delivered under the Act throughout the State, by State agencies responsible for employment, training, and related services (sec. 106(c) (1));

(ii) A description of special programs and services for rural areas outside major labor market areas; (sec. 106(c) (2));

(iii) A description of the extent to which information will be developed and published regarding economic, industrial, and labor market conditions;

(iv) A description of information and technical assistance to be provided to participants at the request of the Governor and State agencies;

(v) A description of any model training and employment programs.

§ 95.53 Application approval and disapproval.

(1) The Governor shall determine whether the application is approved.

(2) It meets the requirements of the Act, the regulations promulgated under the Act, other applicable law, and if the Governor determines that the Governor has demonstrated maximum efforts to meet the goals of the prior year's annual plan.

(c) If an application is approved, the RA shall provide the Governor with a letter indicating approval.
§ 95.54 Modifications.
(a) A modification to a Governor's Special Annual Plan is required under any of the following conditions:
(1) Change in duration of the Annual Plan;
(2) Change in the Annual Plan allotment;
(3) Substantial change in program design and/or program goals defined as follows:
   (i) When the cumulative number of individuals to be served or the planned placement terminations is to be increased or decreased by 15 percent or more;
   (ii) When the cumulative transfer of funds among program activities or cost categories exceeds $50,000 or 15 percent of the total grant budget whichever is greater;
   (iii) When the program design is altered significantly (see § 95.21 (b) (1) (III) (D)).
(4) Major grant modifications shall not be initiated solely to adjust planned performance to meet actual performance.
(b) A-95 Clearance. (1) Modifications require clearance through the A-95 clearinghouse only under the following conditions:
   (i) There is a cumulative increase or decrease in funds equal to or more than 15 percent of the Annual Plan allotment for the current program year and/or;
   (ii) The Annual Plan is extended for a period of more than 3 calendar months and/or;
   (iii) The RA directs that A-95 clearance is required for a particular modification.
(2) (1) When A-95 clearance is required, the Governor, whenever possible, shall provide notification to the appropriate State clearinghouse of its intent to modify its Annual Plan 60 days prior to submission of the formal modification to the RA. The notification of intent should consist of a revised Form SP 424 listing changes made and certification that the changes described in this paragraph (c).
   (d) Special Annual Plan modifications shall not be initiated solely to adjust planned performance to meet actual performance.
   (e) Format. Modifications pursuant to paragraphs (a) and (b) above shall consist of the following:
      (1) Approval Request Letter;
      (2) Revised Form SP 424 (If A-95 clearance is required);
      (3) Revised Special Grant Program Planning Summary and Budget Information Summary for current and future quarters only; except that a modification involving a change in the grant allotment must be received in the regional office within 30 days of the beginning of the current quarter in order to include changes to the current quarter goals.
   (4) Narrative description of the changes made and certification that the review and comment procedures of paragraph (f) have been conducted with.
   (5) A copy of the newspaper announcement required in paragraph (f) of this section.
   (6) Revised portions of the program narrative description, if appropriate.
   (f) Publication and Comment. (1) No later than the date of submission to the RA, the Governor shall provide a summary of any modification pursuant to paragraphs (a) and (b) of this section to each prime sponsor in the State and local offices of general local government within the Balance of State with a population of at least 25,000 to appropriate Indian sponsors, and to representatives of organizations that serve the residents of the area. A-95 clearance shall be transmitted to the RA upon receipt of these summaries. The Governor shall publish in a minimum of one issue of a newspaper or newspapers (including minority news paper(s), where feasible) of general circulation throughout the geographical area to be served a notice of the Governor's intent to modify, the purpose of the proposed modification, and the location and hours when the complete modification can be reviewed and the phone number where questions and comments may be directed.
   (2) Comments pursuant to paragraphs (b) (2) (ii) and (g) shall be transmitted to the RA with the modification within 30 days of publication. All substantive written comments and responses shall be transmitted to the RA with the modification. In no case shall the RA be required to receive comments more than 30 days after the modification's submission, in which case they shall be sent separately to the RA.
   (2) The Governor shall acknowledge any written comments made pursuant to this section, and shall inform any party submitting a substantive written comment of whether any plan revision will be made in response to the comment and the reasons for such determination.
   (g) Notification of Action. (1) The RA shall take final action on approval or disapproval of any proposed modification within 30 days of receipt. Within 7 days after taking action, the RA shall notify the Governor of the action.
   (2) A denial of a Governor's request for a modification shall be subject to the appeal procedures set out in Part 98.
   (3) The procedures in § 95.18 (c) (1) and (2) shall apply to modifications under paragraph (b) of this section.
   (4) The procedures for incremental funding are the same as those specified in § 95.21 of Subpart A.

PART 95—PROGRAMS UNDER TITLE II OF THE COMPREHENSIVE EMPLOYMENT AND TRAINING ACT
§ 96.14 Content and description of grant application.
(a) General. (1) This section describes the grant application for funds under Title II of the Act. Copies of all forms and instructions are contained in the Forms Preparation Handbook.
(b) An Annual Plan for Title II must be submitted by prime sponsors on a date set by the Secretary. The Annual Plan consists of the following:
   (1) Application for Federal Assistance. This form is described in § 96.14 (c) (1).
   (2) Annual Narrative Description of Program. The annual narrative description requirements for Title II are the same as those described in § 95.14 (c) (2) for Title I of the Act. The narrative description on each of these items must be provided as part of the Title II Annual Plan, except as provided below.
   (i) The information required under objectives and needs for assistance, as specified in § 95.14 (c) (2) (i) need not be repeated for Title II if the geographic area to be served by the Title II activity is identical to that described under the Title I Annual Plan.
   (ii) The information required under § 95.14 (c) (2) (iii) (A) program activities and grants, shall only be provided if the Title II applicant intends to conduct Title I activities with Title II funds.
   (iii) If the Title II applicant's geographical area differs from the Title I geographical area described in the Title I annual plan, the information required under geographical area to be served, as specified
§ 96.23 Acceptable public employment positions.

(1) .

(2) .

(3) To the extent consistent with the maintenance of effort requirements of § 96.24, the participant activity limitations of § 96.23 and the personnel procedures and collective bargaining agreements of the eligible applicant and the private nonprofit agencies, jobs may also be allocated to private nonprofit agencies, such as educational, social service, and health agencies, which provide public service, as defined in § 94.4, within an eligible applicant's jurisdiction. Jobs may be allocated to such agencies provided; they offer public services for the general public and not primarily or exclusively for the benefit of their membership or constituencies; and they are determined to be best serve the unemployed population based on the considerations stated in § 96.23(b)(4). Such jobs may include positions in Job Corps Centers other than those operated by private-for-profit organizations.

§ 96.27 Eligibility for participation in Title II program.

(b) A veteran who has served on active duty for a period of more than 180 days or who was discharged or released from active duty for a service-connected disability, shall be immediately eligible, upon discharge or release for participation in a program under Title II of the Act without regard to the 30-day unemployment requirement which would otherwise pertain (38 U.S.C. 2013), provided such veteran has not obtained permanent full-time unsubsidized employment between the time of discharge or release from active duty and the time of application for participation in Title II.

(c) Citizenship may not be used as a criterion to deny participation in a program under Title II. However, program participation shall be limited to nationals of the United States and aliens who have been accorded the privilege of residing in the United States as lawful permanent residents or are refugees.

§ 96.28 Equitable service to the unemployed population serving significant segments.

(a) The prime sponsor shall provide equitable service to the unemployed population in relationship to the population's demographics, race, and sex. A breakout of the unemployed population on the basis of these characteristics shall be included in the Annual Plan.

(b) The prime sponsor shall identify the significant segments, as defined in § 94.4, of its unemployed population to be targeted for service. These significant segments shall be described in the Annual Plan.

(c) Where service, to the identified significant segments results in a plan of service which varies by more than 15 percentage points from the aggregate breakdown identified in paragraph (a) of this section, adequate justification of the variance must be provided by the RA in its Annual Plan.

§ 96.29 Groups to be provided special consideration within the significant segment groups served.

Special consideration shall be given to:

(a) Veterans. (1) Special consideration shall be given to eligible disabled veterans, special veterans, and veterans who served in the Armed Forces and who received other than a dishonorable discharge within four years before the date of their application. In so doing, the eligible applicant shall take into consideration the extent that such veterans are available in the area in selecting participants within its significant segments and/or within veterans in its Annual Plan as significant segments. Specific effort should be made to develop appropriate full or part-time opportunities for such veterans. In order to insure special consideration for veterans, all public service employment vacancies under Title II, except those to which former employees are being recalled, and those into which CETA participants are being transferred, must be listed with the State employment service at least 48 hours (excluding Saturdays, Sundays, and holidays) before such vacancies are filled. During this period those veterans specified above who fall within the significant segments to be served will be referred by SESAs and other referral sources. The veterans of CETA participants are not available, the employment service, upon request, may also refer other members of the significant segments to the prime sponsor. The eligible applicant should utilize the assistance of State and local veterans employment representatives in formulating its program objectives.

(2) Each eligible applicant shall, on a continuing and timely basis, provide information on job vacancies and training opportunities funded under Title II of the Act to State and local veterans employment representatives and to other veterans organizations for the purpose of disseminating information to the veterans (sec. 184(b) of Emergency Jobs and Unemployment Assistance Act of 1974).

(b) Welfare recipients. Eligible applicants shall give special consideration to welfare recipients by taking them into account when selecting participants within significant segments and/or by identifying them as a significant segment in the Annual Plan.

(c) Former manpower trainees. Due consideration shall be given, in developing an eligible applicant's plan and enrolling individuals in the manpower programs funded under Title II of the Act, to persons, falling within the significant segments to be served, who have participated in manpower training programs and for whom工作岗位是not otherwise immediately available (sec. 205(c) (9)).

§ 96.30 Serving the most severely disadvantaged persons.

In meeting the requirements of §§ 96.28 and 96.29 above, the eligible applicant shall give priority to unemployed persons who are the most severely disadvantaged in terms of the length of time they have been unemployed and their prospects for finding employment without assistance under Title II (secs. 205(c) (7) and (210)).

§ 96.33 Placement goals.

(1) (i) To carry out the intent of paragraph (b), each eligible applicant, program agent and subgrantee, to the extent consistent with law and applicable collective bargaining agreements, shall have the goal of accomplishing on an annual basis at least one of the following:

(A) Placing half of the cumulative number of participants terminated in unsubsidized private or public sector employment.

(B) Placing participants in half the open positions occurring in suitable occupations in an eligible applicant, program agent, or subgrantee's manpower program, which are not filled by promotion from within the agency.

(ii) When a suitable job offer or offer of referral to a suitable job is made to and rejected by a participant, this can be construed as being an acceptable grounds for termination of the participant by the prime sponsor regardless of how long the individual has been in the program. Suitable job shall mean a job which is:

(i) Comparable to the participant's CETA job in terms of working conditions and benefits; the same or equivalent to (in terms of the three-digit DOT code) the participant's CETA job or otherwise commensurate with his/her skill level; located within a commuting distance of
PROPOSED RULES

§ 96.37 Use of Title II funds for programs under Titles I and III-A.

Funds available to an eligible applicant may, at its option, be utilized for residents of the areas of substantial unemployment designated under this Part for programs authorized under Title I or Part A of Title III of the Act. Where Title II funds are used for activities other than those authorized under other Titles of the Act, all provisions under this Part, except § 96.21 (b), (c), (e), (g), and (h), § 96.27(e), § 96.31, § 96.33, § 96.34, and § 96.36, shall apply in addition to those provisions applicable for programs under Title I or Part A of Title III of the Act; however, when Title II funds are used to fund public service employment, all of the provisions of this Part 98 shall apply.

§ 96.43 Funding of eligible applicants.

(a) In order to be funded, a potentially eligible applicant must request to operate a program under Title II by complying with the provisions of § 95.11 of the regulations for Indian Employment and Training Programs funded under Section 302 of the Act.

(b) Each potentially eligible applicant will receive a tentative allocation against which it will prepare and submit its grant application.

(c) General. The grant application will consist of two documents, the Prime Sponsor Agreement (PSA) and the Annual Plan (AP). Detailed instructions for completing the application are contained in the Forms Preparation Handbook.

(1) Prime sponsor agreement. An applicant applying for the first time shall not later than 30 days prior to submission of the Annual Plan submit to the Director, Department of Indian Affairs and Native American Programs (DINAP), a signed copy of the PSA. A recipient who has already executed a PSA shall submit with the Annual Plan to the Director, DINAP, a certification that the PSA remains the same or is revised in certain respects which are attached to the certification. The initial submission and subsequent certifications are subject to the comment and publication procedures of § 96.45. The PSA consists of:

(a) A signatory page (see § 95.14(b)(1));

(b) A narrative description of general information; and

(iii) Assurances and certifications.

(2) Annual plan. On the date set by the Director, DINAP, an Annual Plan must be submitted to the Director, DINAP. The submission of the AP is subject to the comment and publication procedures of § 96.45. The Annual Plan consists of:

(a) An Application for Federal Assistance. (See § 96.14(c)(1));

(ii) An Annual Narrative Description of Program;

(iii) A Program Planning Summary (See $ 96.14(c)(3));

(iv) A Budget Information Summary (See § 96.14(c)(4));

(v) A Public Service Employment Occupations Summary (See § 96.14(c)(5));

(vi) A Monthly Schedule (see § 96.14(b)(6)); and

(vii) A Program Summary (see § 96.14(b)(7)).

PART 98—ADMINISTRATIVE PROVISIONS FOR PROGRAMS UNDER THE COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

§ 98.6 Audit.

(a) Each grantee shall establish and maintain an audit program for its contractors and subgrantees to the extent necessary for financial management and conformance with Federal requirements. The Governor shall also establish and maintain such an audit program for vocational education services and activities funded pursuant to § 95.24(c)(4).

(b) Each grantee shall conduct at least once every two years an independent audit of each contractor or subgrantee providing activities and services amounting to a cost of $100,000 or more during one grant year. Audits of those subgrantees or contractors providing activities and services under $100,000 may be conducted on a sample basis as coordinated with and approved by the Regional Administrator for Audit. Of the awards of less than $100,000, the sample selected shall include at least 25% of the total number of awards or 25 percent of the total dollars awarded, during a two-year period. The auditing of contractors and subgrantees on a large scale is in no way lessens the prime sponsor's responsibility to insure that program activities and related costs incurred by contractors and subgrantees in compliance with Federal requirements as stated in paragraph 95.14(c). Fixed price contracts for non-program, administrative type procurements such as materials used in construction, and only when such construction would not normally be performed by an outside contractor, are used for administration, training, support services to public service employment participants, for the acquisition of, rental, or leasing of necessary supplies, equipment, and materials, except as limited by paragraph (c) of this section; and for the rental or leasing of real property. An eligible applicant which is not itself a subgrantor or subgrantee shall be entitled to retain the entire 18 percent for its own use, unless it has agreed to do so under the terms of the written agreement.

(2) No funds granted under the Act may be used, directly or indirectly, as a contribution from the grantee in order to receive such funds, except if authorized under that law. However, the use of funds granted under the Act as a matching contribution in order to obtain additional funds under the Act is prohibited.

(3) Unless otherwise provided in parts 94–97, funds provided under one grant may not be used to support costs of another grant under the Act.

(c) Expenditures for repairs, maintenance, and capital improvements and for construction; home repair; weatherization.

(1) Funds for construction, as defined in § 94.8, and for repairs, maintenance and capital improvements to existing facilities are allowable only under the following conditions:

(i) To pay wages and fringe benefits for public service employment participants;

(ii) To purchase equipment, materials, and supplies for use by public service employment participants and for use in the training of public service employment participants, except for materials used in construction;

(iii) To cover costs of a training program in a construction occupation, including costs such as instructors' salaries, training tools, training equipment, participant salaries and wages; but not including materials used in construction, and only when such construction would not normally be performed by an outside contractor.

(2) Consistent with maintenance of effort requirements of this subtitle, the cost of participant salaries and fringe benefits shall be allowable costs when such participants are used in home repair and weatherization/energy activities where work performed will not inure primarily to the benefit of a profit-making organization. Home repair and weatherization/energy activities shall be limited to dwellings of individuals who are at or below 125 percent of the poverty level (as defined in § 94.1), which are privately owned and owner-occupied, privately owned by a nonprofit organization, units of public housing, or privately owned rental housing projects funded and approved by the Federal Energy Administration for the Community Services Administration. (704(f)).

(3) Costs associated with building repairs, maintenance, and capital improvements of existing facilities used esti-
(f) Fringe Benefits. Allowable fringe benefit costs for participants include, but are not limited to the following: annual, sick, court and military leave pursuant to an established leave system; employer's contribution for social security, employees' life and health insurance plans, unemployment insurance, workers' compensation insurance; retirement benefits in accordance with section 98.25 of this part; and, under public service employment programs, training materials, work tools, uniforms, or other equipment ordinarily provided by the employer to its regular employees, provided these are for benefit and ownership of the participants.

(5) Services. Services include, but are not limited to services to applicants, supportive and manpower services, as set forth in §95.33(d) (5).

(i) Services to applicants include outreach and intake.

(ii) Supportive services include child care, health care, medical and dental services, residential support, assistance in securing bonding, transportation, family planning and legal services.

(iii) Manpower services include orientation, counseling, job development, job placement, and employability assessment.

(g) Travel costs to enable participants to obtain employment or to participate in programs under the Act are allowable as supportive services. Such travel shall be restricted to the grantee's jurisdiction or within daily commuting distance, except:

(I) As provided under §98.28(a)(f);

(ii) To pay for transportation costs at the beginning and end of a training course which is more than daily commuting distance but within the State in which the prime sponsor is located;

(iii) As permitted for good cause by the RA, on a case by case basis, within the United States.

§98.14 Basic Personnel Standards for Grantees.

(a) Each prime sponsor and eligible applicant shall establish and maintain a merit based system of personnel policies and practices for employees including participants, engaged in the administration of the Act. Such system shall be in accord with State and local laws and regulations, but shall at all times reflect the merit principles declared in the Intergovernmental Personnel Act (IPA) of 1970 (Pub. L. 91-648). Prime sponsors whose personnel systems have been accepted by the U.S. Civil Service Commission as being in conformity with the Uniform Standards for a Merit System of Personnel Administration (45 CFR Part 70), including any amendments thereto, shall be deemed to be in compliance with this section (Sec. 703.14).

(b) Except as provided in paragraph (c) of this section, any prime sponsor or eligible applicant whose personnel system has not been accepted as meeting the requirements of this section shall provide to the RA for approval a plan and steps to be taken for obtaining an acceptable system and a reasonable date for completing the plan; and also shall provide a list of those steps it has already taken to provide for merit based personnel system coverage. This plan and description of steps taken shall be submitted to the RA as part of the grant application.

(c) (1) The following are not subject to the requirements of paragraphs (a) and (b) of this section:

(i) Any non-governmental prime sponsor;

(ii) A consortium administrative unit which is not a unit of government;

(iii) Staff of contractors, subgrantes, title II program agents and employing agencies and titles I, II, and VI program participants;

(iv) Employees of the prime sponsor's jurisdiction not engaged in the administration of CETA.

(2) A consortium administered by one of the member governments or a unit thereof or a unit of government not a member shall be subject to paragraphs (a) and (b) of this section.

(d) Units whose staff are exempt under paragraph (c) of this section shall insure equal employment opportunity based on objective standards of recruitment, selection, promotion, classification, compensation, performance evaluation, and employee management relations reflective of the principles contained in IPA.

(e) Prime sponsors and eligible applicants should include individuals on their CETA administrative staffs which at all levels are reflective of the composition of the population to be served by the program within its jurisdiction.

§98.17 Annual Plan settlement procedures.

(a) The settlement of an Annual Plan is the process by which the Department of Labor determines that all applicable administrative actions and all required work of the Annual Plan have been completed by the grantees and the grantor. The following procedures will be completed with during the process of determination:

(b) By a date specified by the RA, each grantee shall submit a TWX containing the following information on each expiring Annual Plan:

(i) Total fund availability;

(ii) Estimated accrued expenditures;

(iii) Estimated carryout.

(c) The RA shall issue a notice of fund availability to the grantee no later than 120 days prior to the end of the grantee's fiscal year. The notice shall be issued by the RA to transfer the carryout from the previous Annual Plan to the new Annual Plan.

(d) In the following months (generally not to exceed six months), the grantee shall take steps as set forth in the Forms Preparation Handbook, or other appropriate issuance, to settle each expiring Annual Plan.

(e) Final settlement of expired Annual Plans shall not be complete until a final audit has been performed, audit findings have been resolved and final reports have been submitted.

(1) End of Prime Sponsor Agreement. The Prime Sponsor Agreement will end with the last day of the prime sponsor planning council, as well as any responsibility for the obtaining of and/or approval of any grant funded under the Act, such as members of the prime sponsor planning council, as well as other officials who have an influence or control over the administration of the program, such as the project director, deputy director and unit chiefs; and

§98.22 Nepotism.

(a) Restriction. No grantees, subgrantees, contractors, or employing agency may hire a person in an administrative capacity, staff position or public service employment position funded under the Act if a member of his or her immediate family is engaged in an administrative capacity for the same grantee or its subgrantees, contractors, or employing agencies. Where a State, or local statute regarding nepotism exists which is more restrictive than this policy, the eligible applicant should follow the State or local statute in lieu of this policy.

(b) * * *

(2) The term "person in an administrative capacity" includes those persons who have overall administrative responsibility for a program, including all elected and appointed officials who have any responsibility for the obtaining of and/or approval of any grant funded under the Act, such as members of the prime sponsor planning council, as well as other officials who have an influence or control over the administration of the program, such as the project director, deputy director and unit chiefs; and

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
persons who have selection, hiring, placement or supervisory responsibilities for public service employment participants.

§ 98.24 General benefits and working conditions.

(a) (1) Each participant in an on-the-job training, work experience or public service employment program under the Act shall be assured of workers' compensation at the same level and to the same extent as other employees of the employer who are covered by a State or industry workers' compensation statute. Whether provided through the State's compensation agency or a private insurance carrier, this coverage includes medical and accident insurance as well as income maintenance insurance.

(2) Where a participant is employed or engaged in any CETA program activity, i.e., work experience, public service employment, on-the-job training, classroom training, services to participants and other activities where others similarly employed or engaged are not covered by an applicable workers' compensation statute, the participant shall be provided with medical and accident insurance coverage. Whether provided through the State's workers' compensation agency or a private insurance carrier, the prime sponsor shall provide such participants with medical and accident insurance coverage equivalent to the medical and accident insurance provided under the applicable State workers' compensation statute. However, prime sponsors shall not be required to provide these participants with the income maintenance insurance coverage in the statute.

§ 98.41 Review of plans and applications, violations.

(a) The Secretary shall not finally disapprove any Comprehensive Manpower Plan or Application for financial assistance submitted under any title of the Act (except where other procedures are set forth e.g., Sec. 97.222), or any modifications, or amendments thereof, without first affording the grantee submitting the plan or application reasonable notice and opportunity for a hearing as provided in section 98.47 et seq.

Signed in Washington, D.C., this 30th day of June 1977.

ERNST G. GREEN,
Assistant Secretary for Employment and Training Administration.

(FR Doc. 77-10558 Filed 7-7-77; 8:45 am)
FRIDAY, JULY 8, 1977
PART V

DEPARTMENT OF LABOR
Employment and Training Administration

MIGRANT AND SEASONAL FARMWORKER PROGRAMS

Fiscal Year 1978 State Planning Estimates, Programs and Areas To Be Renewed Without Competition, and Areas Open for Competition
DEPARTMENT OF LABOR
Employment and Training Administration

MIGRANT AND SEASONAL FARMWORKER PROGRAMS

Fiscal Year 1978 State Planning Estimates, Programs and Areas To Be Renewed Without Competition, and Areas Open for Competition

AGENCY: Employment and Training Administration.

ACTION: Notice.

SUMMARY: Pursuant to 29 CFR 97.211, the Employment and Training Administration is required to announce State planning estimates of resources available to implement programs funded under title III, section 305 of the Comprehensive Employment and Training Act (CETA) of 1973, as amended. This notice also announces the States and/or areas open for competition as provided in 29 CFR 97.219.

FOR FURTHER INFORMATION CONTACT:
Paul A. Maynard, Chief, Division of Farmworker Programs, DOL/ETA, 601 D Street NW., Washington, D.C. 20213, Phone: (202) 774-7283.

SUPPLEMENTARY INFORMATION:

1. Fiscal Year 1978 State Planning Allocations. Planning estimates are announced for planning purposes only and are subject to congressional action on the Fiscal Year 1978 appropriation for the Department of Labor, Employment and Training Administration, CETA. The total amount of planning estimates listed below, $63,080,000, is 85 percent of the total amount planned for all sections 303 purposes in Fiscal Year 1978.

The apportionment of the planning estimate amounts for 49 States and Puerto Rico is based on each State's percentage of the nation's farmworkers and on each State's hold-harmless level of 90 percent of the Fiscal Year 1977 allocation. These estimates are based upon the same data source utilized for the Fiscal Year 1977 estimates. (A description of this data source and the rationale for using it are set forth in the Federal Register, Volume No. 144, page 31293, July 25, 1976.)

Eligible applicants should use the following State planning estimates in developing Fiscal Year 1978 funding requests:

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<td>828,400</td>
<td>103,600</td>
<td>77,500</td>
<td>423,000</td>
<td>532,200</td>
<td>75,700</td>
<td>800,500</td>
<td>1,328,200</td>
<td>3,880,700</td>
<td>294,900</td>
<td>1,289,200</td>
<td>736,800</td>
<td>1,096,900</td>
<td>239,300</td>
<td>650,200</td>
<td>810,900</td>
<td>4,652,900</td>
<td>239,300</td>
<td>555,100</td>
<td>810,900</td>
<td>1,597,200</td>
<td>1,800,900</td>
<td>496,500</td>
<td>2,166,200</td>
<td>354,800</td>
</tr>
</tbody>
</table>

Total 63,080,000

2. Programs and areas to be renewed without recompetition. The Secretary of Labor will exercise the option contained in 29 CFR 97.219(a), to negotiate Fiscal Year 1978 grants without recompetition for existing sponsors whose Fiscal Year 1977 performance was determined to be satisfactory as recorded in the quarterly Program Status Summary (PSS) reports which are used to assess the grantees' performance in carrying out the objectives of the Act, and whose performance continues during the grant negotiation period to be at an acceptable level. (If prior to award of grant, a sponsor's performance is determined not to be acceptable, the Secretary may invite proposals for that area from other organizations and, with or without a panel review, negotiate a grant with one or more proposers pursuant to 29 CFR 92.217.) Satisfactory performance was determined after a review of "actual performance versus planned performance" on 11 factors:

1. Number of participants enrolled.
2. Number placed in jobs.
3. Number of direct job placements.
4. Number of indirect job placements.
5. Number of other positive terminations.
6. Number enrolled in classroom training.
7. Number enrolled in on-the-job training.
8. Number enrolled in work experience.
9. Number enrolled in other activities.
10. Accrued expenditures.
11. Level of nonpositive terminations.

Satisfactory performance for each factor was considered as obtaining at least 85 percent of the planned goal. (For factor 11—level of nonpositive terminations—the grantee had to be at or under the number of planned nonpositive terminations.) For each factor, each grantee was given a positive mark when a factor was acceptable, and a zero mark when a factor was nonacceptable. The number of factors with eight or more positive marks were determined to be satisfactorily performing and were selected as grantees to be renewed without competition.

Grantees experiencing serious audit questioned costs or management difficulties were excluded from the noncompetitive list. Also, the new sponsors (selected in 1977) automatically compete since they did not have a full year's experience to rate their actual versus planned performance. Section 97.210 requires that no grant shall be operated in any State or area for a period of more than 2 years without recompetition. Consequently, all States or areas that did not recompete last year were also excluded from the noncompetitive list.

The following are the organizations which demonstrated satisfactory performance and will not compete for Fiscal Year 1978 sponsors:

<table>
<thead>
<tr>
<th>State</th>
<th>Sponsors</th>
<th>Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>Alabama Migrant and Seasonal Farmworker Statewide Council</td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>County of Los Angeles</td>
<td>Los Angeles Statewide.</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Farmworkers Corp. of New Jersey</td>
<td>New Jersey Statewide.</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Minnesota Migrant Council</td>
<td>Minnesota Statewide.</td>
</tr>
<tr>
<td>Nevada</td>
<td>State of Nevada</td>
<td>Nevada Statewide.</td>
</tr>
<tr>
<td>New York</td>
<td>Farmworkers Corp. of New Jersey</td>
<td>New York Statewide.</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Home Educational Livelihood Program</td>
<td>New Mexico Statewide.</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Tennessee Opportunity Programs</td>
<td>Tennessee Statewide.</td>
</tr>
<tr>
<td>Texas</td>
<td>Community Action Council of South Texas</td>
<td>Texas Statewide.</td>
</tr>
<tr>
<td>Utah</td>
<td>Community Opportunities Development Corporation of San Antonio</td>
<td>Texas Statewide.</td>
</tr>
<tr>
<td>Virginia</td>
<td>Virginia Farmworker Education and Training</td>
<td>Virginia Statewide.</td>
</tr>
<tr>
<td>West Virginia</td>
<td>West Virginia Farmworker Education and Training</td>
<td>West Virginia Statewide.</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Wisconsin Farmworker Education and Training</td>
<td>Wisconsin Statewide.</td>
</tr>
<tr>
<td>Wyoming</td>
<td>Wyoming Farmworker Education and Training</td>
<td>Wyoming Statewide.</td>
</tr>
</tbody>
</table>

Intra-State planning estimates for Texas and California will be published to enable applicants for funding in areas not closed to competition to prepare funding requests. All programs to be renewed without competition are required to submit an updated comprehensive plan for Fiscal Year 1978 and, in addition, are subject to the requirements set forth in 29 CFR 97.217 covering negotiation of final grant which includes procedures in case of the failure of negotiations to result in an acceptable, negotiated grant.
3. Areas Open for Competition. (a) All areas, except those listed in Paragraph No. 2, above, are open for competition. Organizations interested in applying for these funds should consult the January 7, 1977, Federal Register for the procedures to be used. A notice of intent to apply, the Preapplication for Federal Assistance form, Part I (OMB No. 29-R0218), must be submitted by eligible organizations to the Department of Labor, Employment and Training Administration, Patrick Henry Building, Room 7122, 601 D Street, NW., Washington, D.C. 20213, by August 1, 1977. The Preapplication must be registered or certified by the Postal Service on or before August 1, 1977, or actually received in Room 7122 before 4 p.m. EDT, on August 2, 1977. In accordance with 29 CFR 97.212(b), no preapplication received after this time shall be considered for funding.

(b) In a State or area where no organization except the current 303 sponsor submits a Preapplication for a Fiscal Year 1978 grant, the Secretary may elect to negotiate a Fiscal Year 1978 grant without submitting the funding request for panel review.

All programs to be renewed are required to submit an updated comprehensive plan for Fiscal Year 1978 and, in addition, are subject to the requirements set forth in 29 CFR 97.217 covering negotiation of final grant which includes procedures in case of the failure of negotiations to result in an acceptable negotiated grant.

Signed at Washington, D.C. this 5th day of July, 1977.

ERNST G. GREEN, Assistant Secretary for Employment and Training.
FRIDAY, JULY 8, 1977
PART VI

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

RANGE MANAGEMENT AND TECHNICAL SERVICES

Grazing Administration and Trespass
DEPARTMENT OF THE INTERIOR
Bureau of Land Management
[43 CFR Parts 4100, 4700, 9230]
RANGE MANAGEMENT AND TECHNICAL SERVICES
Grazing Administration and Trespass
AGENCY: Bureau of Land Management, Interior.
ACTION: Proposed rulemaking.
SUMMARY: Rulemaking is proposed to update livestock grazing regulations for public lands and to add provisions required by the Federal Land Policy and Management Act of 1976. Changing and increasing land use demands and passage of the new Act necessitate new rulemaking. This proposal changes the grazing regulations to allow for management flexibility to achieve multiple use and environmental objectives.

DATE: Comment by September 6, 1977.

ADDRESS: Send comments to Director (210), Bureau of Land Management, 1800 C Street, NW., Washington, D.C. 20240. Comments will be available for public review in Room 5558 at the above address from 7:45 a.m.-4:15 p.m. on regular working days.

FOR FURTHER INFORMATION CONTACT:
Billy R. Templeton, 202-343-8735.


Proposed rulemaking was published on pages 31504 through 31515 of the Federal Register of July 28, 1976, under authority of the Taylor Grazing Act of 1934 and other Acts. Comments were invited through January 31, 1977. The purpose of that proposed rulemaking was to modernize the rules for grazing on public lands and to conform with changing land use demands and the resulting need for management flexibility to achieve multiple use and environmental objectives.

The proposed rulemaking of July 28, 1976 was the first major proposed revision of the grazing regulations in decades. Following passage of the Taylor Grazing Act in 1934, regulations were adopted to control use of public rangelands and to adjudicate livestock use allowances to qualified ranch operations. The existing regulations have several deficiencies. First, they are divided into two repetitive sections, one covering grazing administration inside grazing districts and the other covering grazing administration outside grazing districts, making the regulations unnecessarily long and unclear. Second, nearly all of the administrative procedures, including those pertaining to base property and commensurability requirements and transfers of grazing preferences, are contained within one section. Third, the existing regulations fail to recognize the multiple use values of the land and the need for management flexibility to achieve multiple use and environmental objectives. In addition, the primary objective of the existing regulations, allocating grazing preferences among ranch operations, was essentially accomplished by the mid-1960's. The rules proposed last July responded to these deficiencies largely by simplifying the rules, and requiring grazing management to be consistent with land use plans. The key substantive change responded to the increasing and changing demand for public land use. Since the total public land area remains constant, demand can only be accommodated through land use planning for multiple use to minimize adverse impact on the land and its resources. Therefore, the proposed regulations base grazing allocation and management on land use plans incorporating environmental and other resource values. In addition, varying degrees of livestock grazing management intensity were recognized based on the resource evaluations made in land use plans.

Approximately 1,000 comments were received on the proposed rulemaking during the comment period the Federal Land Policy and Management Act of 1976 was signed into law. The rulemaking process was delayed to determine the effect of the Act on the grazing rules. The Act amended the Taylor Grazing Act and provided for the following: Including a redistribution of grazing fee revenue, new provisions on permit and lease terms, and a new requirement for cancellation notice and compensation for range improvements. Most importantly, though, the Federal Land Policy and Management Act requires that livestock grazing management be carried out in accordance with multiple use land use plans. This statutory provision thus affirms prior decisions by the mid-1960's.

New provisions were added to the proposed rules in order to implement the new Act.

Many individuals and groups analyzed the initial proposal and submitted good thoughtful comments and suggestions. Since substantive changes were made in the proposed rulemaking because of the new Act, the initial proposal is no longer appropriate. The proposed rulemaking was amended and clarifying language added in several places as a result of the comments received. Interested persons and organizations should critically examine this current proposed rulemaking and comment again.

PROPOSED RULES

DISCUSSION OF COMMENTS RECEIVED ON THE PROPOSED RULEMAKING OF JULY 25, 1976

SHOULD ALLOCATION OF GRASSING USE BE BASED ON HISTORICAL USE OF PUBLIC LANDS BY DEPENDENT PRIVATE PROPERTY OWNERS IN ORDER TO MAINTAIN THE STABILITY OF THE LIVESTOCK INDUSTRY?

Many comments were received from ranchers, state and local governments and extension agents suggesting that maintaining the stability of the livestock industry be included as an objective of the regulations, as stated in the Taylor Grazing Act. This provision has been included in the new proposed rules. These commentators also feared that elimination of the commensurability requirement and much of the adjudication language in the old regulations indicated that grazing would no longer be allocated on the basis of historic use by dependent private property owners. The concept of commensurability and equality of grazing preferences on public lands on the productive capacity of private lands, has been included in the new proposed rules in modified form. Base property must be capable of producing crops or forage that can be used to support livestock, but the new rules do not require that crops or forage be actually produced. Land base property must be owned or controlled and must be used in a livestock operation. Provision is also made for future adjudication, if necessary, in the sections on grazing preference and conflicting applications.

HOW MUCH CONTROL SHOULD THE BUREAU HAVE OVER PRIVATE LIVESTOCK OPERATIONS?

Many ranchers and their representatives criticized provisions in the proposed regulations which they believed interfered unjustifiably with the rancher's judgment on how to run livestock. They especially feared unilateral imposition of allotment management plans by the Bureau. The new proposed regulations require that allotment management plans be developed in consultation with the permittee or lessee. Only if agreement cannot be reached will the Bureau institute a grazing management plan by taking control of the common use grazing.
HOW MUCH PUBLIC PARTICIPATION SHOULD OCCUR BEFORE CLOSING PUBLIC LANDS TO GRAZING?

Some comments criticized the provision allowing public lands to be closed to livestock by notifying livestock operators and the public. Greater opportunity for public comment was suggested. This provision was clarified to emphasize that it will only be used in exceptional circumstances to protect the soil, vegetative or other public land resources usually in cases such as droughts. These circumstances require quick action inconsistent with time-consuming public participation.

HOW MUCH NOTICE IS NECESSARY BEFORE GRANTING A LIVESTOCK OPERATOR A CHANGE OF USE?

The proposed rules required livestock operators to apply for a change in grazing use 30 days before the grazing season or year begins. Permittees or lessees must file their basic grazing schedules with the Bureau and they are billed for scheduled use unless a change in use is allowed in advance. Many comments suggested that these changes be allowed up to the first day of the season or year. The suggestion was not adopted because 30 days is needed to evaluate impact of proposed change with existing operations and management objectives for the allotment and to complete necessary administrative requirements.

SHOULD WILLFUL AND NONWILLFUL TRESPASS BE DISTINGUISHED?

Many comments criticized the proposal to treat willful and non-willful trespass differently. Ranchers believed the penalties were too severe in cases of non-willful trespass. Environmental groups and others believed they were too lenient in cases of willful trespass. The existing rules allow collection of twice the value of the forage consumed in cases of willful trespass, while the proposed rules did not. The new proposed rules distinguish between willful and non-willful trespass and rein脚 the double damage provision in cases of willful trespass in order to provide a real disincentive to trespassers.

COORDINATING GRAZING USE WITH STATES AND PRIVATE LANDOWNERS WHERE THEIR LANDS ARE INTERMINGLED WITH PUBLIC LAND

Many States and ranchers owning land intermingled with public land commented on the inclusion of those lands in allotment management plans and the application of prescribed systems of livestock grazing on these lands. The new proposed rules explain that private and State land shall be considered if those lands are unfenced and intermingled with public lands in the allotment or with consent or request of the rancher. The exchange-of-use permit provision was not changed because in such cases the private owner voluntarily applies for the permit and subjects his private land to Bureau control in exchange for free use of the intermingled public land.

WHO IS THE AUTHORIZED OFFICER?

The existing grazing regulations refer to the State Director of the Bureau and the District Manager. Many comments criticized the shift to the term "authorized officer" in the proposed rules contending that no one knows who this person is. While we agree that the term causes some confusion, it would be even more confusing to have a term which has each particular authority since delegations of authority change frequently. The authorized officer is not a new concept or person. The term refers to any official of the Bureau of Land Management who has been delegated the authority, through specific Secretarial or Bureau delegations, to carry out the management responsibilities of the Secretary of Interior on a particular management area of the public land. The authorized officer may be an Area Manager, District Manager, State Director, or the Director of the Bureau of Land Management depending upon the location and the resource program involved. The authorized officer will most often be an Area Manager or a District Manager under these rules.

SHOULD CONSULTATION WITH ADVISORY BOARDS BE REQUIRED?

Several comments from both ranchers and environmental groups suggested that consultation with advisory boards should be mandatory in certain instances. Ranchers also sought reestablishment of grazing district advisory boards. This was done in a limited way by the Federal Land Policy and Management Act. Regulations governing these boards appear in 43 CFR Subpart 1784.

SHOULD VIOLATION OF STATE AND FEDERAL CONSERVATION LAWS BE GROUNDS FOR CANCELLING OR REDUCING A RANCHER'S GRAZING PREFERENCE?

The proposed rules made violation of a Federal or State law or regulation containing the protection of natural cultural resources or the environment a prohibited act punishable by cancellation or reduction of the violator's grazing preference. This provision was widely criticized. Ranchers contend that the provision is unfair because it punishes them twice, once under the conservation law or regulation violated and once under this provision. Conservation organizations contend that there should be no requirement for criminal conviction, rather that the Bureau should administratively determine whether such laws and regulations have been thoroughly reviewed. The rule proposed in July has not been changed. First, it should be noted that these are the Endangered Species Act and the Endangered Species Protection Act both authorize reduction or cancellation of grazing permits or leases only following criminal conviction. This standard was adopted in the proposed rules to provide due process and because the Bureau cannot legally determine whether these other laws and regulations have been violated. This provision is necessary though because in some instances violation of these laws and regulations indicates that a permittee or lessee has insufficient regard for the public lands and their resources to warrant continuation of his preference.

SHOULD VEGETATIVE RESOURCES BE ALLOCATED TO WILDLIFE AND WILD HORSES AND BURROS BEFORE ALLOCATING FORAGE TO PRIVATE LIVESTOCK?

Several conservation organizations, State governments and university professors commented on the needs of wildlife. The existing regulations explicitly recognize the need to set aside forage for wildlife while the rules proposed last July implied that this would be done through land use planning. The new proposed rules require in § 1102.2-2(a) that grazing preference be allocated to qualified applicants only following the allocation through land use planning of the forage between livestock grazing, wild horses and burros, and wildlife and other forage needs. Similarly the use change use over another since this would not conform with multiple use land use planning objectives. It is also important to note that these regulations only cover domestic livestock grazing. Other regulations now being prepared by the Department will cover land use planning, the process in which vegetative resources are allocated between livestock, wildlife and wild and free-roaming horses and burros.

LIVESTOCK GRAZING CAPACITY

The regulations proposed in July used the term "livestock grazing capacity" without defining it. This omission and failure to explicitly condition grazing permits and leases on available forage were severely criticized. A definition is included in the new proposed rules. In addition, a general condition was added stating that authorized livestock grazing use shall not exceed the livestock grazing capacity. One comment suggested that grazing capacity should be reviewed annually to assure that use matches available forage. This procedure would be costly, cumbersome, and is unnecessary since a number of provisions allow for reductions in grazing if necessary for resource protection.

Accordingly, in line with the above discussion, the proposed rulemaking has been changed as appropriate in accordance with comments received on the July 28, 1976 publication and the applicable provisions of the Federal Land Policy and Management Act. The amended rulemaking is published as a proposed rulemaking and public comments and suggestions are invited.

MAJOR FEATURES

These regulations apply to livestock grazing on all lands administered by the Bureau of Land Management outside of Alaska. Regulations for the public lands within and outside grazing districts are consolidated and the issuance of grazing permits and leases will be treated in nearly identical fashion.
The allocation of grazing preference and the authorization of grazing use on the public lands through the issuance of grazing permits and leases are pending disposal or will be completed in accordance with land use plans which provide for multiple use management and protection of the environment and other resource values.

The regulations provide for issuing grazing permits and leases for a term of 10 years; however, if the public lands involved are pending disposal or will be devoted to nonuse, the Department of the Interior will include livestock grazing prior to the end of 10 years, the grazing permits or leases will be issued for a term coinciding with the anticipated date of disposal or anticipated date for devoting the lands to another public purpose. Grazing permits or leases will also be issued for less than 10 years in the interest of sound land management if necessary to achieve the objectives in the land use plans or if the land use plans have not been completed.

The proposed regulations provide for the application of the appropriate intensity of livestock grazing management, along with associated range improvement, needed to achieve the management objectives for specific areas of public land consistent with land use plans. Allotment management plans will be developed and implemented in consultation with the grazing permittees or lessees. Only if an agreement cannot be reached will the Bureau institute a grazing management plan by decision.

While the commensurability and base property requirements are retained, they have been streamlined to reduce administrative requirements and to provide more livestock operator flexibility. Transfer procedures have been simplified.

No change is proposed in the grazing fee formula. This issue will be dealt with separately after the study required by the Federal Land Policy and Management Act is submitted to Congress. Until then the fee will remain the same. Grazing fees must be paid prior to using the public land for grazing unless a management permit has been issued providing for billing and payment after use. If such a permit or lease has been issued, a fee notice based upon actual use will be written up with the issuance of the grazing season. A $25 service charge will be made for each transfer of grazing preference and for each supplemental or revised billing made on the motion of the permittee or lessee. Unless provided otherwise in an allotment management plan, a request to change the grazing use authorized by a grazing permit or lease must be made in writing and approved by the authorized officer before the change is made.

The means of coping with livestock grazing trespass have been strengthened. Instead of referring nonwillful and $4 willful trespass, fee, settlement for unauthorized grazing use will include a charge for the cash rental value of the forage consumed plus costs arising from damage to the public land and property.

The proposed rulemaking provides for impounding and sale of trespass livestock. The expenses incurred in gathering, impounding, caring for, and disposing of livestock may also be included in the settlement. Additionally, the authorized officer may suspend a grazing permit or lease in whole or in part or may cancel a grazing permit or grazing lease, and grazing preference in whole or in part for nonwillful trespass. The authorized officer is required, under these rules, to suspend a grazing permit or lease in whole or in part or cancel a grazing permit or grazing lease and grazing preference in whole or in part for trespass determined to be clearly willful or repeated.

The Department of the Interior has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Analysis under Executive Order 11821 and OMB Circular A-107.

An environmental impact statement (EIS) for livestock grazing management on national resource lands, released on January 22, 1975, was prepared in accordance with section 102(2) (C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4321(2)(C)). The revised regulations will facilitate implementation of the proposed grazing program described in this statement. Implementation of the proposed action will be completed through the preparation of EIS's which discuss livestock grazing activities on localized areas of public lands.


1. Part 4100 is revised to read as follows:

PART 4100--GRAZING ADMINISTRATION—EXCLUSIVE OF ALASKA

Subpart 4100—Grazing Administration—Exclusive of Alaska; General

Sec.
4100.0-1 Purpose.
4100.0-2 Objectives.
4100.0-4 Authority.
4100.0-5 Definitions.
4100.0-7 Cross-references.

Subpart 4110—Allocation of Grazing Use

4110.1 Mandatory qualifications.
4110.2 Grazing preference.
4110.2-1 Base property.
4110.2-2 Grazing preference allocation.
4110.2-3 Transfer of grazing preference.
4110.2-4 Reimbursability of grazing preference.
4110.3 Changes in available forage.
4110.3-1 Additional forage.
4110.3-2 Decrease in forage.
4110.4 Changes in public land acreage.
4110.4-1 Additional land acreage.
4110.4-2 Loss of land acreage.
4110.5 Conflicting applications.
4110.6 Interest of Member of Congress.

Subpart 4120—Grazing Management

4120.1 Allotments.
4120.2-1 Allotment terms and conditions.
4120.2-2 Allotment management plans.
4120.3 Closure to livestock.

Sec.
4120.4 Ownership and identification of livestock.
4120.5 State livestock requirements.
4120.6 Range improvements.
4120.6-1 Cooperative agreements.
4120.6-2 Range improvement permits.
4120.6-3 Standards and design.
4120.6-4 Assignment of range improve-
4120.6-5 Removal and compensation for loss of range improvements.
4120.6-6 Contributions.
4120.7 Special rules.

Subpart 4130—Authorizing Grazing Use

Sec.
4130.1 Applications.
4130.2 Grazing permits or leases.
4130.2-1 Regular permits or leases.
4130.2-2 Management permits or leases.
4130.2-3 Custodial permits or leases.
4130.2-4 Free-use grazing permits.
4130.2-5 Other permits.
4130.2-6 Exchange-of-use grazing permits.
4130.2-7 Nonrenewable grazing permits.
4130.4-1 Crossing permits.
4130.4-2 Refunds.
4130.4-3 Service charges.
4130.6 Changes in grazing use.
4130.7 Fadge of permit or lease as security for loan.

Subpart 4140—Prohibited Acts

4140.1 Acts prohibited on public lands.

Subpart 4150—Unauthorized Grazing Use

4150.1 Unauthorized grazing.
4150.2 Notice and order to remove.
4150.3 Settlement.
4150.4 Demand for payment.
4150.5 Imposition and disposal.
4150.6-1 Notice of intent to impose.
4150.6-2 Notice of public sale.
4150.6-3 Redemption.
4150.6-4 Sale.

Subpart 4160—Administrative Remedies

4160.1 Proposed decisions.
4160.1-1 Proposed decisions on permits or leases.
4160.1-2 Proposed decisions on alleged violations.
4160.2 Protests.
4160.3 Final decisions.
4160.4-1 Appeals.

Subpart 4170—Penalties

4170.1 Penalty for violations.
4170.1-1 Failure to use.
4170.1-2 Federal and State law or regulation.
4170.2 Penal provisions.

Authority: 43 U.S.C. 315, 315a–315r, 1701 et seq., 1181d.

Subpart 4190—Grazing Administration—Exclusive of Alaska; General

§4190.0-1 Purpose.

The purpose of these regulations is to provide for the uniform administration and management of livestock grazing on the public lands, exclusive of Alaska.

§4190.0-2 Objectives.

The objectives of these regulations are to manage livestock grazing on public lands, to preserve the land and its resources from destruction or unnecessary injury, to stabilize the livestock industry dependent on the public lands, and to provide for the orderly use, improvement, and development of the public lands for livestock grazing consistent with multi-
PROPOSED RULES

§ 4100.0-3 Authority.

(a) The Taylor Grazing Act of June 28, 1934, as amended (43 U.S.C. 315, 315a-315r), authorizes the Secretary of the Interior to establish grazing districts and to make provisions for the protection, administration, regulation, and improvement of the public lands. It also authorizes the Secretary to lease lands outside of such districts for grazing purposes upon such terms and conditions as he may prescribe.

(b) The Federal Land Policy and Management Act of 1976, Pub. L. 94-579, 90 Stat. 2745 (43 U.S.C. 1701 et seq.), provides for the management, protection, development, and enhancement of the public lands and directs the Secretary to manage these lands under principles of multiple use sustained yield in accordance with land use plans.

(c) Executive orders transferring land acquired under the Bankhead-Jones Farm Tenant Act of July 22, 1937, as amended (7 U.S.C. 1701 et seq.), to the Secretary for administration under the Taylor Grazing Act.

(d) Section 4 of the O&C Act of August 28, 1937 (43 U.S.C. 1131d), which authorizes the Secretary, at his discretion, to lease for grazing purposes any reserved Oregon and California Railroad or Reconveyed Coos Bay Wagon Road grant lands in the State of Oregon which may be so used without interfering with the production of timber or other purposes specified in the O&C Act.

(e) Public land orders, Executive orders, or agreements which authorize the Secretary to administer livestock grazing on specified lands in accordance with the Taylor Grazing Act or other authority as specified.

§ 4100.0-5 Definitions.

Whenever used in this part, unless the context otherwise requires, the following definitions apply:


(b) "Allotment" means an area of land designated and maintained on the public lands to meet the livestock grazing and other objectives of land management; and (c) contains such other provisions relating to livestock grazing and other objectives as may be prescribed by the authorized officer consistent with applicable law.

(d) "Animal unit month (AUM)" means the amount of forage necessary for the sustenance of one cow or its equivalent for a period of 1 month. One cow, one horse, one burro, five sheep, or five goats shall be considered equivalent to one cow.

(e) "Authorized officer" means any person authorized by the Secretary to administer regulations in this part.

(f) "Base property" means (1) farm or ranch property (land and improvements) that serves as a base for a livestock operation and has the capability to produce crops or forage that can be used to support authorized livestock for a specified period of the year, or (2) water that is suitable for consumption by livestock and is available, accessible, and adequate for the authorized livestock when the public lands are used for livestock grazing.

(g) "Cancellation" means a permanent termination of a grazing permit or lease and grazing preference in whole or in part.

(h) "Class of livestock" means any group of livestock.

(i) "Contiguous land" means land that borders upon or corners upon public land.

(j) "District" means the specific area of public lands administered by a District Manager.

(k) "Grazing district" means the specific area within which the public lands are administered under section 3 of the Act. Public lands outside grazing district boundaries are administered under Section 15 of the Act.

(l) "Grazing fee year" means the year March 1 to the last day of February which is used for billing purposes.

(m) "Grazing lease" means a document authorizing use of public lands outside grazing districts under section 15 of the Act for the purpose of grazing livestock.

(n) "Grazing permit" means a document authorizing use of the public lands within grazing districts under section 3 of the Act for the purpose of grazing livestock.

(o) "Grazing preference" means the total number of animal unit months of livestock grazing on public lands apportioned and attached to base property owned or controlled by a permittee or lessee.

(p) "Livestock" or "kind of livestock" means species of domestic livestock—cattle, sheep, horses, burros, and goats.

(q) "Livestock grazing capacity" means the number of animal unit months of forage available for livestock grazing on a sustained yield basis on the public lands as determined through land use planning.

(r) "Modification" means a change or revision of the terms and conditions of an unexpired grazing permit or lease including changes in kind or class and number of livestock, season(s) of use, and area(s) of use.

(s) "Other lands under Bureau of Land Management control" means those of private lands controlled by the Bureau of Land Management through lease, agreement, or otherwise.

(t) "Public lands" means any land and interest in land outside of Alaska owned by the United States and administered by the Secretary of the Interior through the Bureau of Land Management, except lands located on the Outer Continental Shelf and lands held for the benefit of Indians.

(u) "Range betterment fund" means the separate account in the Treasury established by Section 401(b) (1) of the Federal Land Policy and Management Act of 1976 consisting of 50 per cent of all moneys received by the United States as fees for grazing livestock on public lands.

(v) "Range improvement" means a structure, development, or treatment used to rehabilitate, protect, or improve the public lands to advance range betterment.

(w) "Secretary" means the Secretary of the Interior or his authorized officer.

(x) "Suspension" means temporarily withholding a grazing permit or lease in whole or in part.

§ 4100.0-7 Cross-references.

The regulations in Subpart 1784 of this chapter govern advisory boards and the regulations in Part 4 of this title govern appeals and hearings.

Subpart 4110—Allocation of Grazing Use

§ 4110.1 Mandatory qualifications.

Except as provided under §§ 4130.3 and 4130.4, the qualifications for grazing use of the public lands an applicant must engage in the livestock business, must own or control land or water base property, and must be:

(a) A citizen of the United States or have properly filed a valid declaration of intention to become a citizen or a valid petition for naturalization; or

(b) A group or association authorized to conduct business in the State in which the grazing use is sought, all members of which are qualified under paragraph (a) of this section; or

(c) A corporation authorized to conduct business in the State in which the grazing use is sought, and in which the controlling interest is vested in persons qualified under paragraph (a) of this section.

§ 4110.2 Grazing preference.

§ 4110.2-1 Base property.

(a) The authorized officer shall find land or water owned or controlled by an applicant to be base property (see § 4100.0-4(f) if...
PROPOSED RULES

§ 4110.2-2 Grazing preference allocation.

(a) Grazing preference shall be allocated to qualified applicants in accordance with the allocation of the forage resources between livestock grazing, wild-free-roaming horses and burros, wildlife, and other forage uses in the land use plans.

(b) Applicants who own or control base property contiguous to public land outside of a grazing district where such public land consists of an isolated or disconnected tract embracing 760 acres or less shall have a preference right for 90 days after the tract has been offered for lease to lease the whole tract.

(c) The annual unit months of grazing preference is attached to the acres of base property on a pro rata basis.

§ 4110.2-3 Transfer of grazing preference.

(a) Transfers of grazing preference in whole or in part are subject to the following requirements:

(1) The transferee shall qualify for a grazing preference under the regulations of this part.

(2) The transfer shall not disrupt the stability of the livestock industry in the area involved and each public land involved is located.

(3) The transfer document, under paragraph (b) of this section or the transfer application, under paragraph (c) of this section, shall evidence the consent of the owner of the base property and the amount of grazing preference being transferred, in animal unit months, within 60 days of the date of sale or lease. If the transfer document has been timely filed and the requirements under paragraph (a) of this section have been met, the authorized officer shall approve the transfer of the grazing preference attached to the affected base property, shall approve the assignment of interest and obligation in range improvements on the public lands, and shall issue a grazing permit or lease.

(b) If a grazing preference is being transferred from one base property to another base property, the transferee shall file with the authorized officer a properly completed transfer application in advance for approval. The transfer application shall (1) state the amount of grazing preference being transferred, in animal unit months, (2) include a description of the new base property, (3) contain the concurrence of any lien holder, and (4) contain the consent of the owner(s) of the base property from which the transfer is to be made, unless the transferee is a lessee of the base property without whose livestock operation a grazing preference would not have been established. In which case the consent of the owner of the base property is not required. If the transfer application has been properly filed and the requirements under paragraph (a) of this section have been met, the authorized officer may approve the transfer of grazing preference between the base properties, may approve the assignment of interest and obligation in range improvements on the public lands, and may issue a grazing permit or lease.

(d) As the date of approval of a transfer, the existing grazing permit or lease shall terminate automatically and without notice to the extent of the transfer.

(e) If an unqualified transferee acquires rights in base property through an order of eminent domain, such transfer shall not affect the grazing preference or any outstanding grazing permit or lease, or preclude the issuance or renewal of a grazing permit or lease based on such preference for a period of 2 years after the transfer. However, such a transfer shall qualify under paragraph (a) of this section when the transfer document, under paragraph (c) of this section or the transfer application, under paragraph (d) of this section, shall evidence the consent of the owner of the base property and the amount of grazing preference being transferred, in animal unit months, within 60 days of the date of sale or lease. The authorized officer may grant extensions of the 2-year period where there are delays solely attributable to probate procedures and the authorized officer may grant extensions of the 2-year period where there are delays solely attributable to probate procedures.

(f) Failure of the transferee to comply with the regulations of this section shall result in the cancellation of the grazing preference.

§ 4110.2-4 Relinquishment of grazing preference.

Upon written request, the authorized officer shall accept the relinquishment of a grazing preference in whole or in part.
Otherwise, grazing use will be allocated under § 4110.5.  
§ 4110.4—Decrease in land acreage.  
(a) Where there is a decrease in public land acreage available for livestock grazing use within a allotment, grazing permits of the lessees and grazing preferences shall be cancelled in whole or in part. The cancellations will be equitably apportioned by the authorized officer or as agreed to among authorized users and the authorized officer.  
(b) When public lands are disposed of or devoted to a public purpose which precludes livestock grazing, the permittees and lessees shall be given two years prior notification except in cases of emergency, before their grazing permit or grazing lease and grazing preference may be cancelled whole. A permittee or lessee may unconditionally waive the two year prior notification. Such a waiver shall not prejudice the permittee's or lessee's right to reasonable compensation for the fair market value of his interest in authorized permanent range improvements located on these public lands (see § 4120.6-5).  
§ 4110.5—Conflicting applications.  
When more than one qualified applicant applies for livestock grazing use of the same public land and/or where additional forage or additional land acreage becomes available, the authorized officer may allocate grazing use of such land or forage consistent with the land use plans on the basis of any or all of the following factors:  
(a) Historical use of the public land;  
(b) Proper range management and use of water for livestock;  
(c) General seeds of the applicants' livestock operations;  
(d) Public ingress and egress across privately owned or controlled land to public lands;  
(e) Topography;  
(f) Other land use requirements unique to the situation.  
§ 4110.6—Interest of Member of Congress.  
Title 18 U.S.C. 431-433 (1970) generally prohibits a Member of or Delegate to Congress from entering into any contract or agreement with the United States. Title 41 U.S.C. 22 (1970) generally provides that in every contract or agreement to be made or entered into, or accepted by or on behalf of the United States, there shall be inserted an express condition that no Member of or Delegate to Congress shall be admitted to any share or part of such contract or agreement, or to any benefit to arise therefrom. The provisions of these laws are incorporated herein by reference and apply to all permits, leases, and agreements issued under these regulations.  
Subpart 4120—Grazing Management  
§ 4120.1—Allotments.  
As land use plans are prepared, the authorized officer shall designate allotments where the public lands and other lands under Bureau of Land Management control are suitable and available for livestock grazing.  
§ 4120.2—Terms and conditions.  
LIVESTOCK grazing permits and leases shall contain terms and conditions necessary to achieve the management objectives for the public lands and other lands under Bureau of Land Management control identified in land use plans.  
§ 4120.3—Land management plan.  
(a) The authorized officer shall specify the kind or class and number of livestock, the season(s) of use, the allotments to be used, and the amounts of use, in animal unit months, that can be made. The authorized livestock grazing use shall not exceed the livestock grazing capacity and shall be limited or excluded to the extent necessary to achieve the objectives established for the allotment.  
(b) The authorized officer may:  
(1) Specify breed of livestock in allotments within which 2 or more permittees or lessees are authorized to graze.  
(2) Authorize and direct the placement of feed and mineral supplements for livestock on the public lands.  
(3) Authorize grazing use by kinds of indigenous animals under specific terms and conditions of the notice.  
(c) If allotment management plans have not been prepared or if it has been determined that allotment management plans are not necessary, the authorized officer shall incorporate terms and conditions under this section in grazing permits or leases. The authorized officer shall modify these terms and conditions if the condition of the range requires modification of grazing use and may cancel grazing permits or grazing leases and grazing preferences as conditions warrant under §§ 4110.3-2 and 4110.4-2. These modifications and cancellations may be made at any time and shall be put into full force and effect on the date specified by the authorized officer.  
§ 4120.2-2—Allotment management plans.  
Grazing management may be applied on allotments through the preparation and implementation of allotment management plans.  
(a) An allotment management plan shall be prepared in consultation with the affected permittees or lessees, approved by the authorized officer and implemented (see § 4100.5-6). The allotment management plan shall include appropriate terms and conditions under § 4120.1 and shall prescribe a system of grazing designated to meet specific management objectives. The plan shall include the limits of flexibility within which the permittees or lessees may adjust his operation without prior approval of the authorized officer. The plan shall provide for the collection of studies data that shall be used to evaluate the effectiveness of the system of grazing in achieving the specific objectives.  
(b) Private and State lands shall be considered in the allotment management plan if these lands are unfenced and are intermingled with the public lands in the allotment or with the consent or at the request of the permittee or lessee.  
(c) Allotment management plans may be revised in consultation with the affected permittees or lessees.  
(d) While allotment management plans have been prepared, the authorized officer shall incorporate these plans in grazing permits or leases when they are issued. If grazing permits or leases have been issued prior to the preparation of allotment management plans, the authorized officer shall incorporate the allotment management plans in the grazing permits or leases when these plans are complete.  
(e) Decisions which specify that allotment management plans are incorporated as terms and conditions of grazing permits or leases may be protested and appealed under Subpart 4160.  
§ 4120.3—Closure to livestock.  
Where required for the protection of the soil, vegetative, or other resources on the public lands, the authorized officer may close allotments to grazing by any kind of livestock and for any period of time. The action authorized officer shall be specified in a notice of closure. The notice shall be published in a local newspaper and shall be posted at the county courthouse and at a post office near the public land area involved. Written notification shall be delivered personally or by certified mail to those who are authorized to graze livestock on the allotments affected. The notice of closure shall be issued as a final decision in full force and effect under § 4100.3(c) and shall require all owners of livestock affected thereby to remove such livestock in accordance with provisions of the notice. The authorized officer may proceed to impound, remove, and dispose of any livestock found in violation of the closing notice after the closure date specified in the notice in accordance with § 4150.5.  
§ 4120.4—Ownership and identification of livestock.  
(a) The permittee or lessee shall own or control and be responsible for the management of the livestock which graze the public lands under a grazing permit or lease. If the permittee or lessee does not own the livestock, he shall furnish the authorized officer a document specifying the kind and number of livestock, the brand or other marking the livestock are carrying, and the arrangements which in fact give him control of the livestock. This document shall be approved by the authorized officer prior to placing the livestock on the public lands.  
(b) All cattle, horses, and burros over 6 months of age shall carry an ear tag which has been filed with the authorized officer. All sheep and goats over 6 months of age shall be branded with an earmark, paint brand, or other marking that has been filed with the authorized officer.  
(c) The authorized officer may exempt certain livestock from the mini-
§ 4120.6 Range improvements.

(a) When appropriated, one-half of the range betterment funds (see § 4130.5-1(d)) shall be available for use in the District from which the grazing fees were collected for the purpose of on-the-ground range rehabilitation, protection, and improvement of public lands after consultation with user representatives. The other one-half of the range betterment funds shall be used for on-the-ground range rehabilitation, protection, and improvement of public lands at the discretion of the authorized officer after consultation with user representatives. See § 4100.5-3 (u) and (w).

(b) Range improvements shall be installed, used, maintained, and/or modified on the public lands in a manner consistent with the land use plans.

(c) Prior to conflicts, installation, use, maintaining and/or modifying range improvements on the public lands permittees or lessees shall have entered into a cooperative agreement with the Bureau of Land Management or must have a range improvement permit.

§ 4120.6-1 Cooperative agreements.

Any permittee or lessee may enter into a cooperative agreement with the Bureau of Land Management for the installation, use, maintenance, and/or modification of range improvements necessary to achieve management objectives within his designated allotment. Cost and/or labor shall be placed between United States and permittees or lessees. The United States shall have title to range improvements authorized under cooperative agreements.

§ 4120.6-2 Range improvement permits.

Any permittee or lessee may apply for a range improvement permit to install, use, maintain and/or modify range improvements that are needed to achieve management objectives within his designated allotment. The permittee or lessee shall agree to provide total funding. The range improvement permits are issued at the discretion of the authorized officer. The permittee or lessee shall have title to range improvements authorized under range improvement permits.

§ 4120.6-3 Standards and design.

Range improvement cooperative agreements and permits shall specify the standards and design for the range improvements and shall contain conditions and construction criteria deemed necessary by the authorized officer to facilitate achieving the objectives in the land use plans. Where an existing range improvement is significantly inconsistent with these objectives, the authorization shall be revoked or modified by the authorized officer to reflect needed changes. Upon failure of the permittee or lessee to comply with the standards and design specified by the authorized officer, the authorized officer may modify the authorized officer's order to modify an existing range improvement, authorization for the improvement may be cancelled.

§ 4120.6-4 Assignment of range improvements.

The authorized officer shall not approve the transfer of a grazing permit under § 4110.2-3 nor approve use by the transferor of an existing range improvements, unless the transferee has agreed to compensate the transferor for the transferor's interest in the authorized, improvements within the allotment at the date of transfer. If the parties are unable to agree as to the amount or manner of reasonable compensation, the matter shall be resolved by the authorized officer.

§ 4120.6-5 Removal and compensation for loss of range improvements.

(a) The authorized officer may require permittees or lessees to remove range improvements which they own on the public lands if these improvements are no longer needed or for which they were installed or if they fail to meet the standards and design criteria under § 4120.6-3 or 4120.6-10.

(b) If grazing permits or grazing leases and grazing preferences are cancelled in whole or in part because the public lands are being disposed of or devoted to a public purpose which precludes livestock grazing, the permittee or lessee shall receive fair market value from the United States for their interest in the authorized permanent range improvements located on the public lands (less salvage value which will not longer be available for livestock grazing).

(c) Permittees or lessees may be allowed a period of 180 days from the date of cancellation of a range improvement permit to salvage materials owned by them and to perform such rehabilitation measures as are deemed necessary by the authorized officer.

§ 4120.6-6 Contributions.

(a) The authorized officer may accept contributions of labor, material, equipment, or money for administration, protection, and improvement of the public lands necessary to achieve the objectives of this part.

(b) The authorized officer may require the permittee or lessee to finance individually or share proportionately with other permittees or lessees, the cost of installation and/or maintenance of range improvements if the permittee or lessee will benefit in substantial measure or should reasonably be responsible for such costs.

§ 4120.7 Special rules.

Whenever it appears to a State Director that local conditions within his administrative jurisdiction require a special rule to achieve improved administration consistent with the objectives of this part, he may recommend such a rule for approval by the Director. These recommendations shall be subject to public review and comment, as appropriate, and upon approval shall become effective when published in the Federal Register as final rules. Special rules shall be published in a newspaper within the local area. Copies of the rule shall be sent to those who are authorized to grazed livestock in the area where the special rule is applicable.

Subpart 4130—Authorizing Grazing Use

§ 4130.1 Applications.

Applications for grazing permits or leases (active use and non-use), free-use grazing permits and other permits shall be filed with the authorized officer at the local Bureau of Land Management office.

§ 4130.2 Grazing permits or leases.

(a) Grazing permits or leases shall be issued to authorize livestock grazing on the public lands and other lands under Bureau of Land Management control. These grazing permits or leases shall specify the amount of grazing use, nonuse, or combination of active grazing use and nonuse that is authorized and shall include appropriate terms and conditions under § 4150.2.

(b) A grazing permit or lease conveys no right, title, or interest in any lands or resource use authorized thereunder and is a privilege for the exclusive benefit of the permittee or lessee.

(c) Grazing permits or leases authorizing livestock grazing on the public lands and other lands under Bureau of Land Management control, shall be issued for a term of ten years unless:

(1) The land is pending disposal; or

(2) The land will be devoted to another public purpose prior to the end of ten years; or

(3) It will be in the best interest of sound land management to specify a shorter term.

If the public lands involved are pending disposal or shall be devoted to a public purpose which precludes livestock grazing prior to the end of 10 years, the grazing permits or leases shall be issued for a term coinciding with the anticipated date of disposal or the anticipated date for devoting the lands to another public purpose. Grazing permits or leases shall be issued for less than ten years in the interest of sound land management if it is necessary to achieve the objectives in the land use plans or if the land use plans have not been completed. The absence of details from allotment management plans shall not be the basis for establishing a term shorter than ten years.

(g) Permittees or lessees holding expiring grazing permits or leases shall be
PROPOSED RULES

§ 4130.2-1 Regular permits or leases.

Regular permits or leases shall be issued for a term of not more than 10 years to authorize livestock grazing on allotments within areas where land use plans have not been completed. The term of the permits or leases shall coincide with the scheduled completion dates for the land use plans for the affected areas.

§ 4130.2-2 Management permits or leases.

Management permits or leases shall be issued for a term of not more than 10 years to authorize livestock grazing on allotments within areas where land use plans have been completed and where allotment management plans have been or will be incorporated into the permits or leases.

§ 4130.2-3 Custodial permits or leases.

Custodial permits or leases shall be issued for a term of not more than 10 years to authorize livestock grazing on allotments within areas where land use plans have been completed and where it has been determined that allotment management plans are not necessary.

§ 4130.3 Free-use grazing permits.

A free-use grazing permit shall be issued to any applicant whose residence is adjacent to public lands within grazing districts and who needs these public lands to support his livestock or his family. The permit may be issued for a period of not more than 10 years.

§ 4130.4 Other permits.

Exchange-of-use grazing permits, nonrenewable grazing permits, and crossing permits have no priority for renewal and cannot be transferred or assigned.

§ 4130.4-1 Exchange-of-use grazing permits.

An exchange-of-use grazing permit may be issued to any permittee or lessee who owns or controls lands within the exterior boundaries of the allotment covered by his grazing permit or lease. An exchange-of-use permit may be issued to authorize use of public land within the allotment to the extent of the livestock grazing capacity of the permittee's or lessee's land within the allotment. The exchange-of-use permit may be issued for a term of not more than 10 years. The expiration date of the exchange-of-use permit shall coincide with the expiration date of the grazing permit or lease issued on the allotment in which the land offered in exchange is located.

During the term of the exchange-of-use permit, the Bureau of Land Management shall have management control of such private land for grazing purposes under which the provisions of this part may and may authorize grazing use as deemed appropriate.

§ 4130.4-2 Nonrenewable grazing permits.

Nonrenewable grazing permits may be issued to qualified applicants when forage is temporarily available, provided this use does not interfere with existing livestock operations on the public lands and it is consistent with the land use plans. This use shall be authorized on a seasonal or annual basis only. Nonrenewable grazing use may be included in a regular grazing permit or lease issued for 1 year under § 4130.2-1.

§ 4130.4-3 Crossing permits.

Any applicant showing the necessity for crossing the public land with livestock for special purposes may be issued a crossing permit upon such terms and conditions deemed necessary by the authorized officer to achieve the objectives of this part.

§ 4130.5 Fees.

§ 4130.5-1 Payment of fees.

(a) The fees for each grazing fee year shall be published annually in the Federal Register.

(b) Fees shall be charged for livestock grazing upon or crossing the public lands and other lands under Bureau of Land Management control at a specified rate per animal unit month. A minimum annual charge of $10 will be made for livestock grazing upon or crossing the public lands. No fee shall be charged for livestock grazing authorized under free-use grazing or exchange-of-use grazing permits.

(c) Fees shall be established by the Secretary in equal annual increments effective with the grazing fee year beginning March 1, 1978, to attain fair market value for livestock grazing use, except during periods or range depletion due to severe drought, fire, or other natural causes or general epidemic of disease that occurs during the term of a permit or lease. During these periods of range depletion the authorized officer may credit or refund fees in whole or in part, or fee payment may be suspended for as long as the emergency exists.

§ 4130.5-3 Service charge.

Except for actions initiated by the authorized officer, a service charge of $5 shall be made for each transfer of a preference and for each supplemental or revised billing issued under § 4130.6.

§ 4130.6 Changes in grazing use.

(a) Permittees and lessees shall have on file with the authorized officer a basic grazing schedule which outlines their annual livestock grazing use on the public lands, including the kind or class and number of livestock, the season(s) of use, the allotment(s) to be used, and the amount of use, in animal unit months. Permittees and lessees shall be billed in accordance with the basic grazing schedule unless a change in use has been requested.

(b) Requests for grazing use different than the basic grazing schedule should

FEDERAL REGISTER, VOL 42, NO. 131—FRIDAY, JULY 8, 1977
be filed with the authorized officer no later than 30 days before the grazing season or year. Requests for change in use filed later than 30 days before the grazing season or year, or after the start of the grazing season or year, shall be subject to a service charge under § 4105.0-3.

(c) A request for change in use may be granted at the discretion of the authorized officer if the request is compatible with existing operations and consistent with the objectives for the allotment.

§ 4105.0-3 Notice of intent to impound.

Where the livestock have been removed, but satisfactory settlement has not been made within the time allowed under § 4105.2, a certified letter demanding payment will be sent or personally delivered to the owner or his agent and a copy of the letter shall be sent to any known lien holder. This letter shall be served upon the alleged violator or his agent by certified mail or personal delivery as provided herein.

§ 4105.0-4 Demand for payment.

Where the livestock have been removed, but satisfactory settlement has not been made within the time allowed under § 4105.2, a certified letter demanding payment will be sent or personally delivered to the owner or his agent and a copy of the letter shall be sent to any known lien holder. Any time after five days of delivery of the notice the unauthorized livestock may be impounded.

(a) A written notice of intent to impound shall be sent by certified mail to the owner or his agent, and a copy of the notice shall be served upon the alleged violator or his agent by personal delivery as provided herein.

§ 4105.0-5 Settlement.

The authorized officer shall weigh the facts and circumstances of the case and shall determine if the violation is non-willful or willful and whether it is a repeated violation. When violations are determined to be non-willful, settlement shall be made under paragraphs (a) (1) and (a) (3) of this section. When violations are determined to be willful, and/or repeated, settlement shall be made under paragraphs (a) (2), (3), and (4) of this section and the authorized officer shall take action under § 4170.1.

(1) "Nonwillful violations." The value of forage consumed as determined by the average monthly rate for pasturing livestock on privately owned land for the 11 Western States as published annually by the Department of Agriculture.

(2) "Willful, and/or repeated violations." Twice the value of the forage consumed as determined in paragraph (a) (1) of this section.

(3) The full value for all damages to the public lands and other property of the United States.

(4) All expenses incurred by the United States including those incurred in gathering, impounding, caring for, and disposing of livestock in cases which necessitate impoundment under § 4150.5.

(b) Payment made under this section does not relieve the alleged violator of any criminal liability under Federal or State law.

§ 4105.0-6 Impoundment and disposal.

Unauthorized livestock remaining on the public lands after the date set forth in the notice and order to remove set forth under § 4105.2 may be impounded and disposed of by the authorized officer as provided herein.

§ 4105.0-7 Notice of intent to impound.

(a) A written notice of intent to impound shall be sent by certified mail to the owner or his agent, and a copy of the notice shall be served upon the alleged violator or his agent by personal delivery as provided herein.

(1) "Nonwillful violations." The value of forage consumed as determined by the average monthly rate for pasturing livestock on privately owned land for the 11 Western States as published annually by the Department of Agriculture.

(2) "Willful, and/or repeated violations." Twice the value of the forage consumed as determined in paragraph (a) (1) of this section.

(3) The full value for all damages to the public lands and other property of the United States.

(4) All expenses incurred by the United States including those incurred in gathering, impounding, caring for, and disposing of livestock in cases which necessitate impoundment under § 4150.5.

(b) Payment made under this section does not relieve the alleged violator of any criminal liability under Federal or State law.

§ 4105.0-8 Impoundment and disposal.

Unauthorized livestock remaining on the public lands after the date set forth in the notice and order to remove set forth under § 4105.2 may be impounded and disposed of by the authorized officer as provided herein.

§ 4105.0-9 Settlement.

The authorized officer shall weigh the facts and circumstances of the case and shall determine if the violation is non-willful or willful and whether it is a repeated violation. When violations are determined to be non-willful, settlement shall be made under paragraphs (a) (1) and (a) (3) of this section. When violations are determined to be willful, and/or repeated, settlement shall be made under paragraphs (a) (2), (3), and (4) of this section and the authorized officer shall take action under § 4170.1.

(1) "Nonwillful violations." The value of forage consumed as determined by the average monthly rate for pasturing livestock on privately owned land for the 11 Western States as published annually by the Department of Agriculture.

(2) "Willful, and/or repeated violations." Twice the value of the forage consumed as determined in paragraph (a) (1) of this section.

(3) The full value for all damages to the public lands and other property of the United States.

(4) All expenses incurred by the United States including those incurred in gathering, impounding, caring for, and disposing of livestock in cases which necessitate impoundment under § 4150.5.

(b) Payment made under this section does not relieve the alleged violator of any criminal liability under Federal or State law.

§ 4105.0-10 Impoundment and disposal.

Unauthorized livestock remaining on the public lands after the date set forth in the notice and order to remove set forth under § 4105.2 may be impounded and disposed of by the authorized officer as provided herein.

§ 4105.0-11 Settlement.

The authorized officer shall weigh the facts and circumstances of the case and shall determine if the violation is non-willful or willful and whether it is a repeated violation. When violations are determined to be non-willful, settlement shall be made under paragraphs (a) (1) and (a) (3) of this section. When violations are determined to be willful, and/or repeated, settlement shall be made under paragraphs (a) (2), (3), and (4) of this section and the authorized officer shall take action under § 4170.1.

(1) "Nonwillful violations." The value of forage consumed as determined by the average monthly rate for pasturing livestock on privately owned land for the 11 Western States as published annually by the Department of Agriculture.

(2) "Willful, and/or repeated violations." Twice the value of the forage consumed as determined in paragraph (a) (1) of this section.

(3) The full value for all damages to the public lands and other property of the United States.

(4) All expenses incurred by the United States including those incurred in gathering, impounding, caring for, and disposing of livestock in cases which necessitate impoundment under § 4150.5.

(b) Payment made under this section does not relieve the alleged violator of any criminal liability under Federal or State law.

§ 4105.0-12 Impoundment and disposal.

Unauthorized livestock remaining on the public lands after the date set forth in the notice and order to remove set forth under § 4105.2 may be impounded and disposed of by the authorized officer as provided herein.

§ 4105.0-13 Settlement.

The authorized officer shall weigh the facts and circumstances of the case and shall determine if the violation is non-willful or willful and whether it is a repeated violation. When violations are determined to be non-willful, settlement shall be made under paragraphs (a) (1) and (a) (3) of this section. When violations are determined to be willful, and/or repeated, settlement shall be made under paragraphs (a) (2), (3), and (4) of this section and the authorized officer shall take action under § 4170.1.

(1) "Nonwillful violations." The value of forage consumed as determined by the average monthly rate for pasturing livestock on privately owned land for the 11 Western States as published annually by the Department of Agriculture.

(2) "Willful, and/or repeated violations." Twice the value of the forage consumed as determined in paragraph (a) (1) of this section.

(3) The full value for all damages to the public lands and other property of the United States.

(4) All expenses incurred by the United States including those incurred in gathering, impounding, caring for, and disposing of livestock in cases which necessitate impoundment under § 4150.5.
§ 4150.5-2 Notice of public sale.

Following the impoundment of livestock under this subpart, the livestock may be disposed of by the authorized officer or, if a suitable agreement is in effect, they may be turned over to the State for disposal. If the authorized officer disposes of the livestock, he shall publish a notice for sale in a local newspaper and post this notice at the county courthouse and at a post office near the land involved. The notice shall describe the livestock, specify the date, time and place of the sale. The sale date shall be at least 5 days after the publication and posting of the notice. Any known owners or agents and known lien holders shall be notified in writing by certified mail or by personal delivery of the sale and the procedure by which the impounded livestock may be redeemed prior to the sale.

§ 4150.5-3 Redemption.

Any owner or known lien holder of the impounded livestock may redeem them in accordance with State law, prior to the time of sale upon settlement with the United States under § 4150.3 or adequate showing that there has been no violation.

§ 4150.5-4 Sale.

If the livestock are not redeemed on or before the date and time fixed for their sale, they shall be offered at public sale to the highest bidder either by the authorized officer or by the State. If a satisfactory bid is not received, the livestock may be reoffered for sale, condemned and destroyed, or otherwise disposed of in accordance with State law. When livestock are sold by the authorized officer pursuant to these regulations, he shall furnish the purchaser's bill of sale or other written instrument evidencing the sale. If sold by the State, the Bureau of Land Management shall be reimbursed for the amount due under § 4150.3 up to the amount received for sale of the livestock.

Subpart 4160—Administrative Remedies

§ 4160.1 Proposed decisions.

§ 4160.1-1 Proposed decisions on permits or leases.

The authorized officer shall serve a proposed decision on any applicant, permittee, lessee, or his agent, who is adversely affected by his proposed action on applications for permits or leases or by his proposed action related to terms and conditions of permits or leases, by certified mail or personal delivery, and shall notify any known lien holder of the proposed decision. The proposed decision shall state the reasons for the action, including reference to the pertinent terms, conditions, and/or regulating provisions, and shall provide for a period of 15 days after receipt of the filing of a protest.

§ 4160.1-2 Proposed decisions on alleged violations.

If the authorized officer determines that a permittee or lessee appears to have violated any provision of this part, he shall serve a proposed decision on the permittee or lessee, or his agent, by certified mail or personal delivery, and shall notify any known lien holder of the proposed decision. The proposed decision shall state the alleged violation and refer to the specific terms, conditions, and/or regulating provisions alleged to have been violated and the reasons for the proposed decision. As applicable, the proposed decision shall state the amount due under § 4150.3 and the action to be taken under § 4170.1. The proposed decision shall be served on the protestant within 15 days after receipt for the filing of a protest.

§ 4160.2 Protests.

Any applicant, permittee, lessee, or any other person adversely affected by a proposed decision of the authorized officer may protest the proposed decision in person or in writing to the authorized officer within 15 days after receipt of the proposed decision.

§ 4160.3 Final decisions.

(a) In the absence of a protest, the proposed decision shall become the final decision of the authorized officer without further notice.

(b) Upon the timely filing of a protest, the authorized officer shall reconsider his proposed decision in light of the protestant's statement of reasons for protest and in light of other information pertinent to the case. At the conclusion of his review of the protest, the authorized officer shall serve his final decision on the protestant, or his agent, and on any other person interested, and shall notify any known lien holder of the final decision.

(c) The final decision shall provide for a period of 30 days after receipt for filing of an appeal. An appeal shall suspend the effects of the final decision from which it is taken pending final action on the appeal unless the authorized officer provides in the final decision that it shall be in full force and effect pending appeal therefrom. Final decisions shall be in full force and effect only if required by administration of the range or for the protection of other resources. See § 4.477 of this title.

§ 4160.4 Appeals.

(a) Any applicant, permittee, lessee, or any other person whose interest is adversely affected by a final decision of the authorized officer may appeal the decision for the purpose of a hearing before an administrative law judge under § 4.411 of this title by filing his notice of appeal in the office of the authorized officer within 30 days after the receipt of the decision.

Subpart 4170—Penalties

§ 4170.1 Penalty for violations.

The authorized officer may suspend the grazing use authorized under a grazing permit or grazing lease in whole or in part or may cancel a grazing permit or grazing lease and grazing preference in whole or in part under Subpart 4160 for violation by a permittee or lessee of any of the provisions of this part. However, the authorized officer shall suspend the grazing use authorized under a grazing permit or grazing lease and grazing preference in whole or in part or shall cancel a grazing permit or grazing lease and grazing preference in whole or in part under Subpart 4160 for willful or repeated violation by a permittee or lessee of § 4140.1(a). Whenever a nonpermittee or nonlessee violates § 4140.1(a) and has not made satisfactory settlement under § 4150.3, the authorized officer shall refer the matter to proper authorities for appropriate legal action by the United States against the violator.

§ 4170.1-1 Failure to use.

(a) Public land administered by the Bureau of Land Management is involved or affected;

(b) Such violation is related to grazing use authorized by permit or lease; and

(c) The permittee or lessee has been convicted of violating any such laws by a court.

§ 4170.2 Penalties.

Under section 2 of the Act and under section 303(a) of the Federal Land Policy and Management Act of 1976, any person who willfully violates the provisions of these Acts or of this part or of approved special rules and regulations may be brought before a designated United States magistrate and is punishable by a fine of not more than $1,000 or imprisonment for no more than twelve months, or both.

Part 4700—Wild Free-Roaming Horse and Burro Protection, Management, and Control

2. Part 4700 is amended by changing references in §§ 4720.3 and 4720.4, and 4730.4. These sections are revised to read as follows:

§ 4720.3 Trespass animals.

Unauthorized horses or burros which have been claimed and have been determined to be privately owned in accordance with the provisions of this section will be considered to have been in trespass and may not be released until a proper trespass charge has been determined by the authorized officer in accordance with the provisions of Subpart 4150 of this subchapter.

§ 4730.3 Habitat reservation and allocation.

The biological requirements of wild free-roaming horses and burros will be determined based upon appropriate studies or other available information. The needs for soil and watershed pro-
§ 4730.4. Closure to livestock grazing.

The authorized officer may close public lands to use by all or a particular class of domestic livestock where it is necessary to allocate all available forage to, or to satisfy other biological requirements of wild free-roaming horses or burros. Such closures may be made only after appropriate public notice and in accordance with the procedures for reduction or cancellation of grazing privileges provided for under provisions in this subchapter. See §§ 4110.2-2 and 4110.3-2 of this subchapter.
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

OVER-THE-COUNTER DRUGS

Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Antirheumatic Products
PROPOSED RULES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration [21 CFR Part 343 ]

[ Docket No. 77N-00941 ]

OVER-THE-COUNTER DRUGS

Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Anti-

rheumatic Products

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This is a proposal to establish conditions under which over-the-
counter (OTC) internal analgesic, antipyretic and antirheumatic drugs are generally recognized as safe and effective and not misbranded, based on the recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Products.

DATES: Comments by October 6, 1977, and reply comments by November 7, 1977.

ADDRESSES: Written comments to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilberston, Division of OTC Drug Evaluation (HFD-510), Food and Drug Administration, Rockville, MD 20857.

SUPPLEMENTAL INFORMATION:

Pursuant to Part 330 (21 CFR Part 330), the Commissioner of Food and Drugs received on April 5, 1977, a report of the Advisory Review Panel on Over-The-Counter (OTC) Internal Analgesic and Antirheumatic Products. In accordance with § 330.10(a)(3)(i) (21 CFR 330.10(a)(3)(i)), the Commissioner is issuing (1) a proposed rule, containing the monograph recommended by the Panel establishing conditions under which OTC internal analgesic, antipyretic and antirheumatic drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs not being generally recognized as safe and effective if used or would result in misbranding; (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel to the Commissioner. The summary minutes of the Panel meetings are on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

In accordance with § 330.10(a)(3)(i) (21 CFR 330.10(a)(3)(i)), all data and information concerning OTC internal analgesic, antipyretic and antirheumatic drug products submitted for consideration by the Advisory Review Panel have been handled as confidential by the Panel and FDA. All such data and information shall be open for public display at the office of the Hearing Clerk, Food and Drug Administration, on or before August 8, 1977, except to the extent that the person submitting it demonstrates that the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) are necessary to protect the confidentiality of such data and information. Requests for confidentiality shall be submitted to FDA, Bureau of Drugs, Division of OTC Drug Products Evaluation (HFD-510), 5600 Fishers Lane, Rockville, MD 20857.

Based upon the conclusions and recommendations of the Panel, the Commissioner proposes, upon publication of the final regulation:

1. That the conditions included in the monograph on the basis of the Panel's determination that they are generally recognized as safe and effective and not misbranded (Category I) be effective 30 days after the date of publication of the tentative final monograph in the Federal Register.

2. That the conditions excluded from the monograph on the basis of the Panel's determination that they would result in the drug not being generally recognized as safe and effective or would result in misbranding (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the Federal Register, regardless whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph on the basis of the Panel's determination that the available data are insufficient (Category III) to classify such conditions either as Category I—generally recognized as safe and effective or not misbranded or as Category II—not being generally recognized as safe and effective or would result in misbranding, be permitted to remain in use for not longer than 3 years (for the specified conditions) after the date of publication of the final monograph in the Federal Register, if the Food and Drug Administration (FDA) receives notification in accordance with § 330.10(a)(7) (21 CFR 330.10(a)(7)) that tests and studies adequate and appropriate to satisfy the questions raised with respect to the particular condition by the Panel will be conducted. The period of time within which such studies must be completed will be carefully reviewed by the Commissioner after receipt of comments on this document.

The Commissioner recognizes that new additional data or information not previously available to the Panel regarding Category III conditions may become available prior to publication of the tentative final monograph in the Federal Register pursuant to § 330.10(a)(7) of the OTC drug review regulations. The Commissioner concludes that it is in the best interest of all parties if additional time is provided for the submission of such data to the FDA. Therefore, the Commissioner shall accept new data or information regarding Category III conditions until January 9, 1978.

Any changes justified by the new data and information will be included in the tentative final monograph. Full opportunities for comment on both the changes and the new data and information will be provided by the opportunity to file objections to the tentative final monograph pursuant to § 330.10(a)(7).

The Commissioner has not yet fully evaluated the report, but has concluded that it should first be issued as a formal proposal to obtain full public comment before any decision is made on the recommendations of the Panel. The purpose of issuing the unaltered formal proposals and recommendations of the Panel is to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report of the Panel represents the best judgment of the members. The report has been prepared independently of FDA and does not necessarily reflect the agency position on any particular matter contained therein.

The Commissioner recognizes that major changes will result in the current marketing practices of these products if the recommendations of the Panel are fully implemented. The recommendations include many revisions in labeling, particularly limitations of indications for use, and additional warnings and cautions. As a result, revised dosage schedules are proposed with major changes in the labeling for pediatric use.

In the final order for antacid products published in the Federal Register of June 4, 1974 (30 FR 18682), the antacid monograph provides that any safe and effective analgesic, as determined by the internal analgesic monograph, may be used in combination with the labeling of the analgesic component of an antacid/analgesic combination would be addressed in the course of reviewing the recommendations of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Products. The Commissioner is aware of the Panel's recommendation that (1) combinations of nonasalicylate ingredients that meet the standard for Category I combination products may be combined with antacid ingredients that meet the requirements of § 353.10 of the OTC antacid monograph and provided the proposed label be evaluated for the concurrent symptoms involved, e.g., "For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever, and for acid indigestion" and (2) aspirin may be combined with antacid active ingredients identified in § 331.11 of the OTC antacid monograph such that the finished product meets certain specifications regarding neutralizing capacity.
and pH and the product is identified as highly buffered aspirin for solution with labeling only as an analgesic and/or antipyretic.

At this time, the Commissioner seeks comment on these recommendations before any final determination is made. After review of the comments and data submitted, the Commissioner will address this issue in the publication of the internal analgesic, antipyretic and antirheumatic tentative final monograph. At that time the Commissioner will also address any related modifications that may be required in the antacid monograph (21 CFR Part 331).

The Commissioner notes that the Panel’s recommendation concerning the dosage of acetaminophen exceeds that set forth in § 310.201(a)(1) (21 CFR 310.201(a)(1)). The Commissioner’s final acceptance of the Panel’s recommendation regarding acetaminophen, including its dosage and labeling, would necessitate withdrawal of NDA’s for acetaminophen drugs and revocation of § 310.201(a)(1).

The Commissioner invites full public comment on all of the Panel’s recommendations. After careful review of all comments submitted in response to the proposal, the Commissioner will issue a tentative final regulation in the Federal Register to establish a monograph for OTC internal analgesic, antipyretic and antirheumatic drug products.

The Commissioner has reviewed the potential environmental impact of the recommendations and proposed monograph for OTC internal analgesic, antipyretic and antirheumatic products and has concluded that the Panel’s recommendations and proposed monograph will not significantly affect the quality of the human environment and that an environmental impact statement is not required. A copy of the environment assessment report file with the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

The conclusions and recommendations in the report of the Advisory Review Panel on OTC Internal Analgesic, Antipyretic and Antirheumatic Products follow:

In the Federal Register of January 5, 1972 (37 FR 85), the Commissioner of Food and Drugs announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory review panels. On May 8, 1972, the Commissioner signed the final regulations providing for the OTC drug review under § 356.10 (formerly § 130-301) published in the Federal Register of May 11, 1972 (37 FR 9464), which were made effective immediately. Pursuant to these regulations, the Commissioner issued in the Federal Register of July 21, 1972 (37 FR 14653) a request for data and information on all internal analgesic and antirheumatic active ingredients in drug products.

The Commissioner appointed the following Panel to review the data and information submitted and to prepare a report on the safety, effectiveness, and labeling of OTC internal analgesic and antirheumatic ingredients pursuant to § 330.10(a)(1):

Henry W. Elliott, M.D., Ph.D., Chairman, deceased August 1976
J. Weidon Belville, M.D., Chairman from August 1976
William B. Ross, Ph.D.
Julius M. Coon, M.D., Ph.D.
Nina I. Redmond, Ph.D., resigned January 1977
Naomi P. Rothfeld, M.D.
George Sharpe, M.D.

The Panel was first convened on October 24, 1972 in an organizational meeting. Working meetings were held on November 21 and 22, 1972; January 22 and 23, February 26 and 27, April 12 and 13, June 11 and 12, July 30 and 31, September 25 and 26, October 22 and 23, November 19 and 20, and December 17 and 18, 1973; March 11 and 12, April 10 and 11, May 9 and 10, September 25 and 26, November 11 and 12, and December 9 and 10, 1974; March 17, 18 and 19, June 23, 26 and 27, August 14 and 15, October 5 and 6, and November 19, 1975; April 8 and 9, May 23 and 24, August 21, 22 and 23, October 15 (telephone conference) and November 22, 23 and 24, 1976.

Two nonvoting liaison representatives served on the Panel. Ms. Kathryn Eilers Van Fluine, nominated by the Consumer Federation of America, served as the consumer liaison and Joseph Pisani, M.D., nominated by the Proprietary Association, served as the industry liaison.

The following FDA employees served: Brigitta Dassler, M.D., served as Executive Secretary until August 1975 followed by Lee Gelman who also served as Panel Administrator. Leo Quon, R.Ph., served as Drug Information Analyst until August 1975, followed by Thomas H. Gingrich, R.Ph., until May 1975, followed by Timothy T. Clark, R.Ph., until June 1976, followed by Victor H. Lindmark, Pharm.D.

The following individuals were given an opportunity to appear before the Panel to express their views:

Clealand Boker
Dorothy L. Carter-Staples, M.D.
Robert E. Cheate
John M. Clayton, Ph.D.
Allan R. Cooke, M.D.
Alan K. Donn, M.D.
Constantine J. Fullier, M.D.
Edward E. Fischel, M.D.
George S. Goldstein, M.D.
Arthur Gromilan, M.D.
Robert John, M.D.
Daniel R. Johnson, Esq.
Charles Jolly, Esq.
Edward H. Kees, M.D.
David Katz, M.D.
Frances Rindal-Smith, M.D. (Australia)
John Krock-Weser, M.D.
Irving Kushner, M.D.
Ben Miriam, M.D.
Louis Lasagna, M.D.
Jack R. Leonards, M.D., Ph.D.
Evelart Levine, M.D.
Dietrich Lorke, M.D. (Germany)

William Madison, Ph.D.
Arnold D. Marcus, M.D.
F. Gilbert McMahon, M.D.
Bernard L. Bird, M.D.
Fred Modder
Ranjit S. Nanra, M.D. (Australia)
William M. O’Brien, M.D.
Peter D. Orhakiane, M.D.
W. K. Poole, M.D.
Laurie Prescott, M.D. (Scotland)
Adrien L. Richman, M.D.
Mervyn A. Sahud, M.D.
George Schreiner, M.D.
Cecil Smole, M.D., C.M.B., D.P.H.
J. Edward Smiley, M.D.
Hale Sweeney, Ph.D.
Curtiss W. Swenson, Esq., R.Ph.
Monroe E. Tros, M.D.
Walter Tucker, Jr., Ph.D.
Ralph W. Vilhark, M.D.
T. E. Watson
Richard M. Welsh, Ph.D.
Harvey Weiss, M.D.
Sidney Wolfe, M.D.
Sumner J. Yaffe, M.D.

No other person requested an opportunity to appear before the Panel. No person who so requested was denied an opportunity to appear before the Panel.

The Panel has thoroughly reviewed the literature and the various data submissons, has listened to additional testimony from interested parties and has considered all pertinent data and information submitted through November 22, 1976 in arriving at its conclusions and recommendations. Because the charge to the Panel required the review of three classes of OTC drugs, i.e., analgesics, antipyretics and antirheumatics, the Panel has presented its conclusions and recommendations in three separate parts. (See part III below—ANALGESIC AGENTS, part IV below—ANTIPYRETIC AGENTS, and part V below—ANTIRHEUMATIC AGENTS.)

Each part covers the submission of data and information discussed below. (See part I below—SUBMISSION OF DATA AND INFORMATION.)

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel’s findings with respect to these classes of drugs are set out in three categories:

Category I. Conditions under which internal analgesic, antipyretic and antirheumatic products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which internal analgesic, antipyretic and antirheumatic products are generally recognized as safe and effective and are not misbranded.

Category III. Conditions under which internal analgesic, antipyretic and antirheumatic products are generally recognized as safe and effective.
Category III. Conditions for which the available data are insufficient to permit final classification at this time.

The Panel recommends the following for each class of drugs:

1. That the conditions included in the monograph on the basis of the Panel's determination that they are generally recognized as safe and effective and are not misbranded (Category I) be effective 30 days after the date of publication of the final monograph in the \textit{Federal Register}.

2. That the conditions excluded from the monograph on the basis of the Panel's determination that they would result in the drug not being generally recognized as safe and effective or would result in misbranding (Category II) be eliminated from the OTC drug products effective 6 months after the date of publication of the final monograph in the \textit{Federal Register}.

3. That the conditions excluded from the monograph on the basis of the Panel's determination that the available data are insufficient to classify such conditions either as Category I—generally recognized as safe and effective and not misbranded or as Category II—not being generally recognized as safe and effective or would result in misbranding (Category III) be permitted to remain in use for 3 years after the date of publication of the final monograph in the \textit{Federal Register}, if the manufacturer or distributor of any such drug utilizing such conditions in the interim conducts tests and studies adequate and appropriate to answer the questions raised by the Panel with respect to the particular condition.

\textbf{I. Submission of Data and Information}

Pursuant to the notice published in the \textit{Federal Register} of July 21, 1972 (37 FR 14633) requesting the submission of data and information on OTC analgesic and antirheumatic drugs, the following firms made submissions relating to the indicated products:

\textbf{A. Submissions by Firms}

\begin{tabular}{ll}
\textit{Firm:} & \textit{Marketed products} \\
Abbott Laboratories, North Chicago, Ill. 60064 & Children's Chewable Aluminum Aspirin. \\
Berry & Withington Co., Cambridge, Mass. 02140 & Aspirin, Aspirin Compound No. 2, Buffered Aspirin, Sodium Salicylate. \\
Block Drug Co., Inc., Jersey City, N.J. 07302 & EC Powder, EC Tablet. \\
Beercie & Tafel, Philadelphia, Pa. 19107 & B & R Tablet No. 171-A, Beercie & Runyon Tablets No. 200. \\
Bristol-Myers Co., New York, N.Y. 10022 & Arthritis Strength Bufferin, Bufferin, Dissolve, Excedrin, Excedrin P.M., Neolin. \\
Cooper Laboratories, Inc., Wayne, N.J. 07470 & Peristin. \\
Curtis Drug Co., Decatur, Ill. 62521 & Curtis A-R Pain Relief. \\
Dorsey Laboratories, Lincoln, Nebr. 68501 & Calmin, Cama Inlay Tablets, Chexit, Pabrin, Triamcin, Tussagesic Tablets/Suspension, Ursinus Inlay Tablets. \\
\end{tabular}

The Dow Chemical Co., Research Center, Zionsville, Ind. 46077.
El Lilly and Co., Indianapolis, Ind. 46206.
Endo Laboratories, Inc., Garden City, N.Y. 11530.
Eneglotarsa Medicine Co. of Puerto Rico, Santurce, P.R. 00917.
Fountain Laboratories, Inc., Fountain Inn, S.C. 29644.
R. L. Gaddy, Pharmacist, Tallahassee, Fla. 32302.
Edgar Larsen, Lafayette, Calif. 94549.
Lewis Manufacturing Co., Pieront, Ohio 44082.
Mead Johnson Labs., Evansville, Ind. 47721.
Miles Laboratories, Inc., Elkhart, Ind. 46514.
Norwich Pharmacal Co., Norwich, N.Y. 13816.
Plough, Inc., Memphis, Tenn. 38101.
Purdue Frederick Co., Yonkers, N.Y. 10701.
Republic Drug Co., Inc., Buffalo, N.Y. 14207.
A. H. Robins Co., Richmond, Va. 23220.

\textbf{FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977}
PROPOSED RULES

Sandoz Pharmaceuticals, East Hanover, N.J.
Sterling Drug, Inc., New York, N.Y. 10016
Templetons, Inc., Buffalo, N.Y. 14223
Upjohn Co., Kalamazoo, Mich. 49001
USV Pharmaceutical Corp., Tuckahoe, N.Y. 10707
Warner-Chilcott Laboratories, Morris Plains, N.J.
Warren-Teed Pharmaceutical, Inc., Columbus, Ohio 43215
T. E. Watson Co., Sarasota, Fla. 33578
Whitehall Laboratories, Inc., New York, N.Y. 10017

In addition, the following firms made related submissions:

Firm: Submission
Monsanto Industrial Chemicals Co., St. Louis, Mo. Aspirin, Phenacetin, Salicylamide.

B. Labeled Ingredients Contained in Marketed Products Submitted to the Panel

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Description</th>
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<tbody>
<tr>
<td>Acetaminophen (N-acetyl p-aminophenol; paracetamol)</td>
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<tr>
<td>Acetanilid</td>
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<tr>
<td>Aluminum aspirin</td>
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<tr>
<td>Aminoacetic acid (glycine, glycocoll)</td>
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<tr>
<td>Aminobenzoic acid (para-aminobenzoic acid (PABA))</td>
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<tr>
<td>Antipyrine</td>
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<td>Ascorbic acid (vitamin C)</td>
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<td>Aspirin (acetylsalicylic acid)</td>
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<td>Bryonin</td>
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<td>Caffeine</td>
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<td>Calcium carbospirin</td>
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<td>Calcium carbonate</td>
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<td>Calcium phosphate dibasic (monoaacetate phosphate)</td>
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<td>Camomile</td>
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<td>Cascara sagrada</td>
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<td>Choline salicylate</td>
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<td>Cinnamonhydrochloride</td>
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<td>Citrated caffeine</td>
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<td>Citric acid</td>
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<td>Codeine phosphate</td>
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<td>Dextromethorphan hydrobromide</td>
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<tr>
<td>Dihydroxyaluminum aminoacetate (aluminum glycinate)</td>
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<td>Dihydroxyaluminum sodium carbonate</td>
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<tr>
<td>Dried aluminum hydroxide gel</td>
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<td>Homatropine methylybromide</td>
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<td>Iodopyrine</td>
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<td>Iris versicolor</td>
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<td>Macromin</td>
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<td>Magnesium carbonate</td>
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<td>Magnesium hydroxide</td>
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<td>Magnesium salicylate</td>
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<td>Metabsyptoline fumarate</td>
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<td>Nux vomica</td>
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<td>Phenacetin (acetophenetidin)</td>
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<tr>
<td>Phenamate maleate</td>
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<td>Phenyltoloxamine dihydrogen citrate</td>
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<td>Phenylpropanolamine hydrochloride</td>
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<td>Potassium bromide</td>
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<td>Potassium iodide</td>
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<td>Pyrilamine maleate</td>
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<td>Quinine</td>
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<tr>
<td>Riboflavin (vitamin B,)</td>
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<td>Salicylamide</td>
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C. Classification of Ingredients

1. Active Ingredients. The Panel has classified the following as analgesic, antipyretic, and antirheumatic agents:

   - Acetaminophen
   - Aspirin
   - Antipyrine
   - Aspirin
   - Calcium carbospirin
   - Choline salicylate
   - Codeine phosphate
   - Iodopyrine
   - Magnesium salicylate
   - Phenacetin
   - Quinine
   - Salicylamide
   - Sodium salicylate

   These active ingredients may be further identified chemically into two groups. One group represents the "salicylates" (SA) in which all of the ingredients are chemically related to salicylic acid. The other group represents the "nonsalicylates" (NSA) in which the ingredients are not chemically related to salicylic acid. The most commonly used salicylate is aspirin or acetylsalicylic acid (ASA). Throughout this document the Panel has used the term aspirin which is the official adopted name for acetylsalicylic acid (ASA).
Aspirin (SA)
combined with active ingredients could
Phenyltoloxamine
Pheniramine maleate
Sodium paminobenzoate
possible analgesic, antipyretic and/or
Sodium salicylate
Salicylamide
Phenacetin
Magnesium salicylate
Iodopyrine
Calcium carbaspirin
Acetanilid
Dihydroxyaluminum aminoacetate (alumi-
Calcium phosphate dibasic (monocalcium
Calcium carbonate
Aminoacetic acid (glycine, glycocolU)

The Panel reviewed aminobenzoic acid, caffeine and phenyltoloxamine (and other antihistamines submitted) as possible analgesic, antipyretic and/or antirheumatic active ingredients and concludes that they cannot be properly included in these classes of internal analgesic ingredients. However, the Panel concludes that they may be considered adjuvants, categorized in the table as follows:

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Analgesic</th>
<th>Antipyretic</th>
<th>Antirheumatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin (SA)</td>
<td>I</td>
<td>I</td>
<td>II (E)</td>
</tr>
<tr>
<td>Phenyltoloxamine</td>
<td>II (S, E)</td>
<td>I</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Pheniramine maleate</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Sodium paminobenzoate</td>
<td>III (S, E)</td>
<td>III (S, E)</td>
<td>III (S, E)</td>
</tr>
</tbody>
</table>

1. Antirheumatic active ingredients are limited to professional labeling.  
2. The term “(SA)” refers to a nonasalicylate active ingredient.  
3. The term “(SA)” refers to safety considerations.  
4. The term “(E)” refers to effectiveness considerations.

2. Adjuvant agents. The Panel has discussed adjuvants and their classification elsewhere in this document (See part VI—ADJUVANTS AND CORRECTIVE AGENTS.) The agents identified below are included as active ingredients because they were submitted as pursuant to the notice published in the Federal Register of July 21, 1972 (37 FR 14633) and the Panel considered that these agents (adjuvants) when combined with active ingredients could affect the activity or safety of the active component(s) of the submitted preparation(s):

(a) Corrective (antacid or buffering) adjuvant agents.

Aminobenzoic acid (glucose, glycocolI)
Calcium carbonate
Calcium phosphate dibasic (monocalcium phosphate)
Citric acid
Dihydroxyaluminum aminosuccinate (alumi-
Dihydroxyaluminum sodium carbonate
Dried aluminum hydroxide gel
Magnesium carbonate
Magnesium hydroxide
Sodium bicarbonate
Sodium carbonate

(b) Direct acting adjuvant agents.

Caffeine
Citrate caffeine
Methyprylline fumarate
Pheniramine maleate

3. Ingredients deferred to other OTC advisory review panels or other experts. Agents deferred to other OTC panels are considered by this Panel not to have analgesic activity and it is not known whether they affect the safety or effectiveness of the analgesics listed above. (See part I, paragraph C.I. above—Active ingredients.)

a. The following agents were deferred for review to the Advisory Review Panel on OTC cold, cough, allergy, bronchodilator and antihistamnic drug products:

<table>
<thead>
<tr>
<th>Adjuvant</th>
<th>Analgesic</th>
<th>Antipyretic</th>
<th>Antirheumatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminobenzoic acid</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Sodium para-aminobenzoate</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Caffeine</td>
<td>III (S, E)</td>
<td>III (S, E)</td>
<td>III (S, E)</td>
</tr>
<tr>
<td>Methyprylline fumarate</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Pheniramine maleate</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Sodium para-aminobenzoate</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
</tbody>
</table>

b. The following agents were deferred for review to the Advisory Review Panel on OTC sedative, tranquilizer, sleep-aid and stimulant drug products:

<table>
<thead>
<tr>
<th>Adjuvant</th>
<th>Analgesic</th>
<th>Antipyretic</th>
<th>Antirheumatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrillamine maleate</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
<tr>
<td>Phenyltoloxamine</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
<td>II (S, E)</td>
</tr>
</tbody>
</table>

4. The following agents were deferred for review to the Advisory Review Panel on OTC vitamin, mineral and hematinc drug products:

(a) Other table active ingredients.

Vitamin, mineral and hematinc drug products:

Vitamin A
Vitamin B comples
Vitamin C
Vitamin D
Vitamin E
Vitamin K
Vitamin B complex

5. The following agents were deferred for review to the Advisory Review Panel on OTC internal miscellaneous drug products:

a. Other table active ingredients.

Bromelain
Chloramphenicol
Ibisol
Methaphylene fumarate (for uses other than as an analgesic adjuvant)
Phenyltoloxamine (for uses other than as an analgesic adjuvant)
Potassium bromide
Pyrillamine maleate (for uses other than as an analgesic adjuvant)
Nux vomica

6. The following agents were deferred for review to the Advisory Review Panel on OTC internal miscellaneous drug products:

a. Other table active ingredients.

acetic acid
Riboflavin
Thiamin hydrochloride

7. The following agents were deferred and recommended for review to experts on homeopathy:

Bryonia
Macrozin
Iris Versicolor
Nux vomica

D. REFERENCED OTC VOLUME SUBMISSIONS

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call for data notice published in the Federal Register of July 21, 1972 (37 FR 14633). The volumes shall be put on public display on or before August 8, 1972, in the office of the Hearing Clerk, Food and Drug Administration, Room 6-65, 5800 Fisher Lane, Rockville, MD 20857.

II. GENERAL STATEMENTS AND RECOMMENDATIONS

A. INTRODUCTION

1. Pain. Pain is the most common symptom for which man seeks relief. While it is best to determine the cause of the pain and treat the underlying process, mild to moderate pain that is self-limited may often be treated symptomatically by self-medication. If pain persists more than 10 days or is severe, medical advice should be sought.

Many definitions of pain have been formulated. There is no doubt that everyone has experienced it. Beecher (Ref. 1), a recognized authority, has defined the symptom as follows:

Unfortunately pain is a universal experience of mankind and everybody knows what it is, even if we do not discuss it among ourselves. If we talk about pain, it is often hard to define the term, which is a common experience. But attempts at definition are useful in that they throw light on the process and on the nature of the difficulties encountered.

Pain is a subjective matter clearly "known to be well by experience and described by illustration" [Ref. 609]. There seems little point for the present purpose to labor a definition of what all understand. Logicians, philosophers, and scientists have none of
them succeeded in defining pain. Having said that it is the opposite of pleasure, or that it is different from other sensations (touch, pressure, pain), it may be used as a sign to aid in treatment and diagnosis. Once the cause of the fever is ascertained, that cause is treated, and treatment of fever, per se, becomes secondary to removal of the underlying cause.

Nevertheless, the Panel believes the availability of OTC antipyretics fulfills a need of a significant target population. The Panel concludes that an acceptable labeling claim for an OTC antipyretic is, "For the reduction of fever".

4. Mechanism of action of an antipyretic agent. The Panel has defined an OTC antipyretic drug as an agent used to reduce fever and antipyresis as "symptomatic treatment of fever rather than of the underlying disease."

The salicylates and other antipyretics, e.g., acetaminophen, lower the temperature in patients with fever but have no effect on the body temperature at a higher than normal level. The antipyretics are said to act on the "central nervous system" so that the body temperature will decrease toward normal 98.6°F (37°C). Heat production is not changed but heat loss is increased by increased peripheral circulation and sweating. The reduction in temperature is not due to a direct effect of the antipyretics on peripheral blood flow or the sweating mechanism but rather to a central action on the hypothalamus.

Elevation in body temperature can occur following infection and inflammation. The causative agents of fever are referred to as pyrogens. Pyrogens may be differentiated into two basic categories: those produced by infectious agents and referred to as exogenous pyrogens and those produced by substances which are external to the body such as those produced by inflammatory agents. The Panel concludes that the term "antipyretic" is limited to relief of fever, which is symptomatic of an underlying illness. The fact that a fever is often an early sign of disease rather than a disease itself is in stark contrast to broadly held medical views of 50 or more years ago when reduction of fever was the end, not the means. In fact, fever was often considered the surest indication of disease by the physician could distinguish among the myriad of untreatable diseases confronting him. With the introduction of antibiotic agents it is less important than as they once were (Ref. 6). Today, in some instances, fever or its absence can be used as a sign to aid in treatment and diagnosis. Once the cause of the fever is ascertained, that cause is treated, and treatment of fever, per se, becomes secondary to removal of the underlying cause.
Identification of prostaglandin as a key mediator involved in fever.

**The Role of Prostaglandins**

Fever is closely linked to the activity of prostaglandins, which are lipid mediators synthesized in response to various stimuli. In the anterior hypothalamus, these substances play a crucial role in maintaining a high body temperature.

**Prostaglandin Activity**

Prostaglandins are produced by cells in response to pyrogens, such as bacterial endotoxins. In the absence of fever, prostaglandin production is minimal, but in response to fever, there is an increase in prostaglandin synthesis. This rise in prostaglandin activity may explain the rise in deep body temperature observed during fever.

**Drugs and Fever**

Drugs such as aspirin and indomethacin, which inhibit prostaglandin synthesis, can reduce fever. These effects are thought to be mediated through the inhibition of prostaglandin synthesis in the central nervous system, where they act to lower body temperature.

**Other Considerations**

While prostaglandins are involved in fever, other factors such as the presence of pyrogens, the role of pyretic agents, and the influence of cytokines on the hypothalamus also play a role. The study of prostaglandins in fever continues to be an active area of research, with a focus on understanding the complex interplay between these mediators and the regulation of body temperature.
reduced ability of the vessel walls to accommodate changes in blood pressure. This results in a more direct transmission of pressure variation to sensory receptors in vessel walls and the subarachnoid areas of the brain and is interpreted as pain.

One type of vascular headache, the hypertensive headache, is related to elevated intracranial blood pressure. A sudden rise in arterial blood pressure in either normal or hypertensive individuals causes headache by virtue of a sudden dilation of the pain-sensitive intracranial blood vessels. Another type of vascular headache is the common migraine. It has been estimated that nearly 12 million people in the U.S. suffer from migraine and 8 percent of all headaches seen by the physician are attributable to migraine. A common feature of the migraine headache is a recurrent, throbbing, unilateral head pain. The Panel concludes that the occasional headache is self-limited and removable by self-medication with an appropriate OTC analgesic.

Next to migraine, the most common vascular headache is the toxic vascular headache produced by fever for which OTC analgesics are usually not appropriate for the treatment of hypertensive or migraine headaches which require diagnosis of the disease by a physician and usually treatment with drugs available only by prescription.

The second major type of headache is the psychogenic headache which is considered one of the commonest types of headache. Apprehension, anxiety, post-traumatic experiences, and depression can precipitate the symptoms. This form of headache is usually accompanied by persistent contraction of the muscles of the head, neck and face. In some individuals, it is described as a sense of pressure rather than a true pain. Wolff notes that "the intensity of the headache is likely to be unaffected by the simple analogics, whereas agents such as opiates or barbiturates that relieve tension to pain may grant significant, Psychogenic headaches, which may account for up to 90 percent of the chronic headaches seen by the physician, are more common in those aged 30 years and over, but can occur at any age, even in childhood. The symptoms are usually described as a generalized pain not localized on one side of the head. The headache is usually difficult to describe. Various factors which may cause a psychogenic headache include the individual's marital relations, occupation, social relationships, life stresses, and the like. (Ref. 39). Another type of headache seen in children is the tension headache. The Panel concludes that the occasional headache is self-limited and removable by self-medication with an appropriate OTC analgesic.
PROPOSED RULES

1. Ingredients. The Panel concludes that analgesic, antipyretic, and anti-rheumatic products should contain only active ingredient(s) plus such inactive ingredients (pharmaceutical necessities) as may be necessary for product formulation. All such drug products should identify the active and inactive ingredients in the labeling. Active ingredients should be listed below Data Required for Evaluation.

2. Safety. The Panel recommends the following additional requirements adopted by the Food and Drug Administration for OTC antacid products containing sodium and magnesium salts (21 CFR Part 331). The Panel concurs with these requirements and for reasons stated later in this document concludes that they be adopted for OTC internal analgesic, antipyretic and anti-rheumatic products containing sodium and magnesium salts. (See part III, subpart D. below.) Therefore, the Panel recommends that the labeling of products containing sodium and magnesium salts in the maximum recommended daily dose, the labeling should contain the warning "Do not take this product if you are on a sodium restricted diet except under the advice and supervision of a physician." For products containing magnesium salts with more than 50 mg of magnesium in the recommended daily dosage, the labeling should contain the warning "Do not take this product if you have kidney disease except under the advice and supervision of a physician."

2. Indications and directions for use. The indications for use should be simply and clearly stated, provide the user with adequate directions and instructions on the label. The potential for harm that might result from abuse or misuse under conditions of widespread OTC availability, the benefit to risk ratio.

REFERENCE


C. LABELING OF ANALGESIC, ANTIPYRETIC AND ANTIRHEUMATIC DRUG PRODUCTS

The Panel reviewed the general labeling requirements previously adopted by the Food and Drug Administration for OTC (analgesic, antipyretic and antirheumatic) products (21 CFR Part 331). The requirements provide for labeling information on the principal display panel of the packaging form, the identity of ingredients, directions for use and general and specific warnings. The Panel believes that these general requirements are appropriate for such OTC preparations. The labeling of individual active ingredients will be discussed later in this document.

After reviewing all submitted labels of OTC analgesic, antipyretic, and anti-rheumatic preparations, the Panel recommends the following additional requirements:...
preparation. For analgesic-antipyretic drugs, the Panel believes that the general indications statement "For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever" answers these needs. This general statement covers the many slightly different claims found on the labeling of presently marketed OTC preparations and discourages the implication that these drugs are to be used for the self-treatment of diseases.

An important area of the Panel's responsibility is concerned with the labeling of OTC analgesic-antipyretic products. In years past it was believed that the greater the number of claims, the better the product. Often the claims would be vague, not easily understood or ambiguous. Even in today's OTC analgesic market there has been some carry-over of this philosophy by industry and government. Specific analgesic studies have been cited to support claims for particular types of pain. However, a plethora of claims may be confusing, and misleading. The Panel recognizes that well-controlled studies have been done with various analgesic-antipyretic agents in patients with specific conditions. These claims are of such as postpartum pain, pain due to causing pain following tooth extraction, etc. It is the Panel's opinion, however, that "pain" is sufficiently broad to encompass the use for pain generally rather than list on the labeling all the specific types of pain that drugs are known to be effectively treated in well-controlled clinical studies.

Some of the claims for alleviation of pain found on the labeling of presently marketed OTC analgesics include: "muscle aches"; "stiffness"; "pain of toothaches", "teething", "dental procedures and dental work"; "muscle soreness"; "boil, headache", "nervous headache"; "tension headache", "pain due to colds"; "simple pain of inunctions and immunizations"; etc. Rather than list all the numerous conditions all based describing the common problem of pain, the Panel believes the term "minor pain" is sufficiently broad to encompass the specific types of pain effectively treated by this group of ingredients.

Another frequent problem with a variety of claims for alleviation of pain is their vagueness and lack of clarity. Often the consumer does not know what is meant by such claims and is misled when similar products have different claims. For example, if the labeling of one manufacturer's product contained claims found on the labeling of another identical product, the consumer would be misled into believing the two preparations are different or are for different indications. Also, the same claim may have a different meaning for one consumer that is exactly opposite to its meaning for another consumer. Furthermore, some claims are not even recognized by the medical community. For example, the Panel does not understand what is meant by "jumpy nerves", "treffulness", "nighttime pain and its tension", or "under the weather". Since the Panel does not comprehend such claims, it appears that the consumer would have similar difficulty.

The Panel further notes that this current labeling of some OTC products lists claims for conditions that they are clearly ineffective such as "depression", "nervous tension", etc. The Panel believes that such claims are inappropriate.

To protect the consumer from unforeseen and potentially hazardous claims, the Panel decided that the best labeling is one which states indications for use in simple, clear and easily understood language. The consumer would benefit greatly from such labeling. Therefore, the Panel recommends the restriction of the claims that may be made for analgesic-antipyretic products. The general indications statement "For the temporary relief of occasional minor aches, pains and headaches, and for the reduction of fever", is the most appropriate.

Since OTC drugs are meant to be used only for the temporary relief of symptoms, the labeling should not indicate or imply that the preparation is for the treatment of general conditions such as arthritis. This is especially important for preparations containing antirheumatic drugs, which if taken without medical supervision, may prevent or delay definitive treatment of arthritis which requires prior diagnosis by a physician, establishment of a proper antirheumatic dosage and concomitant or alternate therapy. Self-medication may lead to irreversible damage in inadequate dosage intermittently for pain relief over prolonged periods by individuals with some forms of arthritis. Since the most common forms of arthritis, rheumatoid arthritis and osteoarthritis, are chronic diseases, "temporary" relief by OTC analgesic doses is inappropriate therapy for these diseases. Therefore, the labeling of products containing salicylates should include the statement, "Take this product for the treatment of arthritis only under the advice and supervision of a physician."

For preparations containing the non-steroidal, e.g., aspirin, labeling should include the statement, "Do not take this product for the treatment of arthritis except under the advice and supervision of a physician."

The Panel has further determined that some of the current claims for specific conditions recognized by the medical community and found on OTC labeling and in product advertising are not amenable to self-diagnosis or treatment. Consumers with these conditions, such as several types of arthritis, gout, and acute rheumatic fever, should seek the care of a physician. The Panel believes that any labeling for diseases such as these which require medical intervention may mislead the consumer who attempts to self-diagnose and self-treat serious diseases. Therefore, the Panel strongly recommends that product names or labeling that imply or suggest the use of these products for specific diseases requiring prior diagnosis by a physician should not be allowed. Any reference to "arthritis", "arthritic strength", "arthritis pain formula", "rheumatism preparation", etc., in product names or labeling is unacceptable to the Panel. As will be noted in this document, the Panel concurs with the Arthritis Foundation's opposition to the term "arthritis" in aspirin brand names and also concurs with their recommendation that sufferers of arthritis consult their physician. Therefore, the Panel recommends that potential users be alerted to possible serious side effects of therapeutic doses and especially serious consequences of overdose.

Because OTC products can be purchased by anyone, it is the view of the Panel that the public generally does not regard these products as drugs, which, if used improperly, can result in injuries or potentially serious consequences. The public needs to be continually alerted to the idea that these products like all medicines carry some risk and should be treated with respect. The Panel, therefore, concurs with the Food and Drug Administration and considers it prudent to include the general warning statements now required under § 330.1(g).

The consumer should be informed of any possible signs of known toxicity or any indication that the use of the drug so that appropriate steps may be taken before more severe symptoms become apparent. For example, one of the first symptoms of salicylate intoxication, or overdose, is tinnitus or "ringing in the ears" which is discussed later in this document. (See part V, below—Analgesic-Antipyretics.) It is important for the Panel to recognize this symptom. With continued dosing, serious intoxication may occur due to the direct inhibition of salicylate metabolism.
PROPOSED RULES

For example, a small increase in the salicylate dose ingested may cause a dispropor- tionate increase in the salicylate blood level and could result in serious conse-
quences. Unfortunately, acetaminophen has no similar side effects. The Panel believes that the best advice to alert the consumer, further, some ad-
vertising for acetaminophen gives the impression that it is much safer than aspirin and implies that the toxic effects of the drugs are less than those en-
countered with aspirin. Actually, a large overdose of acetaminophen can result in serious liver damage which is not as amenable to therapy as salicylate intox-
ication. This is discussed later in this document. (See part III, paragraph B.1.b.
below—Acetaminophen.)

Therefore, the Panel decided to in-
clude the warning, “Stop taking this product if ringing in the ears or other
symptoms occur”, on all products con-
taining salicylates, and the warning, “Do not exceed recommended dosage because severe liver damage may occur” on all products containing
acetaminophen, a nonasalicylate.

Likewise, consumers should be alerted to possible serious side effects from therapeutic doses of these products. Some evidence suggests that aspirin might be contraindicated in pregnancy. (See part III, paragraph B.1.a. (2) (iv) below—Adverse effects during preg-
nancy.) Therefore, the Panel concludes that it is necessary to include the label-
ing warning statement on all aspirin-
containing products, “Do not take this product for a long period of time, i.e., more than 10 days in an adult, or more than 5 days in a child.
he or she is sufficiently ill to require the consultation of a physician. Therefore, the Panel added the word “temporarily” to the general indications statement making it read: “For the temporary re-
6lief of occasional minor aches, pains and headache, and for the reduction of fever”, and has added a general warning statement for adults, “Do not take this product for more than 10 days. If symp-
toms persist, or new ones occur, consult your physician”. Such warnings or cautions will be included in the proposed labeling for in-
dividual preparations presented later in this document.

REFERENCES

(1) Baum, J., “Rheumatoid Arthritis,” in “Current Therapy.” Edited by Conn, H. F.
D. LABELING WARNINGS, ADVERTISING AND THE MEDIA

Because the consumer needs to be cor-
rectly and fully informed, the Panel rec-
ommends that the drug be included in
any medium for these drugs that in any way uses the packaging, label or container not be consistent, even on subtle impli-
cation through mood, focus or context,
with the applicable labeling in the OTC
internal analgesic monograph.

The Panel has noted, with concern, certain aspects of commercial advertis-
ing of OTC analgesics that urge the con-
sumption of these drugs without directing
attention to adequate warnings re-
garding the possible immediate hazards of the use of these products or the poten-
tial hazards from their long-term use.

This concern was shared by repre-
sentatives of consumer and children’s
advocacy groups, by representatives of pharmaceutical firms and drug manu-
facturers, the broadcast media, and re-
searchers from the academic world at a
2-day conference on television OTC drug
advertising that was sponsored by the
comprising the conference the status of research, industry self-regulation, and
government regulation was discussed and
alternatives suggested; governmental
policy decisions were not formulated
(Ref. 1).

As was pointed out to the Panel, based
upon common sources of advertising in-
formation, the advertising expenditures
for internal analgesic drugs are greater
than for other OTC drug categories (Ref.
2). It was noted that analgesic promo-
tion in this country has reached a new
level of sophistication with advertising
references to whole new items such as
“file cabinet backache” or “camper
noise tension”. While the National Asso-
ciation of Broadcasters and the Propria-
tary Association representing many OTC
drug manufacturers have been active in
developing codes for the advertising of
nonprescription or OTC medicinals, the
Panel believes that government require-
ments for the inclusion of warnings and
cautions in the labeling of these drugs in particular as to possible effects of this advertising upon children (Ref. 2).

The Panel notes that the Food and Drug Administration has never regulated
the advertising of OTC drug products.
Therefore, the Panel asks that the pro-
per authority, i.e., the Federal Trade
Commission, with the full support and
active cooperation of the Food and Drug
Administration, more effectively regu-
late commercial advertising of internal
analgesic, antipyretic and antirheumatic
preparations on the basis of the labeling
recommendations contained in this doc-
ument. Further, the Panel strongly urges
the Federal Trade Commission to re-
quire that the cautionary language and
warnings developed by the Panel be given
emphasis in commercial advertising more
so than is currently being done, and
that special attention be given to the regu-
lation of OTC drug advertising on those
products designated as “nausea suppres-
sor” or similar terms, in those segments of the media which in most cases contain labeling

REFERENCES

(1) Transcript of Proceedings, Federal
Communications Commission/Federal Trade
Commission Conference, May 20 and 21,
1976.
(2) Cooke, Robert B., Presentation before
the FDA OTC Review Panel on Internal An-
algesics, March 17, 1976, copy of unpublished
paper is included in OTC Volume 061060.
E. STANDARD DOSAGE UNIT AND ANALGESIC
   EQUIVALENCE VALUE

1. Background. The Panel recognizes that currently the OTC drug market pro-
vides for many different products con-
taining a large variety of analgesic, anti-
pyretic and/or antirheumatic drugs. These products are marketed containing
either single ingredients or combinations
of active ingredients. A majority of these
products contain aspirin with variation
from product to product in the amount
of aspirin per dosage unit. Likewise, there
are many marketed products containing
nonasalicylate ingredients, e.g., acet-
aminophen, or derivatives of salicylic acid
other than aspirin, e.g., sodium salicylate,
which in most cases contain labeling
similar to that found for products containing aspirin. The Panel is concerned with the confusion that may arise when a consumer purchases such products.

To more fully inform the consumer as to the contents and therapeutic capabilities of these products as well as to minimize the hazard of confusion, the Panel recommends for these reasons and for reasons of safety described below, that products containing aspirin be clearly labeled on the principal display panel to indicate the presence of aspirin, that a standard amount of aspirin per dosage unit be established of 325 mg (5 gr) for all marketed products containing aspirin alone, as the single OTC analgesic-antipyretic active ingredient, and that labeling clearly indicate that the product contains the standard or a nonstandard amount of aspirin per dosage unit. The Panel has further determined that a standard dosage unit of 325 mg (5 gr) also be established for acetaminophen and sodium salicylate. It is the Panel's opinion that it is rational to establish standards, not only for aspirin, but for all three commonly used ingredients, thus enabling the consumer to more fully compare marketed OTC products.

2. Standard dosage unit. Aspirin is the most commonly used OTC drug in the United States. The majority of products marketed contain 325 mg (5 gr) aspirin. However, there are products marketed with less than 325 mg and some with 300 mg aspirin labeled as 5 gr. To most individuals these dosages are assumed to be standardized to contain 325 mg of aspirin. The apothecary weight of 1 gr is equivalent to the metric system measurement of 64.8 mg but is often approximated as equal to 60 mg. Therefore, a 5 gr aspirin dosage unit should actually contain 325 mg of aspirin. It is sometimes equated to 300 mg of active ingredient, thus making for a difference of 25 mg of aspirin.

A further factor contributing to a wide range in the amount of available aspirin is the provision of the United States Pharmacopoeia XIX to provide for a variation of ±5 percent of the labeled amount of aspirin per dosage unit (Ref. 1). The Panel recognizes this as an understandable requirement necessary for manufacturing purposes but is concerned with the potentially wide variation in the currently allowable 285 mg or 10 gr aspirin which, because of different interpretations of the "grain," varies for a labeled "5 gr product" between 285 mg and 340.2 mg aspirin from one marketed brand to another.

In dosage can cause a 40 to 60 percent increase in blood salicylate level over a period of time, which can produce a therapeutic response in patients who had not responded to a lower dose, or more importantly, result in an increase of dose-related systemic toxic effects (Refs. 2 and 3). Even those aspirin tablets commonly marketed in 300 mg or 325 mg dosage units, which usually permit variation of ±5 percent active ingredient per tablet as described above, when calculated to each extreme a low of 285 mg and a high of 349 mg for the 325 mg tablet, represent a 20 percent variation in dosage.

This could be a problem in the area of occasional minor aches and pains. A child who is instructed a parent to give a child half or quarter of an aspirin tablet, the child could, depending upon the strength of the tablet, be exposed to a potentially serious toxic dose of antipyretic (fever reduction) for an infant or small child this is especially hazardous because the young child cannot complain of tinnitus (ringing of the ears), one of the early symptoms of aspirin overdose. Further, the symptoms could progress to include fever, one of the later signs of salicylate intoxication (Ref. 4). The parent, noting that the fever has not subsided, may continue to give excessive amounts of aspirin, continuing a vicious cycle.

The Panel believes that the current availability of a variation of ±5 percent of aspirin per dosage unit is very confusing to the consumer. It is the opinion of the Panel that this availability has encouraged the myriad of claims such as "higher levels of pain reliever" or "arthritis strength" that are currently used. Of even more concern to the Panel is the fact that wide ranges in the amount of aspirin per dosage unit can result in either subtherapeutic or even toxic aspirin blood levels.

The Panel strongly recommends, based upon considerations of safety and effectiveness, that all products containing aspirin, acetaminophen, or sodium salicylate be standardized to contain and labeled to indicate either 325 mg (5 gr) per dosage unit for adults or 80 mg (1.23 gr) per dosage unit for children under 12 years of age.

The Panel recommends an adult oral dosage of 325 mg (5 gr) to 650 mg (10 gr) aspirin, acetaminophen, or sodium salicylate every 4 hours while symptoms persist not to exceed 4,000 mg in 24 hours. The Panel finds this dosage regimen safe and effective for the treatment of occasional minor aches and pains, headache, and fever indicated later in this document. The Panel believes that...
a standardized dosage unit of 325 mg (5 gr) is safe and effective when used as directed. More importantly, this adult oral dosage of 650 mg (10 gr) is the amount consumers believe they ingesting, i.e., two 325 mg (5 gr) tablets. However, the Panel recognizes the current availability of products containing an amount different than 325 mg (5 gr) per dosage unit. If the Food and Drug Administration is unable to implement the Panel's advice that products containing less than 325 mg aspirin, acetaminophen or sodium salicylate per dosage unit, the Panel recommends that products contain not less than 325 mg (5 gr) per dosage unit since this is the minimum effective dosage for adults. Since a single dosage greater than 650 mg (10 gr) is not commonly required by the general population, the Panel believes it rational to establish 650 mg (10 gr) as the upper limit for the quantity of drug to be included in a single dosage unit. Therefore, the Panel has defined nonstandard dosage units as dosage units containing less than 325 mg (5 gr) and not greater than 650 mg (10 gr) aspirin, acetaminophen or sodium salicylate. In addition, the Panel concludes that only nonstandard dosage units of 5 gr be recognized for acetaminophen in addition to the standard unit of 325 mg (5 gr) since the Panel is unaware of any other nonstandard dosage units currently available in marketed products containing acetaminophen as the single active ingredient. The Panel recommends that any product containing an amount different than 325 mg (5 gr) per dosage unit be clearly labeled as to the amount of active ingredient the product contains and any product containing more than 325 mg (5 gr) per dosage unit be labeled appropriately. "Contains nonstandard strength of X mg (X gr) aspirin per dosage unit compared to the established standard of 325 mg (5 gr) aspirin per dosage unit." A strength of 500 mg (7.69 gr) acetaminophen per dosage unit compared to the established standard of 325 mg (5 gr) acetaminophen" per dosage unit." On the other hand, "Contains nonstandard strength of X mg sodium salicylate per dosage unit compared to the established standard of 325 mg sodium salicylate per dosage unit." The actual amount of "X" for the specific product shall be used.

3. Analgesic-antipyretic recommended dosage. The Panel has defined the components of a dosage schedule below.

- The basis of the Panel's recommendation and conclusions are discussed elsewhere in this document. (See part II, paragraph F. below—Statement on Recommended Dosage Schedules.

a. Dosage Schedules. The Panel has examined the data submitted and finds for purposes of clarity that it is necessary to define the components of a dosage schedule which include a minimum effective dosage, a usual effective dosage range, a maximum single dosage, and a maximum daily dosage (24 hours). These components of a dosage schedule are defined by the Panel in relation to a general OTC target population seeking relief of symptoms, such as occasional minor aches, pains and headache, and the reduction of fever.

1. Minimum effective dosage. The minimum effective dosage is the amount of drug nec- essary to achieve the intended effect in some individuals in the general OTC target population.

2. Usual single dosage. The usual single dosage is the amount of drug necessary to achieve the intended effect in most individuals in the general OTC target population.

3. Usual effective dosage range. The usual effective dosage range is the amount of drug necessary to achieve the intended effect in most individuals in the general OTC target population.

4. Maximum single dosage. The Panel finds that there may be circumstances when more than the usual single dosage may be needed to provide an adequate effect. An increase in the usual single dosage may be needed, for example, by individuals who because of their large size (overweight or obesity) require a higher dosage. To meet this contingency, the Panel defines the maximum single dosage as the maximum amount of drug necessary when more than the usual single dosage is necessary and may potentially lead to toxic side effects.

5. Maximum daily dosage. The maximum daily dosage is the maximum amount of drug that is safe and effective for use in a 24-hour period. The Panel has established 4,000 mg as the maximum single safe and effective dosage for the standard drugs (aspirin, acetaminophen and sodium salicylate). The Panel does not believe that this maximum single dosage should be encouraged on OTC labeling, except as an initial dosage, as it may be subsequently used when more than the usual single dosage is necessary and may potentially lead to toxic side effects.

Recommended dosage schedule for standard and nonstandard aspirin, acetaminophen or sodium salicylate dosage units.

<table>
<thead>
<tr>
<th>Dosage unit</th>
<th>Initial dosage unit</th>
<th>Frequency</th>
<th>Dosage unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>(milligram)</td>
<td>(milligram)</td>
<td>(tablets/week)</td>
<td>(milligram)</td>
</tr>
<tr>
<td>325 (5)</td>
<td>2</td>
<td>2</td>
<td>325 (5)</td>
</tr>
<tr>
<td>650 (10)</td>
<td>1</td>
<td>1</td>
<td>650 (10)</td>
</tr>
<tr>
<td>1,000 (16.67)</td>
<td>1</td>
<td>1</td>
<td>1,000 (16.67)</td>
</tr>
<tr>
<td>2,000 (33.33)</td>
<td>1</td>
<td>1</td>
<td>2,000 (33.33)</td>
</tr>
<tr>
<td>3,000 (50)</td>
<td>1</td>
<td>1</td>
<td>3,000 (50)</td>
</tr>
</tbody>
</table>

1. The strength of dosage units that cannot be exceeded when dosage is initiated.
2. The number of dosage units per time interval.
3. The maximum total number of dosage units that cannot be exceeded in 21 hours regardless of the total number of dosage units taken or the frequency of repeated dosing.
4. The nonstandard dosage is not applicable to the standard dosage units since only the 500 mg (7.69 gr) nonstandard dosage unit is recognized by the Panel.
4. Analgesic equivalence value. Consumers may be perplexed not only by the variability of the quantity of an active ingredient per dosage unit, but also by any attempt to compare the relative potency of an active ingredient with other active ingredients. For example, if an individual normally takes a product containing 325 mg sodium salicylate and compares its label with the label of a product containing choline salicylate, unit-dosage systems may lead the user to take a total of 650 mg sodium salicylate but 870 mg choline salicylate. This may result in the mistaken notion that because more choline salicylate is taken there will be more of a therapeutic benefit, although 650 mg sodium salicylate is chemically equivalent in salicylate content to 870 mg choline salicylate.

The Panel reviewed the submissions for marketed "combination" products containing aspirin. The Panel found that of the submissions containing "combination" analgesic-antipyretic products, the aspirin content of the products varied from 194.4 mg to 650 mg per dosage unit with the total amount of analgesic ingredients ranging from 380 mg to 842.4 mg per tablet.

It is most important to measure the total amount of analgesic effectiveness for such combination products. While these submissions are not necessarily a representative sample of the dosage variations in all of the currently marketed OTC analgesic products, they represent the major products in this market and do in fact give some concept of the range of aspirin dosages currently available to consumers. This represents a confusing and potentially harmful situation, since consumers may substitute one brand of analgesic product for another containing different active ingredients, ignorant of the fact that there are differences in potency between brands, and inadvertently ingest either too much or too little of the product.

The Panel is concerned that current labeling for some products extols the virtues of different quantities of analgesics for pain relief with such claims as "adult pain formula," "extra added ingredients," or "arthritis formula." The consumer, faced with such different claims has no ready source to consult to determine the validity of these claims. Consequently, an analgesic product may be purchased with the mistaken notion, "if one ingredient is good, two or more are better.

In addition to the current-confusion, i.e., variable aspirin dosages, availability of many combinations of ingredients with and without aspirin, and many labeling claims, there is still another area of concern which involves the clinical evaluation of analgesics in general, i.e., increased blood levels of analgesics-antipyretics do not demonstrate an equivalent increase in the desired effect. The problem of trying to correlate analgesia with blood levels is discussed elsewhere in this document. (See part II, paragraph J, below—Effects of Product Formulations on Drug Absorption and Pharmacologic Effectiveness.)

Therefore, the Panel recommends that standard drugs (aspirin, acetaminophen and sodium salicylate) and standard dosage units of 325 mg (5 gr) be established. The analgesic equivalence to other drugs can then be compared as follows:

<table>
<thead>
<tr>
<th>OTC Analgesics</th>
<th>Equivalency Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 325 mg</td>
<td>1 gr/dosage unit</td>
</tr>
<tr>
<td>Drug</td>
<td>Comparison Drugs</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Aluminum aspirin</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>None</td>
</tr>
<tr>
<td>Sodium salicylate</td>
<td>Magnesium salicylate</td>
</tr>
</tbody>
</table>

The Panel believes that the current availability of so many different products containing derivatives of salicylic acid, other than aspirin or non-salicylate active ingredients with labeling claims similar to products containing aspirin is confusing and recommends that an analgesic equivalence value be established. This value would inform the purchaser as to the contents and therapeutic capabilities of these products and thereby benefit the consumer. The labeling should clearly describe the strength of the product as compared to the standard applicable dosage unit.

5. Labeling of products. Because of the many common side effects observed with the use of aspirin, as later in this document, the Panel recommends that all products containing aspirin be clearly labeled as containing aspirin on the principal display panel. Such labeling will not only benefit all consumers but will alert those individuals having a sensitivity to aspirin.

a. Products containing a standard drug in the standard dosage unit. (1) Aspirin. The Panel recommends that products containing 325 mg (5 gr) aspirin per dosage unit be clearly labeled on the principal display panel: "Contains standard strength of aspirin per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule. In the event that the Food and Drug Administration cannot implement this recommendation, the labeling shall state "Contains standard strength of aspirin per dosage unit".

b. Products containing a standard drug in an amount different from the standard dosage unit. (1) Aspirin. If the Food and Drug Administration is unable to implement this recommendation, the Panel recommends that products containing an amount of aspirin other than 325 mg (5 gr) aspirin per dosage unit be clearly labeled on the principal display panel: "Contains non-standard strength of X gr (X gr) aspirin per dosage unit compared to the established standard of 325 mg (5 gr) aspirin per dosage unit". The actual amount "X" of aspirin for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule. In the event that the Food and Drug Administration cannot implement this recommendation, the labeling shall state "Contains non-standard strength aspirin".

c. Products containing a standard drug in an amount different from the standard dosage unit. (2) Acetaminophen. The Panel recommends that products containing 325 mg (5 gr) acetaminophen per dosage unit be clearly labeled on the principal display panel: "Contains standard strength of aspirin per dosage unit".

(3) Sodium salicylate. If the Food and Drug Administration is unable to implement this recommendation, the Panel recommends that products containing an amount of sodium salicylate other than 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains standard strength of sodium salicylate per dosage unit".

Therefore, the Panel recommends that standard drugs (aspirin, acetaminophen and sodium salicylate) and standard dosage units of 325 mg (5 gr) be established. The analgesic equivalence to other drugs can then be compared as follows:

<table>
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<tbody>
<tr>
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<td>1 gr/dosage unit</td>
</tr>
<tr>
<td>Drug</td>
<td>Comparison Drugs</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Aluminum aspirin</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>None</td>
</tr>
<tr>
<td>Sodium salicylate</td>
<td>Magnesium salicylate</td>
</tr>
</tbody>
</table>

The Panel recommends that products containing 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule. In the event that the Food and Drug Administration cannot implement this recommendation under the current Federal Food, Drug, and Cosmetic Act, the labeling shall state "Contains standard strength of sodium salicylate per dosage unit".

Therefore, the Panel recommends that standard drugs (aspirin, acetaminophen and sodium salicylate) and standard dosage units of 325 mg (5 gr) be established. The analgesic equivalence to other drugs can then be compared as follows:

<table>
<thead>
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<th>OTC Analgesics</th>
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<td>Drug</td>
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</tr>
<tr>
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<td>Aluminum aspirin</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>None</td>
</tr>
<tr>
<td>Sodium salicylate</td>
<td>Magnesium salicylate</td>
</tr>
</tbody>
</table>

The Panel recommends that products containing 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of sodium salicylate per dosage unit".
REFERENCES


1. Statement on recommended dosage schedules

The Panel has defined the components of a dosage schedule elsewhere in this document. (See part II, paragraph E.3. above — Analgesic-anodylic recommended dosage.) The basis of the Panel's conclusions regarding recommended dosage schedules is the safe and effective use of any therapeutic agent in the choice of optimal dosage regimens. The need to carefully define and promote adherence to a safe dosage regimen is particularly important for aspirin and other salicylates for several reasons.

First is the alarming fact that a significant proportion of the serious salicylate toxicities including death are caused by inappropriate multiple dosing during therapeutic use rather than accidental or suicidal ingestion of large single dosages of salicylates (Refs. 1 through 4). Toxicities that result from overzealous multiple dosing during therapy are claimed to be more serious (Refs. 3 and 4) and said to occur at lower plasma salicylate levels than toxicities resulting from doses of aspirin (Ref. 5).

Secondly, the propensity for serious toxicities during multiple dosing can now be explained by the recent discovery that the salicylates are very unusual and complex pharmacokinetic characteristics. They are metabolized by processes which can be saturated by doses within the usual therapeutic range. As a result relatively small increases in the dose may exceed the capacity of the metabolizing systems and cause inordinate increases in salicylate plasma levels during multiple dosing.

A third problem in defining the dosage regimens is that aspirin is used extensively for several effects which may have different dosage schedules, e.g., antipyretic or antiphlogistic effect. Furthermore, these schedules must be adapted to several age groups in which the metabolic capacity may vary greatly.

Different dosage regimens for each type of therapy will also be required as a function of age, weight and other possible relevant variables.

Finally, the problem is further compounded by the large number of dosage forms and chemical derivatives which vary appreciably in the strength of the dosage form and recommended dosage schedules for different purposes. The multitude of strengths in currently marketed aspirin products presents a critical problem in the cases which have the potential for serious toxic effects when the wrong dosage is used. This can be partially overcome by designating a standard strength and standard dosage regimen which will provide the basis for assuring that each patient will be better informed.

In addition to the above considerations, the Panel received several opinions and recommendations regarding its proposed dosage schedules in response to the Panel's various public statements. The Panel's response to these opinions and recommendations are incorporated into this document.

b. Considerations of risk to benefit.

Ideally the evaluation of OTC drugs should be based upon benefit to risk considerations. The Panel, however, that there are no generally accepted protocols or procedures for the objective evaluation of the often cited but seldom quantitated "risk to benefit ratio." Unfortunately this phrase is usually employed to describe a subjective assessment rather than a real value, i.e., a number based on reproducibly quantifiable means.

The absence of a reasonable procedure that can be used to objectively compare the relative effectiveness and safety of different dosage forms and strengths of aspirin for arthritis, is particularly disadvantageous in the case of OTC salicylates. This is due partly because of the toxicity potential related to the dose dependent saturation kinetics of the salicylates and partly to the multiplicity of products which contain different amounts of aspirin, at different doses and different dosing regimens.

There is also no established procedure to address the fundamental question regarding appropriate criteria to determine if the potential risk exceeds the benefit when a product is used for self-medication, rather than under the supervision of a physician or other health professional. The Panel has attempted to address this question in terms of the need for additional types of specific monitoring of drug therapy that is required for safe use and whether this monitoring must be carried out by an individual with training beyond what can be conveyed to the average individual through labeling instructions.

The Panel used the following guidelines in an attempt to establish a systematic means for the evaluation of risk to benefit questions. Based upon certain assumptions discussed below semi-quantitative methods were used for benefit to risk considerations for the Panel's recommendations.

In response to the Panel's various public statements, the Panel received submissions, some of which represented conflicting views on several of the recommendations of the Panel including the need for a standard dosage, the use of aspirin for arthritis, and alternative dosage regimens for pediatric dosing and dosage regimens in which data to support the safety of larger dosages than those recommended by the Panel were presented. The Panel also received support for some of the recommendations of the Panel but suggesting that they should be more stringent. These submissions were considered by the Panel in the recommendations given in this document.

c. Correlation of dose to blood levels.

(1) Maximum salicylate blood levels. A maximum salicylate blood concentration, termed the steady state blood level, is reached and maintained after several repeated dosages at periodic intervals (dosage interval during multiple dosing). This steady state or plateau salicylate blood concentration correlates quite well with early signs of dosage related salicylate toxicity. Tinnitus (ringing in the ears) and deafness which are early signs of dose related salicylate toxicity, occur above a salicylate blood concentration of 20 mg/100 ml of plasma.

The correlation of salicylate blood levels with early signs of salicylism provides the basis for using the steady state blood level as a plasma level to compare the toxic potential of different dosage regimens. Single dosage and multiple dosage regimens should result in plasma salicylate levels which are below 30 mg/100 ml for 95 percent of the population. The mean steady state blood levels are determined by both the total daily dosage and the hourly dosage rate.

The steady state salicylate blood level is a function of the total daily dosage and the average dosage rate throughout the day. Different dosage schedules, e.g., 650 mg every 4 hours or 275 mg every 6 hours can be adequately characterized and compared in terms of the total daily dosage and average hourly rate which is the usual maintenance dosage divided by the dosage interval.

(2) Standard dosage. The standard upper limit of the Panel's recommended dosage regimen for aspirin is 650 mg every 4 hours for six dosages which is within the upper limit of 4,000 mg maximum total daily dosage and 167 mg/hour average hourly dosage rate. The Panel considered this to be the maximum safe dosage for the general population. Dosage regimens exceeding either this total daily dosage or mean hourly rate provide a significantly greater risk without a compensating therapeutic benefit. A single dosage of 975 mg or greater brings about only additional benefits to a few individuals without significant additional risk. Repeated dosing at this level can lead to plasma concentrations in the range where more than 5 percent of the population probably experiences tinnitus.

(3) Nonstandard dosage. Nonstandard single ingredient salicylate products containing nonstandard amounts per dosage unit should provide dosage instructions limiting the number and dosage regimens such that the total daily dosage and mean hourly rate do not exceed the standard.
In the Panel's opinion, single active ingredient salicylate products which contain nonstandard amounts per dosage unit provide a greater potential for confusion and are more likely to produce a toxic effect or therapeutic effect, respectively, in 50 percent of the subjects. Strength, dosage rates specified so as not to exceed daily dosage rate to produce a toxic and therapeutic effect, respectively, in 50 percent of the target population and therapeutic and nonstandard dosage schedules are stated in terms of the initial starting number of dosage units, the number of dosage units per time interval and the maximum total dosage units per day (24 hours).

(i) Hourly dosage rate. Because of the unusual nonlinear kinetics of salicylates, some changes in dosage schedules which are similar to those in the usual pharmacokinetic and clinical studies providing adequate blood level data at different dosage, dosage intervals or different body weights. In many studies, the dosage regimens are given in different units such as daily dosage/subject that have been used to evaluate comparative risk to benefit ratios for drugs. Listed below are those formulas that are applicable to the evaluation of an optimal dosage regimen for a given indication or relative risk to benefit ratio for different therapeutic indications, e.g., use for general analgesic effect compared to use for anti-inflammatory in rheumatoid arthritis.

\begin{align}
E & = \text{minimal therapeutic dose} \\
M & = \text{maximal tolerated dose} \\
D & = \text{Di} = \text{Qt-2 S.D.} \\
Tc & = \text{DE} = \text{QE+2 S.F.} \\
\text{Dosage rate producing toxicity to 2.5 pct of subjects} & = \text{Dose effective to 97.5 pct of subjects} \\
\text{Qt and QS are defined as the median dosage rate to produce a toxic effect, respectively, in 50 percent of the subjects. Di and DE could be a single dosage or multiple dosages where different dosages are given for a specific duration at fixed dosage intervals. This concept is extended in this document to include any multiple dosage rate (dosage/time) given for a sufficient time to reach steady state or the steady state salicylate plasma levels which correspond to toxic or therapeutic effects.} \\
\text{Di} & = \text{Qt-2 S.I.} \\
\text{DE} & = \text{QE+2 S.E.} \\
\text{Qt and QS are defined as the dosage to produce a toxic and therapeutic effect, respectively, in 50 percent of the subjects. S.I. and S.E. represent the standard deviation of the distribution of the toxic or effective dosage respectively, which is usually considered to be log normally distributed. Thus Qt-2 S.I. will represent the dosage that will produce toxic effects in 2.5 percent of the target population, and QE+2 S.E. represents the dosage to produce a desired therapeutic effect in 97.5 percent of the target population. The addition of the urinary loss function of Selndermen et al., as a method to define the optimal dosage which minimizes a loss index (L) and is defined in terms of a "loss" due to the toxicity (q_t) and a loss due to failure to cure (q_c) in which q_t and q_c are equated using a weighing factor (\lambda) thus:} \\
L = (1-\lambda)q_t + \lambda q_c \\
\text{Pharmacokinetic relationships. (1) A relationship between dosage and plasma concentration for most drugs there are linear relationships between the plasma concentration and the variables of the dosage regimen, mg, kg, 24 hours. The complex nonlinear characteristics of the salicylates negate these assumptions, however, and care must be taken in extrapolating from one dosage regimen to another or using the same dosage regimen in individuals of different age or size. Because of the complex pharmacokinetic characteristics of the salicylates, comparison and adjustment of multiple dosage regimens must be based upon substantial experimental data.} \\
\text{Unfortunately there are relatively few carefully controlled multiple dosage studies providing adequate blood level data at different dosage, dosage intervals or different body weights. In many studies, the dosage regimens are given in different units such as daily dosage/m² or mg/kg/24 hours without sufficient additional data on individual characteristics to allow exact conversion to comparable units. Differences in the number of days the dosage regimen was administered and the types of patients (rheumatoid arthritis) compared to normal subjects also made some published data difficult to assess.} \\
\text{Nevertheless, there are data from pharmacokinetic and clinical studies which provide a firm basis for establishing a safe and effective dosage regimen recommendation consistent with the usual pharmacokinetic characteristics of the salicylates. Thus:} \\
\text{The basis of these studies reviewed below, the Panel established standard and nonstandard dosage schedules. The schedules shown below reflect the Panel's recommendations initial and maintenance dosage of 350 mg (5 gr), a maximum initial single dosage of 975 mg (15 gr) to be used only once, and a maximum maintenance dosage of 650 mg (10 gr) every 4 hours (standard) or in the case of nonstandard dosage forms dosage instruction schedules designed so as not to exceed a maximum hourly rate of 167 mg/hour and a total maximum daily dosage of 4,000 mg. The dosage schedules are stated in terms of the initial starting number of dosage units, the number of dosage units per time interval and the maximum total dosage units per day (24 hours).}
strictly true, the apparent rate of elimination is quite constant at the dosages and corresponding plasma concentrations where toxicity begins to occur, i.e., above 200 mg/100 ml. The following simple model correlates quite well with the published data:

\[ A = D/\gamma - M \]

where \( A \) is the rate of accumulation of drug in the body per unit time (hour or day); \( D/\gamma \) is the dosage rate per unit time (hour or day); and \( M \) is the maximum elimination rate per unit time.

The more detailed model of Levy (Refs. 7 through 10) was also used by the Panel in computer simulations. Levy and coworkers have extensively studied the problem of saturable metabolism. They have explained many of the apparent discrepancies in the literature using computer simulations based upon the average values of kinetic parameters describing saturable metabolism obtained experimentally from healthy volunteers. These simulations indicate that simply by increasing the daily dosage by 50 percent from 2 to 4 g daily as four equal doses every 6 hours, the total level of drug in the body at steady state will increase from 1.3 g to 5.3 g, a 400 percent increase (Ref. 7).

They also show that the time to reach the steady state plateau increases with dosage levels in the OTC range. Their simulations show that a dose of 0.5 g (7.5 g) when given every 8 hours will reach a constant maximum level of salicylate in the body (plateau level) of less than 0.5 g after 2 days of dosing. However, if two tablets were taken every 8 hours, the amount in the body would continue to increase for at least 7 days reaching a total body load six times greater than that reached in the one tablet dosage.

After careful consideration of the various risk factors discussed above, the Panel developed the following table for standard and nonstandard dosage units:

**Relation of dosage unit, frequency and hourly dosage rate**

<table>
<thead>
<tr>
<th>Dosage unit 1 (mg gr)</th>
<th>Initial dosage units 2 (mg)</th>
<th>Frequency 3 (tablets/hour)</th>
<th>Dosage unit 1 (mg)</th>
<th>Hourly dosage rate 2 (mg/hour)</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 (5)</td>
<td>1 to 2 (800 to 1600)</td>
<td>1 after 4</td>
<td>12 (3,000)</td>
<td>3 (750)</td>
</tr>
<tr>
<td>300 (7.5)</td>
<td>1 to 2 (1200 to 2400)</td>
<td>1 after 3</td>
<td>18 (4,500)</td>
<td>3 (750)</td>
</tr>
<tr>
<td>400 (10)</td>
<td>1 to 2 (1600 to 3200)</td>
<td>1 after 2</td>
<td>24 (6,000)</td>
<td>3 (750)</td>
</tr>
<tr>
<td>500 (12.5)</td>
<td>1 to 2 (2000 to 4000)</td>
<td>1 after 1</td>
<td>30 (7,500)</td>
<td>3 (750)</td>
</tr>
<tr>
<td>600 (15)</td>
<td>1 to 2 (2400 to 4800)</td>
<td>1 after 2</td>
<td>36 (9,000)</td>
<td>3 (750)</td>
</tr>
</tbody>
</table>

1 The amount of aspirin contained in a single dosage unit (tablet).
2 The maximum number of dosage units (tablets) that cannot be exceeded when dosage is initiated.
3 The maximum total number of dosage units (tablets) (mg) that cannot be exceeded in 24 hours, regardless of the initial number of tablets taken or the frequency of repeated dosing.
4 The amount of aspirin contained in a single dosage unit (tablet) taken at each time interval divided by the number of hours in a time interval gives the hourly dosage rate.

(ii) Other factors increasing risk. It is emphasized that the upper dosage level of 4,000 mg aspirin daily for a limited period of time (7 to 10 days) may frequently be below the optimal adult daily dosage required for anti-inflammatory effects in patients with rheumatoid arthritis but above that needed by the vast majority of "normal" adults for occasional use as an analgesic and antipyretic agent. This upper dosage was selected by the Panel as the upper limit above which a significant risk of toxicity increases dramatically in the majority of the target population. Furthermore, in some individuals other factors may increase the risk of exceeding salicylate plasma concentrations that are considered safe.

Any factors, such as diet, diuretics or other drugs which may affect the acidity of urine will be greatly magnified at the 4,000 mg daily dosage level. Levy and Leonards (Ref. 11) found the average salicylate plasma concentration of 13 normal adults receiving 1 g aspirin four times daily (4,000 mg daily) for 7 days was 15.0 mg/100 ml plasma (standard deviation is 4.6) if urine pH was kept above 6.3 by administration of sodium bicarbonate. When urine pH was allowed to fall to the usual range below 6 (5.6 to 6.1), the average plasma salicylate levels increased to 27.0 mg/100 ml (standard deviation is 7.9) which is above the desired level to avoid ototoxicity.

It should be noted that the plasma salicylate level of 27 mg/100 ml but not the level of 15 mg/100 ml would usually be suitable for treatment of rheumatoid arthritis. Thus, subtherapeutic levels might occur in patients who were adjusted to a dosage satisfactory at normal pH levels but greatly reduced if the patient also was taking antacids which increase the urine pH. For this reason, Levy and Leonards, (Ref. 11) recommend that in the 15 mg/100 ml dosage level of rheumatoid arthritis the urine pH should be routinely monitored particularly if antacids are being taken.

The data of Brewer (Ref. 12) illustrate several points which form the basis of the Panel's recommended dosage schedule. In this study, 32 children ranging in age from 2 to 15 years with rheumatoid arthritis (mean age 9.4 years) were given a dosage of aspirin based upon the body surface area. A dose of 600 mg/m² aspirin was given every 4 hours for four doses and no drug was administered during the night. During the first 12 hours this hourly dosage rate (200 mg/hour/m²) resulted in a mean increase in the steady state plasma concentration from 35 mg/100 ml at 8 a.m. to 48 mg/100 ml at 8 p.m. Thus, the net plasma concentration accumulation rate (A) was +10 mg/L/hour during a dosage input of 30 mg/kg over the maximum mg/L/hour during zero input. Therefore, during dosing the values of the equation, (dC/dt) Vd = D/\gamma - M, are (10 mg/L/hour) Vd = 200 mg/hour/m² - Vm, and (M) = -10 mg/L/hour/Vd = Vm. The apparent volume of distribution (Vd) can be calculated from the equation 210 mg/L/hour/Vd = 200 mg/hour/m². Therefore, Vm = 100 mg/hour/m². If the mean dosing rate exceeds 100 mg/hour/m², the plasma concentration will not reach a plateau but will continue to increase during dosing for the entire 10-day dosing period.

It is important to note that the maximum safe rate determined in this study for an average adult of 1.73 m² surface area was 1.73 mg/hour. This is only slightly higher than the upper hourly rate recommended by the Panel.

The Brewer study also illustrates the effect of using a dosage regimen in which the hourly dosage rate for part of the day even though the total dosage is below the critical daily dosage. The hourly rate was 200 mg/hour/m² for 12 hours during the day and reduced to 100 mg/hour/m² for the remaining 12 hours. The rate was zero. Although the mean hourly rate was 100 mg/hour/m², the daily dosage is also just below the maximum rate. The increased hourly rate in the first 12 hours results in a plasma accumulation from 38 mg/100 ml, the upper desired therapeutic level for rheumatoid arthritis, to 46 mg/100 ml which is in the potentially toxic range because the dosage used by Brewer was on the average just equal to the mean maximum elimination rate for this group.

It would be expected therefore that the maximum individual elimination rates will be just above and below this standard dosage input rate and therefore the range multiple dose plasma concentration will be very large. This is in fact the case. The plasma levels range from 14 mg/100 ml to 62 mg/100 ml at 8 a.m. and 27 mg/100 ml to 77 mg/100 ml at 8 p.m. for this dosage regimen.

For these children, the mean dosage calculation from body weight was 32.8 mg/kg (standard deviation is 5.3), and therefore, the ratio of body weight to surface area was 53.2 kg/m² (standard deviation is 5.3). Therefore the mean maximum dosage per kg of body weight for this group would be.
PROPOSED RULES

100 mg/hour/m² = 4.5 mg/hour/kg of
23.7 kg/m² = 33.5 mg/kg

(4.5/33.5 mg/kg) = 8.45
(2) = 4.2 mg/hour/kg or 101.4 mg/kg/day.

From the study of Makela et al. (Ref. 13), it is clear that use of body weight to determine the dosage in children can be misleading and lead to toxicity because the ratio of body weight to surface area changes with different age groups. The average kg/m² ratio for this group of children was 23.7 kg/m² but would be about 40 kg/m² for an adult. When surface area is used to calculate the equivalent dosage for adults a maximum hourly input rate for a 70 kg adult (1.73 m²) would be 173 mg/hour which is in good agreement with the maximum hourly rate (167 mg/hour) recommended by the Panel. If body weight is used to calculate the adult dosage, the corresponding dosage would be 7,000 mg/day or 280 mg/hour.

Dosage forms which contain more than 10 gr must be taken at intervals which will generally not sustain blood levels unless the plasma levels are above 20 mg/100 ml (Ref. 14). They are therefore justified only for treatment of rheumatoid conditions under the direction of a physician. Most of the sustained release type microspheres do not significantly prolong the release of the drug. The plasma sustained levels are more a result of the prolonged duration in the body rather than delayed release during absorption (Ref. 15).

The change of dosage interval with constant daily and hourly dosage rates. Because of limited published data, the Panel used analog and digital computer simulations to study the effect of increasing the dosage interval when the dosing rate every hour.

Relationship between dosage and dosage interval (with constant daily and hourly dosage rates) to steady state concentration.

From these simulations, it appears that as long as the total daily dose and the mean hourly dosage regimen are kept constant, reasonable increases in the dosage interval of 3 to 8 hours will not greatly increase the total maximum and minimum body load of salicylates at steady state. As the dosage interval is increased from 3 to 8 hours, the difference between the total maximum and minimum amounts of salicylate in the body is less than 10 percent providing the dosage per dosage interval is also increased. The dosage interval of 8 hours was therefore selected as the single dosage which produces salicylate plasma levels (6 mg/100 ml to 10 mg/100 ml) comparable to those achieved by the maximum dosage (325 mg) in a standard multiple dosage regimen known to be effective and free of major side effects. Thus, the maximum single dosage will produce rapid increase in plasma levels in multiple dosing which can be maintained by smaller dosages of 325 to 650 mg given every 4 hours.

Leonards (Ref. 15) found that comparable plasma salicylate levels of less than 10 mg/100 ml were produced by administration of 1,300 mg (20 gr) aspirin in three different ways. A total of 1,300 mg was given as a single dosage of one 1,300 "sustained release" capsule, a single dosage of four 325 mg tablets and two dosages of two 325 mg tablets (650 mg) given 4 hours apart.

The maximum plasma concentration time curves following one 1,300 mg dosage were similar for the sustained release product and the large dosage of regular aspirin. Thus, the microsphere aspirin product did not produce a sustained plasma level due to a prolonged release or decreased absorption rate but simply because of saturated elimination which occurs independent of the product used.

The larger single dosage resulted in a greater total area under the plasma time curve than the divided dosage. The increase in the total area under the plasma time curves even though these regimens have the same total dosage and hourly dosages illustrates the effect of saturable metabolism which augments plasma levels from a large single dosage compared to the usual 650 mg (10 gr). The plasma concentrations were essentially the same, 8 hours after the initial dosing in both cases. Eight hours after the initial dosing, both regimens resulted in essentially identical plasma levels of about 5 mg/100 ml. This may indicate that a dosage schedule of one 1,300 mg (20 gr) capsule every 8 hours could possibly produce blood levels that would be probably equivalent to blood levels produced by a standard dosage regimen of 650 mg (10 gr) dosage every 4 hours since the hourly rate is the same 167 mg/hr. Although the final plasma concentrations are similar, the increased area under the curve for the higher dosage may indicate potential differences in this two regimens. Additional data on the mean plasma levels and variability about the mean after several days of multiple dosing are required before the 1,300 mg (20 gr) capsule can be considered a safe dosage form for OTC analgesic and antipyrptic use. The Panel is concerned that while this dosage form may be appropriate for treatment of conditions requiring high dosages such as arthritis, it offers no advantage in the treatment of pain or fever. It lacks flexibility when adjusting dosages.
(2) Relationship between plasma concentration (and dosage) and toxicity. Although it has not been possible to establish the plasma levels of aspirin or salicylic acid required for analgesic effects, estimates are available on the blood levels associated with several types of toxic effects.

The levels of aspirin following usual dosages of 600 mg are relatively low (2 mg/100 ml) and decline rapidly (half-life about 20 to 40 minutes). Aspirin levels have not been correlated with toxicity. Plasma levels of salicylic acid, however, correlate well with probability of toxicities.

Tinnitus is the most frequent and reliable symptom of salicylate levels of about 20 mg/100 ml. Other early symptoms of salicylism include deafness, headache, vertigo, vomiting and hyperventilation. Above 30 mg/100 ml, irritability and psychosis may occur. Above 60 mg/100 ml, vomiting and hyperventilation. Above 90 mg/100 ml, delirium and convulsions may occur (Ref. 16). A target concentration of 20 mg/100 ml for the treatment of rheumatoid arthritis is usually sought of 20 mg/100 ml for the treatment of adults while, children can often tolerate doses 200% higher (60 mg/100 ml). In the treatment of rheumatoid arthritis, but monitoring for toxicity is essential (Refs. 17 and 18). Children often develop more serious symptoms (deafness, hyperventilation) before experiencing tinnitus (Refs. 13 and 17).

Done found a very poor correlation between serum salicylate concentrations at the time of admission and the severity of salicylate intoxication (Ref. 19). The serum salicylate concentrations were extrapolated back to the time of ingestion (65), assuming a half-life value of 20 hours (0.05945 hours) and a much better correlation was observed. Of additional significance was the fact that the correlations were similar for both children and adults indicating that serum salicylate concentrations may provide a reasonable basis for comparing the potential of different dosage regimens to produce toxicities in adults and children.

The reversible effects of salicylates on hearing function are the most useful indicators of toxic salicylate serum levels. Although permanent hearing loss has occurred with the use of salicylates (Ref. 20), this is relatively uncommon. Since the major symptoms of effects are rapidly reversible and correlate quite well with individual plasma levels of the population who are already deaf, the incidence of tinnitus and common reversible hearing loss are the most reliable and earliest indicators of potentially toxic doses.

Salicylates can produce two effects on hearing function which is ear-splitting sensation, and deafness which involves a reversible loss of pure tone sensitivity affecting all frequencies. Both effects correlate with individual serum salicylate concentrations.

Progressive loss of the sensitivity to hear pure tones was demonstrated in volunteers receiving doses of three tablets (975 mg) every 4 hours (244 mg/hour) for 4 days (Ref. 21).

Simlar' effects of increasing aspirin dosage on actual hearing loss were studied by Myers et al. (Ref. 22). Auditory brainstem responses were measured before and after administration of aspirin to 25 patients.

Myers et al. found that a dosage of 5,000 to 8,000 mg daily was usually necessary to produce tinnitus and subject hearing loss (Ref. 22). In patients with normal hearing, high salicylate concentrations produced a bilateral hearing loss of 20 to 60 decibels in frequencies which were reversible in all patients within 3 to 10 days.

Hearing loss did not occur below salicylate plasma concentrations of 20 mg/100 ml. Seventeen of 43 patients experienced hearing loss of more than 10 decibels (30 to 40 decibels in most) when salicylate concentrations were above 20 mg/100 ml. The hearing loss increased as plasma levels increased. Usually, hearing loss reached a maximum at 40 mg/100 ml.

The median dose at which tinnitus occurs was 4.5 g daily, with a range of 2.4 to 6.0 g in a study by Ropes (Ref. 23) and at 5.3 g in the study by Mongan et al. (Ref. 24). Neither tinnitus nor deafness occurs at salicylate levels below 30 mg/100 ml in adults or children indicating that serum salicylate concentrations much better than with the use of salicylates, it is appropriate to determine and compare the toxicity potential of different dosages and dosage regimens required for analgesic and antipyretic effects.

Although it has not been possible to relate analgesic effect to plasma salicylate concentrations, it is possible to determine the plasma salicylate concentrations that are attained with the dosages known to produce analgesia. Since plasma salicylate concentrations much better than with the use of salicylates, it is appropriate to determine and compare the toxicity potential of different dosages and dosage regimens required for analgesic and antipyretic effects.

The maximum salicylate plasma levels which are achieved with recommended multiple dosages with all different types of salicylates are less than 15 mg/100 ml (Refs. 15, 26, 28, and 27). Even the highest possible effective single dosage, 1300 mg (20 gr), doesn't usually result in plasma levels which exceed 15 mg/100 ml (Ref. 15). Thus, 20 mg/100 ml is both the lower toxic limit and the concentration which should not be exceeded with multiple dosing of 650 mg every 4 hours or the equivalent. However, repeated administration of aspirin 650 mg at the usual dosage interval will accumulate in the body to produce higher concentrations that can be expected to produce toxic symptoms in a significant number of the population, i.e., greater than 5 percent of the population.

(4) Relationship between plasma concentrations and anti-inflammatory effect in rheumatoid arthritis. In contrast to analgesic and antipyretic effects, the suppression of inflammation increases with the dosage of salicylates even beyond the point of toxicity (Ref. 28). Mills states that the therapeutic objective is to employ as large a dosage as possible short of toxicity and the most common reason for therapeutic failure is use of inadequate dosage.

The usual target concentration tolerated by most patients is the range of 20.0 to 25.0 mg/100 ml. This is the region where small increases in dosing can result in very large increases in plasma levels. Special directions must be given.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
to the patient and, depending on the dosage and condition, special monitoring for adverse effects may be required and therapeutic dosing must be determined for each patient.

Fremont-Smith and Bayles (Ref. 29) gave increasing dosages of salicylates to 11 hospitalized patients with rheumatoid arthritis over a period of 5 days until the largest tolerated dose was reached. In most cases the increase was stopped because of auditory effects, either tinnitus or deafness, which occurred at an average daily dosage of 5.2 g. Fremont-Smith and Bayles established that salicylates can produce an important anti-inflammatory effect in rheumatoid arthritis which was in addition to the analgesic effect. This effect, which could be quantified by decreased joint size, measured by standard jewelers rings, or grip strength, was rapidly reversed when subtherapeutic doses were administered. These authors concluded that all patients with rheumatoid arthritis, whether mild or severe, should receive salicylates regularly in the largest tolerated dosages. The average maximum tolerated dosage was 5.2 g.

Boardman and Hart (Ref. 30) compared placebo with prednisone, paracetamol, high doses of salicylate (5.3 g daily), and low doses of salicylate (2.6 g daily) administered in multiples of 10 mg tablets given in four equal dosage daily for 7 days followed by 7 days rest. Therapeutic response was objectively measured by the occurrence of predefined significant changes in joint size, grip strength and also subjectively by patient preference. A significant change in joint size (4 mm or more over 7 days) was produced by high doses of salicylates but not by low doses of salicylate, paracetamol or placebo. Changes in joint size, compared sequentially with placebo, proved the most objective measures of assessing the anti-inflammatory effect of a salicylate or prednisone as a drug known to have anti-inflammatory effects but not significant direct analgesic effects. It is significant that the drug therapies with analgesic, but not anti-inflammatory, effects may be most effective that would result from any attempts of untrained layman to determine and monitor an individual dosage regimen required to maximize the great potential anti-inflammatory effects adequate to suppress inflammation and minimize the great potential risk from only slightly higher dosages which can cause serious toxicity.

In summary, on the basis of pharmacokinetic considerations, the Panel concludes that there is an abundance of published literature which clearly establishes that self-medication of even minor symptoms of rheumatoid arthritis constitutes irrational therapy. There is a lack of evidence that an analgesic therapy that would result from any attempts of untrained layman to determine and monitor an individual dosage regimen required to maximize the great potential anti-inflammatory effects adequate to suppress inflammation and minimize the great potential risk from only slightly higher dosages which can cause serious toxicity.

The available literature clearly shows that in the case of rheumatoid arthritis, aspirin should not be used simply to relieve symptoms but rather to actively treat the disease by giving individualized dosages adequate to suppress inflammation. Because of the unusual pharmacokinetic characteristics of the salicylates only recently recognized, the determination of the appropriate dosage for rheumatoid arthritis requires skilled professional assistance. Furthermore, dosages and duration of therapy required for adequate therapeutic treatment are determined by the patient and dose titrated to the dosage for unsupervised OTC dosing. Many factors must be considered beyond the capability of the general population and indeed requiring skilled clinical judgment and assessment.

In some cases, careful monitoring is required involving clinical laboratory tests, such as determination of plasma salicylate concentration, liver function tests and urine pH, which are not accessible to or interpretable by the untrained general public.

The Panel, therefore, believes that any labeling which encourages unsupervised treatment of rheumatoid arthritis even for relief of "minor symptoms" constitutes an unacceptable risk. The Panel recognizes that because of the large dosages required over a long period of time, it would create an unnecessary economic hardship to require a prescription status for the use of salicylates in the treatment of rheumatoid arthritis. By analogy, insulin can be purchased by diabetics without a prescription for medically supervised use. It would be illogical to require the labeling directions or promotional material to encourage the target population to determine the dosage to relieve their symptoms or attempt to monitor the effects of their drug treatment or their disease progress without laboratory testing and supervision by a physician.

REFERENCES


cylate in Patients with Rheumatoid Arthritis. "


2. Statement on standard and non-standard non-salicylate dosage schedules.

The components of a salicylate dosage schedule also apply to a nonsalicylate dosage schedule. (See part II. paragraph E.3.a. above—Analgesic-antipyretic recommended dosage for the use of aspirin, a salicylate, in standard and nonstandard dosage units, were discussed above by the Panel. The Panel also considered dosage schedules for the use of acetaminophen, a nonsalicylate, in standard and nonstandard dosage units.

There was much less information available to the Panel on the pharmacokinetics of acetaminophen in animals and man than of aspirin. Therefore, however, there is good evidence that the pharmacokineti-
cics of this drug are simpler than those for aspirin, and acetaminophen probably shows linear kinetics. However, the Panel finds it reasonable to recommend the use of acetaminophen in the same dosages as those recommended for the use of standard aspirin dosage units, i.e., 325 and 650 mg. (See part II. paragraph E.3.b. above—Recommended dosage for products containing standard dosage units.)

Of particular concern to the Panel in considering the possibility of increasing the dosages of acetaminophen was the paucity of data regarding the toxic effect of acetaminophen from single dosages that exceed the dosages recommended for products containing standard dosages of 325 and 650 mg longer than the 5-day interval in children or the 10-day interval in adults, or from dosages that exceed the maximum adult daily dosage of 4,000 mg. Elsewhere in this document the Panel has discussed the toxicity of acetaminophen and its relationship to dosage level. (See part III. paragraph B.1.b.2 below—Safety.)

While data based on increasing the standard dosage of acetaminophen was the Panel also considered dosage schedules currently in use by the practicing physician.

While not included in the example for aspirin in Pediatric Schedule C, the Panel has included appropriate pediatric dosage recommendations for acetaminophen, aspirin, and other drugs. (See part II. paragraph E.3.c above—Recommended dosage for products containing nonstandard dosage units.)


a. Introduction. The Panel has reviewed OTC drug labeling for currently marketed products containing aspirin. The Panel finds that there is a lack of a single recognized pediatric dosage schedule. Initially, the Panel attempted to compile a pediatric dosage schedule based upon common features of dosage schedules presently found in the labeling of marketed pediatric products. This representative dosage schedule is given below in Pediricec Schedule B.

The Panel also sought comments from the drug industry, through the industry liaison panel member, regarding a recommended pediatric dosage regimen for aspirin products. One drug manufacturer (Ref. 1) submitted data containing a review of the medical literature regarding pediatric dosage schedules for aspirin, survey information on the aspirin dosages currently used by practicing pediatricians, and data pertaining to the pharmacology and pharmacodynamics of aspirin dosages through consultation with pediatric clinical pharmacologists. In addition, a new regimen was proposed by the drug manufacturer discussed below as Pediatric Schedule B.

To support the submission, data and comments were submitted that the currently labeled OTC pediatric dosage schedule (Pediatric Schedule A) is inadequate (Ref. 2). It was stated that the dosage in the labeling is too low particularly in the youngest age group. Because of this, therapeutic failure may cause consumers to either exceed the labeled dosage or repeat dosing before the recommended 3-hour interval. This may result in the problem of overdosing. This new dosage schedule was proposed to prevent the problem of overdosing by initiating treatment with an adequate dosage and then repeating after 4 hours to maintain the desired effect.

The Panel further modified this proposal (Pediatric Schedule C) which is discussed more fully below. It should be further noted, that based upon a review of the use of aspirin in children, the Panel also considered the pediatric dosage schedules for acetaminophen, aspirin, and other drugs. While not included in the example for aspirin in Pediatric Schedule C, the Panel has included appropriate pediatric dosage recommendations for other category I ingredients, where applicable, in the appropriate sections of this document.

b. Discussion. The following dosage schedule based upon current recommendations given on many aspirin-containing products currently marketed for OTC use, was initially considered by the Panel:

Pediatric schedule A—representative current pediatric dosage schedule on marketed products for 81 mg (125 pt) aspirin tablets

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of tablets taken</th>
<th>Total dosage (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 3</td>
<td>1</td>
<td>81</td>
</tr>
<tr>
<td>3 through 6</td>
<td>2</td>
<td>162</td>
</tr>
<tr>
<td>6 through 10</td>
<td>3</td>
<td>243</td>
</tr>
<tr>
<td>10 through</td>
<td>4</td>
<td>324</td>
</tr>
</tbody>
</table>

As directed by physician

As was pointed out by one drug manufacturer, this dosage schedule was selected primarily on the basis of safety considerations to assure minimal potential for toxicity, particularly in the youngest group (Ref. 1).

In a survey of 2,241 pediatricians regarding the current pediatric dosage schedule on marketed products of as-
The published results of two studies comparing the antipyretic effect of a single dosage of acetaminophen with the antipyretic effect of a single dosage of aspirin were also submitted to the Panel (Refs. 10 and 11). The comparison was made in children between the ages of 6 months and 72 months (6 years). For the purposes of this study the same dosages of acetaminophen and aspirin were approximately the same as the aspirin dosages. For example, the dosages for children 30 to 48 months of age in one study were 225 mg and 210 mg, respectively (Ref. 10). In the second study, the dosage for children 30 to 42 months of age was 180 mg for both aspirin and acetaminophen (Ref. 11). These pediatric dosage schedules have been recommended dosages for this age group in the labeling of marketed aspirin-containing products.

The Panel appreciates the desirability of standardizing the percent of the adult dosage required for different age ranges. Ideally, it would be advantageous to establish the pediatric dosage for a given age range as the same percent of the adult dosage as for drugs commonly used together. The Panel recommends that when these agents have similar changes in pharmacokinetic and dose-response characteristics as a function of increasing age. When two or more therapeutically active agents are used which do not have proportional changes in their dosage requirements for children in different age groups, fixed combinations may not be suitable for pediatric use. In some cases, the dosage of one or both agents may be different in the combination than when used alone. The dosage regimen would have to be adjusted relative to the agent of highest potential toxicity. The pediatric dosing regimen as a percent of the adult dosage regimen is listed below. The pharmacokinetic basis and clinical data supporting the recommended dosage regimen are reported elsewhere in this document. (See part II, paragraph F.1. above—Statement on standard and nonstandard salicylate dosage schedules.)

As noted above, the Panel originally considered the currently used dosage regimen for marketed products (Pediatric Schedule A) but later considered industry's proposed regimen (Pediatric Schedule B) because the doses in the former are too low at lower ages. The latter schedule was based essentially upon the commonly used daily pediatric dosage of 65 mg/kg of body weight with a maximum of five dosages daily. It is commonly stated that this dosage is equivalent to 1.5 g/m² daily dosage schedule based upon surface area. This is strictly true only at the ages (years) when the average surface area is 1.5 m². It is significant to note that after the age of 7 years, dosages based upon body weight will be greater than dosages based upon surface area.

The increasing deviation of body weight per age curve from the surface area per age curve may result in overdosing toxicity particularly in older the most accurate predictor for dosage. This effect is clearly shown in the data of Makela et al. (Ref. 12) in which 100 mg/kg daily was administered every 8 hours. This dosage regimen generally resulted in plasma levels of more than 35 mg percent which is adequate for patients with rheumatoid arthritis but excessive for antipyretic activities. Additionally, it is of the 19 subjects (37 percent) toxicity occurred which was calculated with plasma levels of more than 35 mg percent (37.3 mg percent to 48.3 mg percent). In 50 percent of toxic cases, the patient was 11 years of age or older and weighed more than 40 kg. The 100 mg/kg schedule, therefore, is not suitable if it results in a schedule in which 3.0 g/m² daily is exceeded since every toxic case received dosages of more than 3.0 g/m² daily while those who were nontoxic received a dose of 2.4 g/m² daily.

This study illustrates several important points. First, body surface area is probably the most accurate predictor for dosage. There are two other reasons why the Panel believes that body surface area should be the standard means of calculating the salicylate dosage. The reason that the prediction that can be better done by dosing on the basis of surface area rather than body weight is clear from basic pharmacokinetic data. Accumulation of drugs and toxicity occurs when dosage input exceeds maximum output. Levy has shown that maximum output of salicylic acid, the primary metabolite, is formed at a maximum rate (Vmax) which is proportional to body surface area (Ref. 13). Even though all subjects in the Makela study received usual rheumatoid arthritis dosage schedules of 100 mg/kg, salicylate levels were too high because at age 12 years and over, when weight per age curve from the surface area per age curve was used, the dosage prescribed was too low at younger ages. The published results of two studies comparing the antipyretic effect of a single dosage of acetaminophen with the antipyretic effect of a single dosage of aspirin were also submitted to the Panel (Refs. 10 and 11). The comparison was made in children between the ages of 6 months and 72 months (6 years). For the purposes of this study the same dosages of acetaminophen and aspirin were approximately the same as the aspirin dosages. For example, the dosages for children 30 to 48 months of age in one study were 225 mg and 210 mg, respectively (Ref. 10). In the second study, the dosage for children 30 to 42 months of age was 180 mg for both aspirin and acetaminophen (Ref. 11). These pediatric dosage schedules have been recommended dosages for this age group in the labeling of marketed aspirin-containing products.

The Panel also considered the dosage of salicylates for individuals 12 years and over as equivalent to adult dosages, a concept accepted by the Advisory Review Panel on OTC Cold, Cough, Allergy, and Pain Relieving Products, as published in the Federal Register of September 9, 1976 (41 FR 38419). This would conform to the dosage schedules for other therapeutic agents which are used in combination with salicylates. The Panel concludes that because of the unusual pharmacologic characteristics of the salicylates, an adult dosage schedule would not be reasonable for children under 12 years of age. The data of Makela et al. (Ref. 12) clearly establishes the potential for overdosing in children weighing more than 40 kg if dosages based upon surface area were used. Therefore, the Panel set a dosage for this age group of 10 to 15 mg/kg of body weight every 4 hours as needed was the preferred dosage schedule.

The medical literature lists many methods of calculating dosages based on either age, body weight or body surface area. Some methods have utilized the body weight of the child in a pediatric dosage schedule proposed for pediatrics in the United States Pharmacopeia XIX is 11 mg/kg of body weight (66 mg/kg/day) for 40 mg/kg/m² of body surface area per age, six times daily (1.5 g/m²/day), to 16 mg/kg of body weight (64 mg/kg/day) or 375 mg/m² (1.5 g/m²/day), of body surface, four times daily (Ref. 4). In this latter case, the official commensal regimen is based on patient parameters likely to be understood by the consumer and in the Panel's view is inadequate for product labeling. However, as noted later, dosage by age is not stochastic to dosages calculated by surface area up to age 12 years. Therefore, age can be used to indicate dosages based upon surface area calculations.

One drug manufacturer (Ref. 1) stated: "We recommend as effective (Refs. 6 through 12) and is similar to that found in the dosage for body weight recommendation of the United States Pharmacopeia XIX.

The Panel considered the following pediatric dosage schedule proposed by industry:

### Pediatric Schedule B—drug industry proposal for pediatric dosages of 81 mg (1.25 g) aspirin tablets

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Number of tablets</th>
<th>Total dosage (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 9</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>2 through 5</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>6 through 6</td>
<td>7</td>
<td>11</td>
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<tr>
<td>7 through 9</td>
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<td>12</td>
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<tr>
<td>9 through 12</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>11 through 12</td>
<td>10</td>
<td>18</td>
</tr>
<tr>
<td>13 and older</td>
<td>12</td>
<td>24</td>
</tr>
</tbody>
</table>

1. Not to exceed 5 dosages in 24 h except under the advice and supervision of a physician.
2. As directed by physician.

3. As directed by physician.
children from ages 3 to 12 years. Body weight is a nonlinear function of age, however, in ages over 7 years. This explains the preference of the majority of clinicians for a dosing system based upon age.

Based on these pharmacokinetic considerations and clinical data, the Panel has revised the industry proposed schedule (Pediatric Schedule B) to conform with a daily dosage of 1.5 g/m² daily rather than 65 mg/kg daily. These two methods produce similar values at ages below 8 years. However, in ages over 6 years, the Panel's recommended schedule (Pediatric Schedule C) and the industry proposal occur mainly at higher age levels where weight is not the best predictor of dosage.

The Panel concludes that the dosage should never exceed 2.5 g/m² daily (approximately 100 mg/m²/hour). Therefore, the dose of 1.5 g/m² daily will provide effective plasma levels for analgesic should never exceed the Panel's recommended schedule (Pediatric Schedule C) and the industry proposal occur mainly at higher age levels where weight is not the best predictor of dosage.

The Panel concludes that the dosage should never exceed 2.5 g/m² daily (approximately 100 mg/m²/hour). Therefore, the dose of 1.5 g/m² daily will provide effective plasma levels for analgesic should never exceed the Panel's recommended schedule. This conventional unit of dosage is approximated from ages 2 to under 12 years by the relationship:

\[\text{mg/day} = 650 \text{ mg} + (100 \text{ mg/year of age})\]

It is important to note that the use of the full maximum daily adult dosage at 12 or 13 years of age may exceed the critical dose rate toxicity level. The total daily dosage (calculated divided by the usual body weight should be about 2.5 mg/kg/day which is equal to the lower level of the toxic level found by Makuda (Ref. 12).

For children age 11 to 15 years, a 25 percent difference in dosage increase from 2.4 ± 0.2 g/m² daily dosage to 3.2 ± 0.5 g/m² daily will increase the plasma concentration from 25 to 29 mg/100 ml to 40 mg/100 ml. For children 4 to 7 years, a similar increase in dosage will result in a change of 20 to 25 mg/100 ml at the lower dosage to a plasma concentration of 500 mg/100 ml.

The dosages established are based upon the 1.5 g/m² daily dosage for that age as described by Done (Ref. 19). Under the Panel's proposed schedule, the age minimum for OTC use is lowered to 2 years and the frequency of administration is increased by 1 hour to every 4 hours. The Panel concludes that this dosage schedule is more reasonable than that currently being used. The Panel further concludes that the regimen is safe and effective and is much clearer and more concise for the OTC drug consumer.

It should further be noted that, based upon a review of the use of aspirin in children, the Panel also considered and included a pediatric dosage schedule for acetaminophen in Pediatric Schedule C which applies to all dosage forms, e.g., tablets, liquids, etc. For these ingredients, the Panel has included appropriate pediatric dosage recommendations for Category I ingredients, where applicable, in the appropriate sections of this document.

PROPOSED RULES

After consideration of the data and submitted comments, the Panel recommends the following pediatric dosage schedule for aspirin and acetaminophen:

Pediatric Schedule C—the Panel's proposed (new) pediatric dosage schedule

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Dosage units</th>
<th>Total dosage (mg)</th>
<th>Adult (25g) dosage units</th>
<th>Total dosage (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 2</td>
<td>2</td>
<td>150</td>
<td>1</td>
<td>180</td>
</tr>
<tr>
<td>2 to under 6</td>
<td>5</td>
<td>250</td>
<td>1</td>
<td>290</td>
</tr>
<tr>
<td>6 to under 9</td>
<td>400</td>
<td>110</td>
<td>1</td>
<td>120</td>
</tr>
<tr>
<td>9 to under 12</td>
<td>450</td>
<td>115</td>
<td>1</td>
<td>130</td>
</tr>
</tbody>
</table>

1 Not to exceed 5 single doses in 24 h or be used for more than 5 days except under the advice and supervision of a physician.

2 Not to exceed 5 single doses in 24 h or be used for more than 5 days except under the advice and supervision of a physician.

3 There is no recommended dosage except under the advice and supervision of a physician.

C. Conclusion. In view of these findings, the Panel concludes that it is appropriate to revise the reviewed OTC pediatric dosage recommendations. In its evaluation, the Panel adopted the definitions of the Advisory Review Panel on OTC Cold, Cough, and Antihistaminic Products, as published in the FEDERAL REGISTER of September 9, 1976 (41 FR 38419): "Infant or baby (under 2 years), child (2 years to under 12 years), and adult (12 years and over)."

The Panel further concludes on the basis of the available data on the use of aspirin in children, that the duration of use for all OTC analgesic products should be limited to 5 days for children under 12 years of age rather than 10 days as recommended for adults. It is the opinion of the Panel that this restriction should also apply to acetaminophen to avoid confusion in the labeling of pediatric products. Therefore, labeling should contain the following warning: "Do not take this product for more than 5 days. If symptoms persist, or new ones occur, consult your physician". This recommendation is based upon reports from data available from poison control centers that suggest a large incidence of aspirin overdose among children for periods longer than 5 days. This is also consistent with computer simulations, which demonstrate that while using the maximum daily recommended dosage, the plasma concentration could exceed 20 mg/100 ml among some smaller children of a particular age category following the recommended dosage schedule after 5 days.

The Panel concludes that the pediatric dosage unit of 80 mg (1.23 gr) of aspirin should be retained because there is long standing acceptance. One, two, or three pediatric units can easily be obtained by quartering or halving a standard 325 mg aspirin tablet, and surface area gain and age of children correlate closely over the first 12 years of life, permitting a regular increase in dosage according to age. Therefore, the Panel reasons that dosage by square meters of body surface alone would be more accurate, it believes that basing pediatric dosage recommendations on age will be more readily understood by the average consumer. This recommendation is implemented by the Food and Drug Administration, there will be of necessity an interim marketing period at which time both the old Pediatric Schedule A and new Pediatric Schedule C will be simultaneously available to the OTC drug consumer. The Panel recommends that the Food and Drug Administration establish an orderly process to reduce the likelihood of confusion in interpreting product labeling. Perhaps the improved labeling can be clearly identified as "new" or "revised" on the traditionally marketed products that consumers are accustomed to purchasing.

The Panel has examined the regulations of the Poison Prevention Packaging Act of 1970 as set forth in 16 CFR 1700.150, (b) and (c) of the regulations, that provide for poison prevention packaging standards for aspirin-containing products in a dosage form intended for oral administration. The standards for child-resistant safety closures required on the containers of these products are intended to protect children from intentional or accidental ingestion without hampering the adult-use effectiveness of the products. The Panel concurs with these standards and is of the opinion that the standards for child-resistant safety closures should apply to all the containers in which aspirin-containing oral products are packaged as well as aspirin-containing products.

The Panel further recommends that the restrictions on the maximum number of tablets permitted in containers of aspirin products for child use should also apply to acetaminophen products formulated for use in children only. Therefore, acetaminophen products containing 60 mg (1.23 gr) tablets intended
for oral use in children should contain no more than 36 tablets to reduce the hazard of accidental ingestion. (See part V. paragraph B.1. below—Category I Labeling.) Two major types of combination products were considered by the Panel. One of these types consists of combinations of analgesic and/or antipyretic active ingredients reviewed for safety and effectiveness by this Panel. The other group is composed of combinations of analgesic and/or antipyretic active ingredients combined with active ingredients having different pharmacologic activities, such as antihistamines or diuretics. In this second group of combination products, the Panel only reviewed the rationale of combining nonanalgesic-nonantipyretic active ingredients with analgesic-antipyretic active ingredients. The nonanalgesic-nonantipyretic ingredients were deferred to other OTC Advisory Panels for a review of their safety and effectiveness. (See part I. paragraph C.3. above—Ingredients deferred to other OTC advisory review panels or other experts.) The Panel is not opposed to the concept of combinations of active ingredients which have been shown to be individually safe and effective, provided that the specific combination has been shown to be at least as safe and effective as therapeutic doses of the individual active ingredients. For example, if two active ingredients A and B, with similar pharmacologic activity, are combined such that each is combined at one half the usual therapeutic dose when used alone, the combination (AB) should be at least as safe and effective as the full therapeutic dose of either A or B when used alone. It should be noted that for the drugs reviewed by this Panel three variations are possible. The variations would include combinations of analgesics, combinations of antipyrretics or an analgesic-antipyretic combination. However, the Panel has found that the active ingredients submitted for review and classified as analgesics are unacceptable. Therefore, even though three different variations are possible, in reality, the ingredients currently available all possess analgesic activity, as antipyretics. In the event that at a later date ingredients are identified as having one of these pharmacologic activities, the Panel believes that the drug combination standard should provide for all possible safe and effective combinations of active ingredients and for all acceptable labeling. Therefore, the concept of combining analgesics and antipyretics or of analgesics-antipyretics is acceptable. The marketplace is filled with a variety of single ingredient analgesic-antipyretic products, and many of these ingredients are also present in combination products. The Panel has found that the concepts used to explain the reasons for marketing combination products have not yet been supported by adequate clinical data. The Panel concludes that combinations must be safe, effective and rational in order to be included in the proposed drug monograph.

An OTC drug may combine two or more safe and effective ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and adequate warnings of safe use, provides rational concurrent therapy for a significant proportion of the target population.

The Panel recognizes the regulation and believes that each active ingredient in a combination product must contribute to the claimed effect(s) and that the combination provides rational concurrent therapy. It is the view of the Panel that it is irrational to use a combination product unless each of its active ingredients contributes to the effective treatment of at least one of the labeled symptoms for which the combination of ingredients is recommended. The specific combination should be at least as safe and effective as the therapeutic doses of the individual active ingredients when used alone.

The Panel recognizes the safety and effectiveness studies are desirable, especially, when it becomes known or suspected that one of the drugs in the combination may influence the metabolism or the action of another drug. However, Category I ingredients, known to be individually safe and effective, may be combined as described below in Standard No. 4.

2. Limitation of Ingredients in Combination Products. The Panel recognizes that, in general, an OTC product with fewer ingredients provides safer use. Also, the interests of the consumer are best served by exposing the user of OTC drugs to the smallest number of ingredients possible at the lowest possible dosage regimen consistent with a satisfactory level of effectiveness. The possibility of adverse reactions increases with the number of drugs ingested resulting in potential increased risk to the user without a concurrent increase in benefit. Therefore, with fewer ingredients there is a better chance of avoiding toxic effects, undesirable additive or possibly synergistic effects, allergic and/or idiosyncratic reactions.

The Panel recommends that not more than two active analgesic-antipyretic ingredients from Category I be included in any combination without further study unless the addition of a third analgesic-antipyretic ingredient can be demonstrated to contribute to the effectiveness or safety of the combination. This does
not preclude the use of adjuvants or correctives which are discussed later in this document. See part VI below - Adjuvants and Corrective Agents. The Panel bases this conclusion, not only on the fact that fewer ingredients generally provide safer use, but also on the fact that no combination was submitted to the Panel containing three Category I analgesic-antipyretic active ingredients. In addition, the Panel can find no data to support the combining of more than two analgesics in the same product. Therefore Category I combinations are limited to combinations of two analgesic-antipyretic ingredients. (See part II, paragraph G.4. below - Standards for Category I combination products.)

The Panel is aware of the inclusion of inactive ingredients (pharmaceutical necessities) in the preparations for use as preservatives, fillers, coatings, colorants, vehicles, aromatics, binders, sweeteners, flavoring agents, etc. Such inactive ingredients are acceptable for marketing purposes provided they are pharmacologically and do not adversely affect the bioavailability of the active ingredient(s). However, the Panel is of the opinion that such pharmaceutical necessities be studied by a separate body for the evaluation of their safety and attention needs to be given to the effects of these pharmaceutical necessities on children. The Panel considers it important that the advisability of including them in drug products be reviewed by an appropriate body. Since many of these inactive ingredients are used in the formulation of many drug products other than those reviewed by this Panel, it is not appropriate that they be dealt with specifically and solely in relation to analgesic, antipyretic and antihistaminic active ingredients, except as they might affect the actions of these active ingredients.

Nonanalgesic-nonantipyretic active ingredients may be included in products only if safe and effective at doses and either provide relief for symptoms designated by this or other panel(s) or beneficially influence the actions of the active ingredient(s). In summary, marketed combination products should contain only those active and inactive ingredients that are rational for a safe and effective product as described above.

The Panel concurs with the following conclusions of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antihistaminic Products, as published in the Federal Register of September 9, 1976 (41 FR 38341), regarding the labeling of inactive ingredients:

For various reasons, individuals may wish to avoid using certain inactive ingredients found in these marketed products and may therefore prefer to make a choice in this regard unless the full contents of drug products are listed on the label. Therefore, this Panel strongly recommends that the Food and Drug Administration require full ingredient labeling of inactive as well as active ingredients in descending order of quantities present in all drug products.
causes an increase in occult bleeding and in some individuals massive gastrointestinal bleeding. The adverse effects of long-term use of aspirin on the gastrointestinal tract are discussed elsewhere in this document. (See part III. paragraph B.1.a.(2) (i) below—Adverse effects on the gastrointestinal tract.)

1. Aspirin may be combined with antacid active ingredient(s) identified in § 331.11 of the OTC antacid monograph such that the finished product contains at least 1 g/lb of acid neutralizing capacity per 325 mg (5 gr) aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 381.25 of the OTC antacid monograph and provided the product is identified as buffered aspirin with labeling only as an analgesic and/or antipyretic: "For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever".

In addition, the Panel classified the following as Category III labeling which may be included on the principal display panel:

(1) "Provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes, and is not to be taken by certain individuals with stomach disorders as cautioned elsewhere on the label".

(2) "Faster to the bloodstream than plain aspirin"

The Panel has discussed the above Category III labeling elsewhere in this document. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.)

5. Standards for Category II combination products. a. Combination products containing a Category II analgesic-antipyretic or Category II labeling, except for the inclusion of caffeine used as an adjuvant, are classified as Category II. The classification and role of caffeine is discussed later in this document. (See part VI. paragraph B.3. below—Caffeine (citrated caffeine).)

b. Combination products containing Category I analgesic-antipyretic(s) combined with any active ingredient(s) not reviewed by this or other OTC advisory review panels or found to be either unsafe or irrational are classified as Category II.

c. Aspirin in combination with any generally recognized as safe and effective oral bronchodilator active ingredient is classified as Category II. Aspirin may cause a severe, and possibly fatal reaction in some asthmatics taking such a product. This adverse effect is discussed later in this document. (See part III. paragraph B.1.a.(2) (iii) below—Adverse effects on hyperresponsive individuals.)

d. Combinations of analgesics with laxatives, or vitamins, or minerals, and provided the combination is intended for general use only since any conditions requiring such drugs should not be treated by fixed-ratio combination products. Conditions requiring treatment with such drugs should be treated with such ingredients. Vitamins combined with analgesic may encourage unnecessary prolonged use of analgesics and are therefore classified as Category II.

6. Standards for testing Category II combination products. a. Combination products containing a Category III analgesic-antipyretic active ingredient and no Category II analgesic-antipyretic active ingredient are classified as Category III.

b. Combination products containing any Category I analgesic-antipyretic active ingredient at least at the minimum effective dosage are classified as Category III.

c. Combination products containing more than two analgesic-antipyretic active ingredients are classified as Category III. (See Standard No. 4.b. above.)

d. One Category I analgesic-antipyretic active ingredient or a combination of two such ingredients as provided above in standard No. 4.b. combined with a suitable target population requiring treatment with this active ingredient or a combination of two such ingredients as provided above in standard No. 4.b. combined with caffeine is classified as Category III.

e. One Category I analgesic active ingredient or a combination of two such analgesic ingredients as provided above in standard No. 4.b. combined with a generally recognized as safe and effective nighttime sleep-aid active ingredient is classified as Category III provided the product is labeled for the concurrent symptoms involved, e.g., "For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever, and for the relief of occasional sleeplessness". The Panel concludes that there are insufficient data available to evaluate the adjuvant effect of caffeine. The Panel finds that there is little evidence to show that this ingredient contributes to analgesic, antipyretic and/or antirheumatic effects in the clinical situation. Additional studies are necessary as described below in this document. (See part VI. paragraph C.2. below—Combination products containing an analgesic, antipyretic and/or antirheumatic adjuvant.)

f. One Category I analgesic-antipyretic active ingredient or a combination of two such ingredients as provided above in standard No. 4.b. combined with phenyltoloxamine (or methapyrilene fumarate, phenyltoloxamine maleate or pyrilamine maleate) used as an adjuvant is classified as Category III.

The Panel concludes that there are insufficient data available to evaluate the adjuvant effect. The Panel finds that there is inadequate data to show that these ingredients contribute to analgesic, antipyretic and/or antirheumatic effects in the clinical situation. Additional studies are necessary as described below in this document. (See part VI. paragraph B.4. below—Antihistamine-containing ingredients.)

7. Standards for testing Category III combination products. The Panel concludes that additional testing is required for Category III combination products. Since aspirin is considered as a standard for all drugs in this class, all combinations must demonstrate at least as much analgesic and/or antipyretic as 325 mg (5 gr) to 650 mg (10 gr) of aspirin in a single dosage unit. (2 dosage units) the recommended maximum dosage of 4,000 mg in 24 hours.

To establish Category I status for a Category III combination product requires a minimum of two studies by independent investigators which conform to the standards and guidelines included and discussed above for ingredients for which safety is unquestioned. (See part II. paragraph B.2. above—Safety and part II. paragraph G.4. above—Standards for Category I combination products.) If the ingredient is placed in Category III for reasons of safety, at least two, 3-month safety studies by independent investigators should be required. This requirement does not apply to antipyretic. (See part III. paragraph B.3.b.(5) below—Evaluation.)

Each study should include an appropriate number of subjects, a placebo, known drug active ingredient, and the appropriate intervals of administration of the drug in question to controlled subject populations in whom side effects can be checked daily, and where applicable to specifically cited organ function tests are checked weekly or more often if necessary.

Clinical studies should be pertinent to each of the symptoms for which the combination is designed to give relief. The combination, a placebo, and each active ingredient alone should be subjected to well-controlled, suitably-blinded studies to determine both units, e.g., salves, and actions or significant side effects, and effectiveness. In addition, where provided, objective methods should be employed as described elsewhere in this document. (See part III. paragraph B.3. below—Category III conditions for which the available data are insufficient to permit final classification at this time, and part IV. paragraph B.3. below—Category III conditions for which the available data are insufficient to permit final classification.
H. Drug Interactions With Analgesic, Antipyrretic, and Antirheumatic Agents

Numerous reports have indicated possible harmful interactions between salicylates and other drugs (Refs. 1 through 5). The Panel is concerned that the average individual using these agents, particularly aspirin, will consider the OTC drug innocuous and not realize the possibility of a drug interaction.

The Panel is aware that instances exist where individuals suffering from serious illness or other medical conditions are instructed by their physician to use OTC analgesics, antipyretics or antirheumatic drugs.

The Panel is also aware that many other individuals experiencing illnesses with OTC medications, antipyretics or antirheumatics on their own volition to alleviate pain, fever or inflammation. These individuals may not be aware of possible interactions between the salicylates, aspirin in particular, and prescription drugs.

Therefore, the Panel recommends that the labeling caution against the concurrent use of salicylates and some prescription drugs without consulting a physician. The Panel concludes that the warning on products containing salicylates should read “Caution: Do not take this product if you are presently taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis except under the advice and supervision of a physician”.

This salicylate drug interaction warning is based upon the concept that maintenance drugs prescribed for certain chronic illnesses or conditions may interact with salicylates, most often aspirin. A discussion of aspirin effects of comonitant use with other drugs or by persons with specific disease is discussed elsewhere in this document (Part II, paragraph B.1.a.(viii) below).—Adverse effects of concomitant use with other drugs or by persons with certain disease states.

The prescription drugs used in the treatment of these chronic illnesses and the drug interactions with salicylates which are hazards are as follows:

1. Cardiovascular diseases. Individuals with heart disease or other circulatory diseases who are currently taking anticoagulants, specifically of the coumarin type, will experience increased anticoagulation when large doses of salicylates, especially aspirin, are ingested. This phenomenon is due to depressed prothrombin formation in the liver and the displacement of the anticoagulant from secondary binding sites. These mechanisms may lead to severe hemorrhage unless the dosage of the anticoagulant is reduced or the individual ceases taking the OTC aspirin.

2. Diabetes. Individuals taking oral antidiabetic drugs concurrently with salicylates may experience an additive hypoglycemic (low blood sugar) effect due to displacement of the antidiabetic drugs from protein binding sites. This can result in poor control of diabetes. (Ref. 5).

3. Gout. Individuals with gout have high serum uric acid levels. Several drugs are prescribed for gout to decrease uric acid blood levels. These drugs include probenecid, the sulfinpyrazone and allopurinol.

Probenecid and salicylates interfere with two kidney processes, i.e., secretion of uric acid by the distal tubule and reabsorption of uric acid by the proximal tubule. The result of taking both drugs at the same time depends on which process is predominant. At usual OTC doses, retention may be affected resulting in uric acid retention with a decrease in probenecid effects (Ref. 5).

In individuals receiving probenecid for gout therapy the effects of this drug are altered by salicylates because these agents when given with probenecid inhibit uric acid excretion by competing for active transport mechanisms in the proximal and distal tubules of the kidney.

Also, when analgesic doses of salicylates are taken concurrently with sulfinpyrazone the uricosuric effects are antagonized, and the effect of sulfinpyrazone is diminished (Ref. 5).

When phenylbutazone is taken with salicylates, uric acid retention results. This occurs because the phenylbutazone reduces reabsorption of uric acid and salicylate for excretion from the kidney. This combination of drugs produces mutual suppression of uricosuric action, thus negating any therapeutic benefit. Since both drugs are ulcerogenic, the possibility of gastrointestinal bleeding is increased (Refs. 1 and 5).

4. Arthritis. Certain individuals who suffer from arthritis have corticosteroids prescribed for them to relieve inflammation. Sometimes these individuals also take salicylates, especially aspirin, for the analgesic and antiinflammatory effects. However, if corticosteroids and salicylates are taken together, the ulcerogenic effect on the mucous membrane of the stomach, their combined use may be serious, sulfonamides are usually used for treatment of acute infections not for chronic conditions and thereby do not merit inclusion in the warning. Another interaction occurs between salicylates and drugs used to acetyde the urine since acidic urine decreases the excretion rate of salicylates and thus increases their half-life (Refs. 4 and 5). Also, salicylates taken with phenylbutazone result in small increase in urine acidity when high doses of aspirin are used. Conversely, urine alkalinizers (Refs. 3 and 4) decrease activity of salicylates by increasing the excretion rate. While these interactions demonstrate an interaction, the Panel does not consider them enough of a hazard to justify inclusion in the warning. When salicylates are taken with ascorbic acid (vitamin C), the salicylates accumulate in the blood due to decreased salicylate excretion and ascorbic acid excretion rate is increased (Ref. 5). This interaction is probably not important since it is unlikely that the ascorbic acid-salicylate interaction will result in toxic salicylate levels in the blood.

Reference


I. Definitions

The Panel has adopted and uses the following definitions throughout this document:

1. Acetaminophen analgesic equivalence value. The analgesic effectiveness for a product containing acetaminophen when compared to the standard acetaminophen 325 mg (5 gr) dosage unit.

2. Acetaminophen (pediatric dosage unit). A single dosage unit containing 60 mg (1.23 gr) acetaminophen for children under 12 years.
3. Acetaminophen (standard dosage unit). A single dosage unit containing 325 mg (5 gr) acetaminophen.

4. Adjuvant. An agent which, in the amount used, has no significant analgesic effect itself but contributes to the therapeutic effect of the active agent either directly or indirectly.
   a. Direct acting. An adjuvant which enhances the pharmacologic response directly by synergistic or additive effects at the site of action.
   b. Indirect acting. An adjuvant which does not have effects at the site of action, but indirectly increases the activity of the active agent(s) of the preparation by modifying the disposition (absorption, metabolism, excretion or distribution) of the active agent.

5. Age (dosage) usage. Infant or baby (under 2 years), child (2 years to under 12 years), and adult (12 years and over).


7. Antacid. An agent that reacts with acid, such as the hydrochloric acid in the stomach (gastric acid), to neutralize it (decrease its amount).

8. Antipyretic drug. An agent used to reduce fever.

9. Antirheumatic drug. An agent which reduces joint or muscle tenderness or swelling.

10. Aspirin analgesic equivalence value. The analgesic effectiveness for a product containing aspirin or aspirin salts, e.g., aluminum aspirin or calcium carbasyprin when compared to the standard aspirin 325 mg (5 gr) relief time-acting formula.

11. Aspirin (buffered). A solid dosage form containing 325 mg (5 gr) aspirin with sufficient buffering capacity with antacid active ingredient(s) identified in § 331.11 of the OTC antacid monograph such that the finished product contains at least 1.9 mg of acid neutralizing capacity per 325 mg of aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of the OTC antacid monograph and provided the product is identified as buffered aspirin with the information only as an analgesic, and/or antipyretic.

12. Aspirin (highly buffered) for solution. A solid dosage form to be dissolved in water prior to oral administration as a solution. The product shall contain 325 mg (5 gr) aspirin and sufficient buffering capacity with antacid active ingredient(s) identified in § 331.11 of the OTC antacid monograph such that the finished product contains at least 20 mg of acid neutralizing capacity per 325 mg of aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of the OTC antacid monograph and provided the product is identified as highly buffered aspirin with labeling only as an analgesic and/or antipyretic.

13. Aspirin (pediatric dosage unit). A single dosage unit containing 80 mg (1.23 gr) aspirin for children under 12 years.


15. Bioavailability. The rate and extent of absorption as determined by the measurement of the blood levels of the parent drug and/or its active metabolites relative to a standard product. The standard product chosen must be one which has been demonstrated to be safe and effective.


17. Sodium salicylate analgesic equivalence value. The analgesic effectiveness for a product containing sodium salicylate or other salicylates, e.g., choline salicylate, magnesium salicylate, or salicylate when compared to the standard sodium salicylate 325 mg dosage unit.

18. Sodium salicylate (standard dosage unit). A single dosage unit containing 325 mg sodium salicylate.

J. EFFECTS OF PRODUCT FORMULATIONS ON DRUG ABSORPTION AND PHARMACOLOGIC EFFECTIVENESS.

1. General Comment. Analgesics, antipyretic and antirheumatic drugs are the major nonprescription OTC medications. Of these medications, aspirin is most commonly taken. These products may be purchased in a wide variety of dosage forms which may affect their absorption and ultimately their pharmacologic effectiveness. The Panel recognizes that these drugs are intensively promoted through labeling and advertising with a myriad of claims including "fast pain reliever", "long-lasting pain reliever", "enhanced relief of pain", "night-time pain reliever", "faster to the bloodstream", etc. The claims are numerous and in the opinion of the Panel, many are confusing or misleading to the consumer.

The Panel has discussed certain labeling claims classified as Category III elsewhere in this document. (See Part VI. Paragraph B.1.d. below—Labeling claims, the importance of using analgesics combined with antacid or buffering ingredients.)

The Panel was charged to evaluate the safety and effectiveness of these OTC analgesics and to review their labeling. It was necessary for this Panel to consider finished dosage forms because of their significant effect on the rate and extent of absorption and therefore potential effect on the therapeutic activity of the active ingredients. For example, buffered aspirin formulations must be considered because some buffered preparations may have an effect on the rate of dissolution and subsequent absorption of aspirin (Ref. 1). The pharmacological characteristics of the finished dosage form are claimed to affect the performance of the active ingredients. By definition, therefore, these agents might be considered as indirect acting adjuvant agents as discussed elsewhere in this document. (See part VI. below—Adjuvants and Corrective Agents.)
DOSAGE FORMS IN SUBMISSIONS OF MARKETED DRUG PRODUCTS

Number of product submissions

Solid dosage forms:

<table>
<thead>
<tr>
<th>Tablets</th>
<th>Buffers</th>
<th>Chewable</th>
<th>Enteric-coated</th>
<th>Capsules</th>
<th>Powders</th>
<th>gums</th>
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<tr>
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Liquid dosage forms:

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<th>Suspensions</th>
<th>Syrups</th>
<th>Suppository</th>
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<td></td>
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</tr>
</tbody>
</table>

a. Solid dosage forms. It is evident from the above chart that the greatest number of OTC internal analgesic, antipyretic and antirheumatic drug products marketed in a solid dosage form. Of these, the tablet in several variations, i.e., unbuffered, enteric-coated, timed-release and chewable, is the most predominant solid dosage form used to market these products. Even though all of these formulations are in tablet form, formulation variations between them can affect the bioavailability, i.e., bioavailability as manifested in blood levels of the active ingredient(s) contained in them. The Panel, recognizing the variety of claims made for these different formulations, has attempted to evaluate the safety and effectiveness of active ingredients. Some evidence relating to possible differences between dosage forms was developed by the drug manufacturers to meet other needs of the consumer, such as decreasing the incidence or severity of a drug's side effects, e.g., the buffering of aspirin to modify its irritating effects on the lining of the stomach, or to provide dosage forms that can be more conveniently taken, e.g., timed-release forms, etc. The Panel has considered the advantages and disadvantages of these formulations which are briefly described below.

Unbuffered (plain) aspirin tablets are the most common dosage form available in the marketplace. One might assume that all the products containing unbuffered aspirin are comparable with respect to their bioavailability, i.e., the amount of aspirin absorbed into the blood in a given time. This unfortunately has not been demonstrated to be the case in those studies in which the dissolution rates of commercial unbuffered aspirin products have been compared, as discussed below. The rate of bioavailability of most of the analgesics, such as aspirin, is related to its dissolution rate.

Several studies have shown that all aspirin products do not have the same ability to be absorbed and therefore to produce comparable blood levels in a specified time. The Panel concludes that significant variation in dissolution rate and absorption rate between aspirin products demonstrates the need for a standard dissolution test which could be used to detect preparations which will be so slowly absorbed as to potentially increase local adverse effects on the gastric mucosa or decrease therapeutic effects due to decreased bioavailability. The Panel has proposed a standard tablet dissolution test elsewhere in this document. (See part VI, paragraph C.1.b., below—Aspirin (plain and buffered) tablet dissolution testing procedure.)

The other major tablet solid dosage form is buffered aspirin products. Buffing agents have been used for aspirin products to increase the dissolution rate in an attempt to lessen the onset of activity and reduce gastric irritation. The testing of buffered aspirin is discussed later in this document. (See part VI, paragraph C.1.a., below—Buffered aspirin acid neutralizing testing procedure.) The labeling of buffered aspirin is also discussed later in this document. (See part VI, paragraph B.1.d., below—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.)

Two forms of buffered aspirin are combined with the Panel has distinguished as "buffered" and "highly buffered for solution".

The Panel has defined a buffered aspirin product as a solid dosage form containing 325 mg (5 gr) aspirin and sufficient buffering capacity with antacid active ingredient(s) identified in the OTC antacid monograph (21 CFR 331.31) such that the total acid neutralizing capacity of each minimum labeled dosage unit contains at least 1.9 meq of acid neutralizing capacity following the testing procedures discussed later in this document. (See part VI, paragraph C.1.a., below—Buffered aspirin acid neutralizing testing procedure.)

The quantity of alkaline buffers is sufficient to increase the dissolution rate of the product without necessarily increasing the pH of the gastric fluid. The principal reason for increasing the dissolution rate of aspirin is to facilitate its removal from the stomach as rapidly as possible to reduce the irritating effects of the drug on the gastric mucosa.

Buffered aspirin preparations are claimed to reduce the possibility of gastric distress due to the aspirin. Even though the amount of buffer is not sufficient to markedly affect the pH of gastric fluids, the buffering agent will increase the pH immediately around the dissolving particle, resulting in more rapid dissolution and removal from the stomach and hence decrease the likelihood of local gastric irritation.

The Panel concurs with the general consensus of a large number of studies which demonstrate that buffered aspirin is more rapidly absorbed from the gastrointestinal tract. The evidence also
seems to indicate that some individuals in the small subset of persons who regularly experience subjective symptoms of gastric distress may experience less gastric intolerance with some buffered aspirin compared to unbuffered (plain) aspirin. Suitable Category III labeling claims are discussed elsewhere in this document. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.)

The dissolution rate limting process for gastrointestinal absorption of salicylates given in solid form. The greater dissolution rate of aspirin in the small subset of persons who regularly experience subjective symptoms of gastric distress, may explain a difference in the rate of absorption of buffered aspirin (Ref. 3).

The Panel has defined a highly buffered aspirin for solution products as a solid dosage form which must be dissolved in water prior to oral administration as a solution. The product shall contain 325 mg (5 gr) aspirin and sufficient buffering agent to neutralize at least 20 nEq of acid neutralizing capacity of the gastric mucosa and are discussed later in this document. (See part VI. paragraph C.1.a. below—Buffered aspirin acid neutralizing testing procedure.)

The quantity of alkaline buffers in these highly buffered preparations is greater than that in buffered tablet preparations. This buffer aids in absorption since the gastric fluid is increased. Some highly buffered aspirins have been shown to significantly decrease gastric distress that results from direct effects of aspirin on the gastric mucosa and are discussed later in this document. (See part III. paragraph B.1.a.(2) below—Safety.) The Panel finds that this is a desirable method of increasing gastric pH at the same time increasing gastric tolerance by buffering the aspirin. However, it may also be the case that some individuals in the small subset of persons who regularly experience subjective symptoms of gastric distress, may experience less gastric intolerance with some highly buffered aspirin for solution products compared to unbuffered (plain) aspirin. However, the Panel has also concluded that this or any other dosage form does not necessarily reduce the potential for massive gastrointestinal hemorrhage. Suitable Category III labeling claims are discussed elsewhere in this document. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.)

Although numerous buffering agents are available for tablet formulations, few studies have been done to compare the effects of different buffering agents on the dissolution rate of aspirin from solid dosage forms. In a study of investigators found a definite difference in the rate of dissolution of aspirin from tablets depending on the agent used to buffer the aspirin. Eleven different buffering agents were studied. The time required for 50 percent of a given aspirin tablet to dissolve ranged from 1 to 20 minutes depending on the buffering agent used. In general, it was determined that carbon dioxide producing buffering agents (sodium bicarbonate, magnesium carbonate and calcium carbonate) caused a more rapid dissolution than the readily water-soluble buffering agents (sodium ascorbate and sodium citrate), and both hydrogen and hydroxyl ions gave rise to a much faster dissolution than water-insoluble buffering agents such as aluminum compounds and magnesium compounds other than magnesium carbonate. The Panel finds that simply adding buffering agents to aspirin does not guarantee an increased dissolution rate over unbuffered aspirin. Important factors appear to be the type of buffering agent used and other undefined factors, e.g., tablet compression during manufacturing, etc. This may be an explanation for the discrepancy of results between buffered aspirin and buffered aspirin with buffered aspirin. The buffering agent used with the aspirin may to some extent determine the outcome of the study. For this reason, actual testing of different aspirin products is necessary to determine if the buffering agent actually does affect the dissolution rate of the aspirin products and to what extent.

The Panel notes that an adequately buffered aspirin product may not have an advantage over a well-formulated unbuffered aspirin. In some studies, unbuffered aspirin performs as well as buffered aspirin.

The total of formulation variables of unbuffered and buffered aspirin products therefore plays a very important role in determining their dissolution times. Levy has compared the dissolution of commercial unbuffered aspirin products with the dissolution of an aspirin product buffered with aluminum monohydrate (Ref. 1). In this study, three unbuffered products were tested. He found that 68 percent of the 300 mg buffered aspirin tablet dissolved in 10 minutes, whereas the amounts of the three 300 mg unbuffered aspirin tablets that dissolved in 10 minutes were lower and varied among the three products. The three values were 42, 52 and 55 percent. There was a 13 percent difference between the fastest dissolving buffered product and the buffered product, the same difference as between the fastest and slowest dissolving unbuffered products. He concluded that the variation in dissolution times among the unbuffered products could be due to differences in the formulation between the three products. It is evident that the dissolution rates among unbuffered aspirin products can be as great as the difference between buffered and unbuffered aspirin products. Levy studied another unbuffered salt of aspirin, namely calcium acetylsalicylate, had a dissolution rate of 81 percent in 10 minutes, which was greater than the dissolution rate of the buffered aspirin product.

In another study, Levy and Hayes compared six commercial unbuffered aspirin products with an aspirin product buffered with aluminum glycinate and magnesium carbamid (Ref. 9). The dissolution half-times (the time required for half (150 mg) of a 300 mg tablet to dissolve) of these six products were within the range of 81/2 to 133/4 minutes. In determining the dissolution rate, samples were not measured at less than 5 minutes so that an accurate measure of the dissolution half-time of the buffered aspirin was not ascertained. A product consisting of a calcium acetylsalicylate carbamid complex was also tested in this study and its dissolution half-time, like that of the buffered aspirin, was less than 5 minutes. Actually this product dissolved somewhat faster than the buffered aspirin. Whereas 68 percent of aspirin was absorbed from unbuffered aspirin dissolved in 10 minutes, 81 percent of the calcium acetylsalicylate carbamid complex dissolved in that time. This study showed again that marketed unbuffered aspirin products could differ widely in terms of the range of dissolution rates. The six products showed dissolution half-times of 81/2, 81/4, 101/4, 11, 111/2 and 133/4 minutes. There was approximately a 62 percent difference between the fastest and the slowest values.

It is apparent that different nationally distributed brands of unbuffered aspirin exhibit significant differences in dissolution rate. These product-to-product differences probably account for some of the conflicting clinical reports concerning the relative advantages of unbuffered and buffered aspirin products. Some investigators have reported that the buffered form is more rapidly absorbed and causes less gastric irritation than the unbuffered drug. Other workers could find no difference between manufactured buffered and unbuffered aspirin. It is now clear that because of the differences in dissolution rates of different brands of both unbuffered and buffered aspirin products, differences might vary depending on the products compared. Since the dissolution rates of buffered products might vary because of the type of buffering agent used and the dissolution rates of unbuffered aspirin products might vary because of formulation differences, the Panel concludes that unbuffered (plain) aspirin products should be tested for dissolution rate as well as buffered aspirin products. The Panel has proposed suitable testing procedures elsewhere in this document. (See part VI. paragraph C.1. below—Aspirin standard testing procedure.)

Chewable tablets offer a convenient method of administering the drug to individuals who have difficulty in swallowing whole tablets. Chewable tablets are especially popular for use in children. There are many marketed children’s chewable aspirin tablets, which are usually flavored, containing 30 mg (1.25 gr.) of aspirin per dosage unit. These
It has been found that a significant proportion of commercially available enteric-coated tablets are either not resistant to gastric fluid or not fully absorbed after reaching the small intestine (Ref. 9). Part of the problem may be due to the enteric-coated tablets undergoing changes on aging which can markedly alter their release characteristics (Ref. 10). In addition, the absorption of aspirin from physically or chemically available enteric-coated tablets is highly variable depending upon individual factors such as gastric emptying time.

The Panel has therefore classified enteric-coated tablets as Category III until adequate testing can demonstrate the bioavailability (blood levels).

Timed-release dosage forms encompass the principle of a controlled release of drugs from oral dosage units. They provide the advantages of increasing the intervals between dosing and at the same time increasing the duration of action. However, effective preparations of timed-release drugs have been difficult to achieve in the past, because of technical problems associated with their manufacture. Timed-release products are formulated so as to dissolve in gastrointestinal fluids in a controlled manner so that the total dose will be released over a longer period of time, e.g., over 3 to 6 hours rather than 1 hour, and the duration of drug action will be extended over a longer period, e.g., 8 to 12 hours rather than 3 to 5 hours.

These formulations usually contain more than one single dosage of the drug intended to be released in a continuous and controlled manner so that the duration of the claimed effect is increased. However, it can be debated whether a 1,300 mg aspirin sustained-release tablet is as effective as two 650 mg doses of aspirin given 4 hours apart (Ref. 2).

Sevelius and Colmore (Ref. 11) showed in a clinical study that a sustained-release aspirin preparation had analgesic properties comparable to unbuffered aspirin and was not superior to these forms of aspirin with respect to the duration of analgesic effect in postpartum patients. Stubbe et al. (Ref. 12) found that cellulose acetate phthalate coating on tablets slows salicylate release and increases the duration of action. There was little gastrointestinal blood loss with this coating and the blood levels were higher the following morning than with uncoated aspirin.

Several timed-release aspirin preparations have been marketed, but the labeling on these products suggests that they provide long lasting relief, are useful at bedtime for relief of pain during the night, etc. The Panel has classified these timed-release products with such labeling in Category III until it is demonstrated that blood levels (rate and extent of absorption) or pharmacologic effectiveness are comparable to, and the incidence of side effects are not greater than, those seen with preparations given in conventional dosage.

Micronized aspirin refers to aspirin formulated in smaller than the usual size of particles. Such forms are as safe and effective as ordinary aspirin but if special claims relate to such characteristics as rapidity of onset or higher blood levels they are classified as Category III. However, no convincing data are available that micronizing confers any favorable properties to aspirin beyond those found with regular aspirin.

Car-capsules are solid dosage forms in which the active ingredient(s) is enclosed in either a hard or soft, soluble container or shell of a suitable form of gelatin. Its principal advantage in OTC products is that some individuals find it easier to swallow capsules than tablets. Otherwise, considerations of absorption and pharmacologic effectiveness are similar to those for tablets.

Powders are a dosage form which are not as commonly used. They are rapidly absorbed however, often reaching peak blood levels more rapidly than the tablet dosage form. The rapid absorption from finely divided powders is directly related to the large surface area of these products. Powders have the advantage of ease of administration to young children who cannot swallow capsules or tablets. They may present problems if the dosage unit is not individually packaged. The chief disadvantage for bulk products is in measuring an accurate dose of a powder. Consequently, the use of bulk powders as a dosage form should be discouraged unless there is assurance that an adequate measuring device is attached and likely to be used routinely. The Panel recommends that powders containing salicylates be mixed with a full glass of water and stirred prior to use.

Historically, aspirin has been used as a gargle for the treatment of minor sore throat pain. Chewing gum formulations containing aspirin in a gum base were developed to provide for greater retention and absorption of the drug and to produce a topical, local effect on the surrounding tissues. These formulations may also make the medication more pleasant to take. Chewing containing aspirin are primarily used and labeled for "relief of minor sore throat pain". However, other traditional labeling is also included such as "for head aches and pains". The latter claims can only be attributed to the absorption of the drug into the systemic circulation.

The Panel concludes that aspirin or any analgesic in a gum base, with the specific claims for the relief of sore throat, has not been adequately tested for effectiveness and therefore cannot be considered safe or efficacious. If the tissue is highly inflamed or abraded because aspirin is irritating to the mucosal tissue as discussed above, the Panel recommends that claims of aspirin-containing gum for the relief of sore throat or the use of aspirin as a gargle for a local effect properly belongs in a review of ingredients claimed for the treatment of sore throat in general and should therefore be deferred to the Advisory Review Panel on OTC oral cavity drug products for evaluation.
The Panel finds marketing of an OTC analgesic, in a chewing gum formulation acceptable if the product contains the active ingredient(s) which are then absorbed and produce a pharmacologic effect. Factors affecting gastrointestinal function such as gastric emptying, intestinal transit time, and intestinal and hepatic metabolism may greatly affect the availability of the drug for absorption in the systemic circulation. Poorly absorbed drugs have a longer residence time in the gastrointestinal tract. In some cases this may lead to adverse local effects on the gastrointestinal mucosa. The blood levels of a drug depend on the rate and amount of drug absorbed. Blood levels will rise and fall in proportion to the dose of the drug available and be subject to the vicissitudes of formulation and to physiological variables such as gastrointestinal function. For example, if only one-half the drug is absorbed, the effect is equivalent to lowering the dose. If absorption is sufficiently slow, minimum pharmacologic effectiveness may never be attained. On the other hand, if the rate of absorption is too rapid, toxic levels can be achieved. This assumes that there is a direct correlation between blood levels and the pharmacologic effect of a drug. In the case of analgesics the relationship between blood levels and pharmacologic effectiveness has not been well established. A comparison of blood levels may offer a basis of comparison between different formulations of the same agent, but are at present almost meaningless in comparing chemically different classes of analgesic agents.

4. Determination of pharmacologic effectiveness, evaluation of pharmacologic groups. a. Analgesic effectiveness. The most important measurement in evaluating the effectiveness of an OTC analgesic is its ability to relieve minor aches and pains, and headache in a suitable target population. However, pain, which is discussed later in this document, is a subjective symptom and presently no objective evidence is available with which to evaluate patients suffering from pain and as to the detection of its presence, absence, or modification. (See part III. paragraph B.l.a above—Pain.) The study of analgesics, or analgesometry, must be based primarily on observations in man. The medical literature stresses the need for laboratory animal procedures, as yet not fully reliable, which will yield results that can be correlated with those in man. Hence, the Panel finds that the literature on analgesics is conflicting as to the effectiveness of specific drugs because of the subjective, imprecise methods of testing and the difference of opinion regarding suitable methods of testing.

The Panel notes that the most successful efforts to quantitate pain in the clinical situation have been those that have accepted the patient's own reports as appropriate indices of the pain experience and of relief resulting from analgesic administration. The Panel's recommendations pertaining to the evaluation of the effectiveness of a claimed OTC analgesic drug is discussed later in this document. (See part III. paragraph C. below—Data Required for Evaluation.)
b. Antipyretic effectiveness. The obvious measurement in evaluating the effectiveness of an OTC antipyretic is its ability to reduce fever. This is a clinical sign that can reasonably be determined by objective measurement. The Panel has recommended that clinical studies be conducted in several populations of patients, such as, patients with fever secondary to cancer and associated infections, and fever in children and adults with acute infectious diseases. The Panel’s recommendations pertaining to evaluation of effectiveness of a claimed OTC antipyretic drug is discussed later in this document. (See part IV. paragraph C. below—Data Required for Evaluation.)

c. Anti-inflammatory effectiveness. The critical measurements in evaluating the effectiveness of an OTC antihistamine agent is its ability to restore joint function and to blood level determinations. Many of the studies the Panel has reviewed, either in the literature or in data submissions to the Panel, have utilized drug blood levels as a measure of analgesic effectiveness in comparison with other drugs in which assays of blood salicylate levels are made rather than direct measurements of the analgesic effectiveness of these agents. The Panel has evaluated this technique and concludes that there is inadequate evidence that the amount of drug in the blood correlates directly with clinical analgesia. The Panel emphasizes that this is not to say that a relationship between blood levels and clinical response does not exist, but rather, that the relationship is not understood. However, the Panel does recognize that an important value of drug blood level comparisons is that they do give an indication of comparative dissolution rates. If an analgesic product produces a blood level higher than another product within a given period of time, e.g., 10 to 20 minutes after administration, the higher blood level of the product might be attributed to a faster dissolution rate. The Panel concludes that there should be no reference to blood levels in the labeling which implies a corresponding clinical effect without substantiation of a correlation between blood level and clinical analgesia. e. Other labeling and display. The Panel recognizes that drug labeling related to the onset, intensity and duration of pharmacologic effects may influence the consumer’s selection of a product but can find no convincing evidence to support labeling claims which suggest a faster onset of effectiveness, e.g., “fast pain relief” or “on time release preparations no evidence was found to support claims such as “night-time pain reliever.” There is also no direct evidence available to the Panel which suggests a greater intensity of analgesia for comparable products with claims such as “enhanced relief of pain.” In the discussion above, the importance of product formulation on drug absorption has been stressed. The dissolution rate of the drug determines the rate of absorption. As mentioned earlier, studies have demonstrated that the role of drug buffer can be played by some buffers that buffer aspirin enhances the rate of absorption of the drug, thus causing less gastric irritation. Consequently, some buffered aspirins are somewhat more rapidly absorbed from the gastrointestinal tract than unbuffered aspirin and might also be expected to show earlier higher salicylate blood levels. On the other hand, some buffered aspirin preparations that are not absorbed any faster than unbuffered aspirin products, as noted above. However, the Panel is unaware of any data that demonstrate that buffered aspirin provides a more rapid onset, a greater peak intensity or a more prolonged duration of analgesic effectiveness than unbuffered aspirin.

REFERENCES


K. ABSORPTION, DISTRIBUTION, BIOTRANSFORMATION (METABOLISM) AND EXCRETION OF ASPRIN AND SALICYLATES IN MAN

1. Absorption. Aspirin and salicylate absorption occur by passive diffusion primarily of the nondissociated lipidsoluble molecules, salicylic acid and acetylsalicylic acid (ASA) across the intestinal membranes and is influenced by gastric pH. If the pH is increased, salicylate is more ionized and this tends to decrease rate of absorption; however, a rise in pH also increases solubility of salicylate, which has the opposite effect on absorption. Actually, there is little meaningful difference between the rates of absorption of sodium salicylate, aspirin and the numerous buffered preparations of salicylates. For example, in man, the absorption half-time for unbuffered aspirin is about 30 minutes, for buffered aspirin about 20 minutes, and for aspirin solution only slightly less. The presence of food delays absorption of salicylates. Oral ingestion salicylates are absorbed rapidly, partly from the stomach but mostly from the upper intestine. Approximately 70% of the small intestinal concentrations are found in less than 30 minutes; after a single dose, a peak value is reached in about 2 hours and then gradually declines. Rate of absorption is determined by many factors, particularly the disintegration and dissolution rates if tablets are given, the pH at the mucosal surfaces, and gastric emptying time.

2. Biotransformation. Aspirin, which is absorbed as such, is first rapidly hydrolyzed to salicylic acid by esterases present in the gastrointestinal tract, red blood cells, and serum, but primarily in the liver. This is a rapid reaction which has a half-life of 15 to 20 minutes (Refs. 1 and 2). As a result of this rapid hydrolysis, plasma concentration of aspirin is low (less than 20 micrograms/ml) at steady state. Once the salicylic acid, then undergoes biotransformation which occurs in many tissues but particularly in the liver by the enzymes.
from the microsomal drug metabolizing system.

The three chief metabolic products are salicylic acid (the glycine conjugate), the ether or phenolic glucuronide, and the ester or acetylglycuronide. In addition, a small fraction is oxidized to gentisic acid (2,3-dihydroxybenzoic acid) and to 2,3,6-trihydroxybenzoic acids. These metabolites are found in the urine; the conjugates and genitic acid have also been identified in plasma, liver, and some other tissues. The sum of all these metabolites in plasma is generally only about 1 percent of the total plasma salicylate.

The biotransformation routes of aspirin in man have been reviewed by Levy and Leonardis (Ref. 2). Aspirin is hydrolyzed rapidly in the body to salicylic acid which is conjugated in part with glycine to form salicylic acid and with glucuronic acid to form acyl and phenolic glucuronides. Salicylic acid is further hydroxylated to gentisic acid. There may be several other minor metabolites. Free salicylic acid and its metabolites are eliminated from the body by renal excretion.

The conjugates (salicylic acid, phenolic and ester glucuronide) and the other minor metabolites are excreted almost exclusively in the urine (Refs. 1 and 2). Levine (Ref. 1) in her short review of salicylate metabolism states:

"All the processes of biotransformation and excretion are first order with the exception of the conjugation of salicylic acid with glycine to form salicyluric acid and with glucuronic acid to form the ether glucuronide... Salicylic acid formation has been found to change from first-order to near zero-order kinetics when the amount of salicylic acid in the body exceeds the quantity derived from the biotransformation of about 1 g of aspirin: the glucuronide conjugating system is saturated at somewhat higher levels of salicylic acid. When conventional dosage forms are administered and the aspirin is absorbed normally, it would take only two tablets to reach the level at which salicylic acid formation becomes to a first-order phenomenon." When the salicylic acid derived from aspirin in the saturating levels exceeds the overall rate of elimination of salicylate follows first-order kinetics because all the elimination processes are first order, for the expression [sic] dose of aspirin. The half-time of elimination under first-order conditions is about 3.1 hours. At these low doses the major process responsible for salicylate elimination is its conjugation with glycine, since the first-order rate of salicylic acid formation is much faster than the rates of the glucuronide syntheses. When doses of aspirin of 1 g or more are administered, the glycine conjugation with the phenolic group of salicylate also approaches the limit of its capacity. As a consequence, the overall rate of elimination of the salycylate derived from large doses of aspirin displays complex kinetics, indicative of a mixture of apparent zero-order and first-order processes. The curves for the 1.0 and 1.5 g doses of aspirin do not until about 200 mg of salicylic acid remaining in the body drops to the quantity equivalent to about 300 mg of aspirin. This indicates a lack of conformity with first-order kinetics. Below 300 mg the curves for all three doses are linear and first order. Moreover, the time required to eliminate 50 percent of the salycylate in the body lengthens as the dose of aspirin increases, because the rate of rapidly formed salicylic acid is contributing to the overall elimination process."

This was reported originally by Levy (Ref. 4) who in 1950 reported:

"Salicylate elimination kinetics was studied on a dose range of from 0.25 to 2.0 g. When small doses of aspirin, 0.5 g, was administered the amount of salicylate in the body of normal adult test subjects exceeded approximately 1 mg/mL. Since the overall rate of elimination of salicylic acid with glycine reached a maximum rate and thus proceeded by zero-order kinetics. The overall elimination of salicylate was found to proceed by first-order kinetics at very small doses and by parallel zero and first-order processes at higher doses. A kinetic was done to determine the appropriate rate constants were determined which make it possible to reconcile apparent half-lives for salicylate elimination ranging from about 3 hr. to over 20 hr. which have been reported in the literature. The pharmacokinetics of salicylate elimination were found to be both qualitatively and quantitatively, and the results of the present study have potentially important therapeutic, toxicologic, and pharmogenetic implications."

The half-life of salicylate in doses between 300 and 650 mg has been reported to be between 3.1 to 3.2 hours (Ref. 1). However, if the dose is increased to 1 g the half-life is increased to about 12 hours (Refs. 4 and 5). If the dose is increased to 2 g the half-life is increased to about 24 hours (Ref. 4). Not only is the half-life markedly increased, but the urinary excretion of salicylate is increased from 0.32 g to 0.57 g (Refs. 4 and 5). If the urinary excretion is decreased, more salicylate will be retained in the body with a great toxic potential since it probably will occupy most of the available albumin binding sites and displace other drugs or endogenous products, e.g., bilirubin.

Levy has expressed concern (Ref. 4) that: "Any search for genetic differences in salicylate elimination by salicylic acid formation must be directed not only toward the determination of individual first-order rate constants for this process (which requires that the administered doses be small), but must also include the determination of the individual maximum salicylate formation rate capacities. Either one or the other (or both) could show genetically determined differences, if existent." He has also expressed concern (Ref. 4) about how little is known concerning the formation of salicylic acid in children (as a function of age and maturity) and in other individuals taking large doses of salicylates. Levy et al. (Ref. 7) have studied the kinetics of salicylic acid formation in man and have confirmed that this is the limiting step for the excretion of salicylate in urine. There is no information available in the literature to suggest that salicylates induce their own rate of biotransformation. More caution is necessary when large, frequent doses are used. Some data are available from a study in dogs (Ref. 8) which showed no change in the kinetics of salicylate elimination on constant dosing. However, it is not known how validly this data can be extrapolated to man.

The half-life probably reflect differences in salicylamide formation capacity (glycine conjugation) and is probably genetically determined. Levy has pointed out (Ref. 4) that: "Any search for genetic differences in salicylate elimination by salicylic acid formation must be directed not only toward the determination of individual first-order rate constants for this process (which requires that the administered doses be small), but must also include the determination of the individual maximum salicylate formation rate capacities. Either one or the other (or both) could show genetically determined differences, if existent."
Plasma Concentration and Distribution

After a single oral dose of 0.6 Gm of aspirin in normal men, the average peak salicylate level in the plasma is approximately 4 mg/100 ml and is reached about 30 to 60 min. After a fasting human subject, the drug may reach its peak plasma level in 40 min; after a heavy meal, however, it may take 3 hr for the plasma level to be reached. According to Bodogh, there is a 200-fold increase in plasma level after a heavy meal, however, the desired plasma level is in the range of 30 mg/100 ml, which requires doses of 2 Gm several times daily. Sustained-action tablets are also available, which may plateau Gm several times daily. Sustained-action drug may reach its peak plasma level in 40 ter ingestion 100 mg/100 ml. Binding involves primarily the free carboxyl group, but the phenolic group markedly enhances the attraction for proteins. Aspirin, phenylbutazone, and salicyluric acid have little or no binding. Binding may be strikingly altered in disease states. Although the albumin present varies with the species, per molecule, the total albumin concentration may be markedly lowered, thus reducing the free fraction of 50 percent.

The salicylate concentration is usually greater in the plasma than in whole blood. It appears that the red cell membrane is readily permeable to salicylate and that the drug is not bound by the proteins of the erythrocytes.

The exact significance of blood levels of salicylate is still unclear. In dogs salicylate levels after oral administration can actually be increasing after the absorption phase, in response to bradycardia has worn off. It seems obvious that the site of action are more meaningful than in blood but are more difficult to obtain. In a few cases salicylate concentrations in joint fluids have been measured. Although unbound concentrations in plasma and synovial fluid are essentially equal, the total concentration in joint fluid is only one-half of the peak plasma concentration, since joint fluid contains less protein and therefore less protein-bound drug. However, the synovial fluid drug concentration remains higher for considerably longer periods.

The salicylates are distributed through a volume of body water much greater than that of the extracellular fluid. Studies on rats showed that the concentrations in the liver, kidneys, and lungs of the rats were similar to those in the serum. When the salicylate concentration is calculated on the basis of water content, the liver contains about two-thirds as much as the serum, and muscle approximately one-fifth as much.

Passage across the blood-brain barrier is relatively impeded except for the administration of either aspirin or salicylate, salicylate is found in brain water in rats and reaches a maximum of 30 percent of the plasma concentration. In four mammalian species, including the monkey, no free salicylate was found in brain. It is possible that salicylate is completely hydrolyzed to salicylate in the blood or brain, or else it does not penetrate the brain at all. It is possible that the selective concentrations in certain portions of the brain. At first, the more vascular gray matter tissues were similar to those in the plasma. In contrast, the putative gray of several mammalian species contains a twofold or threefold excess concentration compared to the other portions of the central nervous system. Goldberg has reported the effects of alterations in carbon dioxide tension on the penetration of salicylate into brain. A two-fold increase in brain penetration of drug whereas hypoventilation produces a 50 percent decrease. These observations may be of importance in salicylate toxicity. It is of interest that insulin markedly increases the uptake of salicylate and raises its concentration in brain and liver, kidney, and lung were similar to those of tissue. In contrast, the pituitary gland of several mammalian species contains a two-fold increase as much as the serum, and muscle approximately one-fifth as much.

It is of interest that insulin markedly increases the uptake of salicylate and raises its concentration in brain and liver, kidney, and lung were similar to those of tissue. In contrast, the pituitary gland of several mammalian species contains a two-fold increase as much as the serum, and muscle approximately one-fifth as much.

As far as traversing the placental barrier, Woodbury (Ref. 2) states this fact more emphatically: "The drug readily crosses the placental barrier." Woodbury also mentions in reference to distribution that:

The volumes of distribution of aspirin and sodium salicylate in normal subjects average about 150 ml/kg of body weight, a value equi-

l. Aspirin is essentially completely absorbed from the gastro-

intestinal tract. In particular, high carbohydrate test meals have been found to retard acetaminophen absorption (Ref. 2). Acetaminophen absorption has also been found to be inhibited by activated charcoal (Ref. 3). The authors found that 10 g activated charcoal administered immediately after the oral administration of 1 g acetaminophen reduced absorption by 69 to 77 percent in 2 subjects (Ref. 3).

Peak plasma concentrations after the administration of acetaminophen have been reported to occur in 30 to 60 min-
utes (Ref. 1). In a published study, it was found that peak plasma levels after acetaminophen administration were reached between 40 and 67 minutes.
using different pharmaceutical forms of acetaminophen (Ref. 4).

The plasma half-life has been reported to be from 1 to 3 hours (Ref. 1). In an unpublished study (Ref. 5), the mean plasma half-life using several pharmacological forms was 80.4 minutes. Acetaminophen is relatively uniformly distributed throughout most body fluids (Ref. 1). Binding of the drug to plasma proteins is variable and depends on the dose. During acute intoxication, as much as 20 to 50 percent may be bound to plasma proteins (Ref. 1). Dearden and Tomlison (Ref. 6) studied the protein binding abilities of some p-sulphoxide and acetanilid derivatives including acetaminophen and found that at therapeutic doses the association constant was low, which would permit high free drug concentration in blood and plasma for a relatively long period of time.

Acetaminophen is conjugated in the liver to form glucuronide and sulfate conjugates. Cummings et al. (Ref. 7) showed that 95 percent of the dose was accounted for as follows: 58.5 percent as the glucuronide, 49 percent as the sulfate. This interaction may have therapeutic and/or toxicological implications since the inclusion of salicylamide in an analgesic mixture will inhibit the two major processes for the elimination of acetaminophen. This interaction with salicylamide becomes more important if one considers the capacity-limited formation of sulfate described above (Ref. 8). On the other hand, concurrent administration of salicylic acid has been found to exert no significant effect on the formation of acetaminophen glucuronides or sulfate or in the half-life of acetaminophen (Ref. 10).

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(4) OTC Volume 000026, p. 0111.

(5) OTC Volume 000026, p. 0135.


The Panel considered all pertinent data and information in arriving at its conclusions and recommendations. The Panel was charged with the review of OTC analgesic analogues, antipyretic, and anti-inflammatory agents to be added to the OTC analogues. After carefully reviewing all of the available data, the Panel has classified the data into analgesic, antipyretic, and antirheumatic agents. (See part II. paragraph I. above—Definitions.)

III. ANALGESIC AGENTS

A. GENERAL DISCUSSION

The Panel has defined OTC analgesic drugs as agents useful to relieve occasional minor aches, pains and headache. These agents are intended for the relief of the type of pain that is self-limited and requires no special treatment or prior diagnosis by a physician. Such analgesic agents are commonly referred to as the "mild analgesics" in contradistinction to the strong analgesics such as the potent narcotic and morphine-like analogues. The mild analogues can be chemically divided into two main subgroups: Those agents chemically related to the strong analogues, e.g., codeine, ethoheptazine, and propoxyphene; and those analogues like aspirin, with anti-inflammatory and anti-rheumatic activity, e.g., salicylates, salicylamide, aniline derivatives, phenylpyrazoles, etc. It is the latter group of mild analogues that have generally been associated with OTC use.

The mild analogues which are acceptable for OTC use include the salicylates, e.g., aspirin and the nonsalicylates, e.g., acetaminophen. Intensity, particularly headache, myalgia, arthralgia and other pains arising from integumental structures.

The salicylates have lower maximal effects than do the narcotic analogues at concentrations of mild to moderate intensity. The salicylates are more widely used for pain relief than any other class of drugs. Although OTC analogues may effectively ameliorate the pain due to various physical conditions, disease entities, or specific physical sites, the listing of a multitude of conditions and sites in order to be both factual and all inclusive would not only result in a lengthy list that would tend to be confusing but could also mislead the consumer by the implied assumption, that the product treats the physical condition drug. In general, it is the accumulation of acetaminophen in the plasma of poor excretory capacity but only in minor changes in the plasma concentrations of free acetaminophen (Ref. 1).

The metabolism of acetaminophen has been shown to be markedly changed by the concurrent administration of salicylamide (Ref. 8). The authors found evidence of competitive inhibition by salicylamide in the formation of acetaminophen glucuronide and sulfate. This effect was counteracted or prevented by the administration of L-cysteine (source of sulfate). This interaction may have therapeutic and/or toxicological implications 

The plasma half-life has been reported to be from 1 to 3 hours (Ref. 1). In an unpublished study (Ref. 5), the mean plasma half-life using several pharmacological forms was 80.4 minutes. Acetaminophen is relatively uniformly distributed throughout most body fluids (Ref. 1). Binding of the drug to plasma proteins is variable and depends on the dose. During acute intoxication, as much as 20 to 50 percent may be bound to plasma proteins (Ref. 1). Dearden and Tomlison (Ref. 6) studied the protein binding abilities of some p-sulphoxide and acetanilid derivatives including acetaminophen and found that at therapeutic doses the association constant was low, which would permit high free drug concentration in blood and plasma for a relatively long period of time.

Acetaminophen is conjugated in the liver to form glucuronide and sulfate conjugates. Cummings et al. (Ref. 7) showed that 95 percent of the dose was accounted for as follows: 58.5 percent as the glucuronide, 49 percent as the sulfate. This interaction may have therapeutic and/or toxicological implications since the inclusion of salicylamide in an analgesic mixture will inhibit the two major processes for the elimination of acetaminophen. This interaction with salicylamide becomes more important if one considers the capacity-limited formation of sulfate described above (Ref. 8). On the other hand, concurrent administration of salicylic acid has been found to exert no significant effect on the formation of acetaminophen glucuronides or sulfate or in the half-life of acetaminophen (Ref. 10).
the advice and supervision of a physician. If the consumer feels the need to continue self-medication beyond 10 days, it may be indicative of an underlying serious condition requiring medical supervision. Self-medication without consulting a physician may in some conditions cause irreparable damage. It is the Panel's opinion that if symptoms require the use of an OTC analgesic for more than 10 days, the individual is sufficiently ill to require consulting a physician. The 10 day limit is based on historical precedent and past marketing experience. The Panel has concluded elsewhere in this document that the duration of use of all analgesics should be limited to 5 days for children under 12 years of age (See Part II, paragraph F.3. above—Statement on children's dosage.) Therefore, the Panel recommends that all OTC analgesics contain the warning for adults, "Do not take this product for more than 10 days. If symptoms persist, or new ones occur, consult your physician", and for children under 12 years of age, "Do not give to children under 12 years of age. If symptoms persist, consult your physician." If symptoms persist, or new ones occur, consult your physician.

b. CATEGORIZATION OF DATA

1. CATEGORY I conditions under which analgesic agents are generally recognized as safe and effective and are not misbranded:

   CATEGORY I—ACTIVE INGREDIENTS

   The Panel has classified the following analgesic active ingredients as generally recognized as safe and effective and not misbranded:
   
   Aspirin Magnesium salicylate
   Acetaminophen Sodium salicylate
   Calcium carbamiphen Choline salicylate

   a. Aspirin. The Panel concludes that aspirin is a safe and effective OTC analgesic when taken in the recommended dosage of 325 to 650 mg every 4 hours while symptoms persist, not to exceed 4,000 mg in 24 hours for not more than 10 days.

   (1) Effectiveness. Aspirin is by far the most widely used OTC ingredient in the U.S. In fact, many dosage unit packages are sold annually. During the 75 years that have elapsed since aspirin was introduced to the U.S. market, and because of its immense popularity in this country, it has been extensively discussed in the medical and scientific literature.

   Aspirin is useful in mild to moderate pain not only when the pain is localized but also when it is widespread. Studies on cancer pain suggest that aspirin may also relieve mild to moderate pain of visceral origin.

   Numerous articles have been written on aspirin since the first pharmacological data were reported in the literature by Dresser in 1899 (Ref. 1). Virtually all of the experiments described in the articles showed aspirin to be superior to placebo in "mild" to "moderate" pain. Kantor states that "modern clinical pharmacologic testing has established that aspirin is an effective analgesic in the treatment of moderate pain states" (Ref. 2).

   Beavé, in an extensive discussion of mild analgesics in 1965, summarized the findings of over 40 controlled human analgesic studies which demonstrated the superiority of aspirin to placebo. (Ref. 3)

   The Panel has included the following table which summarizes the studies reported by Beavé (Ref. 3):

<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Type of patient, etiology of pain, or both</th>
<th>Aspirin dose (milligram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beecher et al.</td>
<td>Postoperative</td>
<td>0, 600, 1,200</td>
</tr>
<tr>
<td>Boyle et al.</td>
<td>Mixed chronic</td>
<td>600</td>
</tr>
<tr>
<td>Bruni and Hof.</td>
<td>Postoperative</td>
<td>0, 600, 1,200</td>
</tr>
<tr>
<td>Chalmers et al.</td>
<td>Headache, outpatients</td>
<td>300 to 600</td>
</tr>
<tr>
<td>Chas and Frederik et al.</td>
<td>Mixed chronic</td>
<td>250 to 600</td>
</tr>
<tr>
<td>Czerski and Wetzberg</td>
<td>Headache, outpatients</td>
<td>600</td>
</tr>
<tr>
<td>DeBenedict and Lasagna</td>
<td>Postoperative</td>
<td>0, 600, 1,200</td>
</tr>
<tr>
<td>Feinberg et al.</td>
<td>Mixed musculoskeletal, outpatients</td>
<td>325 or 650</td>
</tr>
<tr>
<td>Forrest</td>
<td>Headache, inpatients and outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Hous &amp; Wallenstein</td>
<td>Cancer</td>
<td>400, 600 and</td>
</tr>
<tr>
<td>Kanter et al.</td>
<td>Postoperative and fracture</td>
<td>325, 600, 1,200</td>
</tr>
<tr>
<td>Lesagna et al.</td>
<td>Postoperative</td>
<td>0, 600, 1,200</td>
</tr>
<tr>
<td>More and D'Amelio</td>
<td>Headache, outpatients</td>
<td>600 and 1,200</td>
</tr>
<tr>
<td>Mols et al.</td>
<td>Mixed chronic</td>
<td>103, 203, 303, 403</td>
</tr>
<tr>
<td>Murray</td>
<td>Headache outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Orkin et al.</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>&amp; Perlman</td>
<td>Postoperative</td>
<td>252 (0), 000, 1,000</td>
</tr>
<tr>
<td>&amp; Selinger</td>
<td>Postoperative</td>
<td>000, 1,000</td>
</tr>
<tr>
<td>&amp; Singhal</td>
<td>Mixed acute</td>
<td>203</td>
</tr>
<tr>
<td>&amp; Ulberg</td>
<td>Postoperative</td>
<td>625 or 650</td>
</tr>
<tr>
<td>&amp; Valentine &amp; Martin</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>&amp; Zeldelander</td>
<td>Mixed chronic</td>
<td>600</td>
</tr>
</tbody>
</table>

   Beavé also noted that because of the consistency of aspirin's analgesic activity in well-controlled analgesic studies, most researchers often included it as a standard in their experiments. For example, Lesagna (1952), in a series of 23 separate consecutive studies conducted on patients with postpartum pain (after childbirth) found in 22 of these studies that the analgesic response to 600 mg of aspirin was superior to that of placebo. (Ref. 4). Similarly, Housé demonstrated a significant superiority of aspirin over placebo in 9 of 10 studies in patients with cancer (Ref. 5).

   The Panel has included the following table which summarizes some other more recent studies which also demonstrate the superiority of aspirin to placebo.

<table>
<thead>
<tr>
<th>Investigator(s)</th>
<th>Type of patient, etiology of pain, or both</th>
<th>Aspirin dose (milligram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloomfield, et al. (reference 6)</td>
<td>Epistomy</td>
<td>600</td>
</tr>
<tr>
<td>Bloomfield, et al. (reference 8)</td>
<td>Epistomy</td>
<td>600</td>
</tr>
<tr>
<td>Calabria et al. (reference 9)</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Hain and Turner (reference 11 and 12)</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Leshner et al. (reference 13)</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Moertl et al. (reference 14)</td>
<td>Headache, outpatients</td>
<td>600</td>
</tr>
<tr>
<td>Moertl et al. (reference 15)</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Moertl et al. (reference 16)</td>
<td>Cancer</td>
<td>600</td>
</tr>
<tr>
<td>Parikh-Houson et al. (reference 17)</td>
<td>Headache</td>
<td>600</td>
</tr>
<tr>
<td>Parikh-Houson et al. (reference 18)</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Parikh-Houson et al. (reference 19)</td>
<td>Postoperative</td>
<td>600</td>
</tr>
<tr>
<td>Perret et al. (reference 20)</td>
<td>Orthopedic, postoperative</td>
<td>600</td>
</tr>
</tbody>
</table>

   In 1967, Murray compared placebo, 648 mg aspirin, 325 mg acetaminophen plus 235 mg sallcylamide, and 467 mg acetaminophen plus 467 mg sallcylamide in medical and pharmacy students with pain due to headaches (Ref. 17). He found that aspirin produced relief in 78 percent of the cases, placebo in 46 percent and the acetaminophen-sallcylamide mixtures in 69 percent and 75 percent, respectively. All medications were found to be statistically superior to placebo but no significant differences were found among the drugs tested. The importance of this study is that the pain evaluated was that from common headache, the most frequent reason for aspirin ingestion.

   The blood level below which aspirin is ineffective as an analgesic has not been adequately demonstrated because analgesia has not been shown to correlate directly with levels of salicylates in the blood. However, Beavé noted that the use of graded doses can illustrate the threshold phenomenon (Ref. 3).

   In another study by Murray, a group of medical and pharmacy students used graded doses of aspirin to treat headache (Ref. 21). He showed that 163 mg
and 325 mg doses of aspirin did not statistically differ from placebo response. Results were significant, however, in those using 650 mg doses. A statistically significant immediate dose of about 500 mg was not used in this study. It would appear that a minimum dose of between 325 and 650 mg is needed to produce meaningful headache analgesia, but additional studies are necessary to confirm this.

In addition, once some measurable level of analgesia is achieved, its duration and intensity also do not necessarily correlate with salicylate levels in the blood (Ref. 3).

However, with regard to intensity of analgesia, Murray demonstrated an increase in analgesia when the dose of aspirin was increased from 325 mg to 650 mg (Ref. 21). A study by the Veterans' Administration Cooperative Analgesic Study Group also showed a difference in analgesic effect between 300 and 900 mg aspirin in patients with postoperative pain (Ref. 22). In this study, the low dose of 300 mg was significantly better than placebo.

In another study, Modell and Houde showed a dose related increase in pain relief when 400 mg, 600 mg and 900 mg aspirin were administered to patients with cancer (Ref. 23).

Kantor found that within a population of postpartum patients there were two response groups. The patients whose main complaint was pain following episiotomy (a surgical incision made to aid removal of the infant from the vagina) were able to discriminate between 300 mg and 600 mg doses of aspirin while those patients whose main complaint was uterine cramp pain could not (Ref. 2).

Bloomfield et al., in a double-blind study performed in 1967, were unable to show a significant difference between the analgesic effects of 300 mg and 600 mg doses of aspirin. However, both levels of aspirin were significantly more effective than placebo (Ref. 6). Later in 1970, Bloomfield et al. confirmed Kantor's results regarding the different levels of effectiveness of aspirin in relieving the pain of episiotomy.

Hill and Turner (1969) approached the analgesic evaluation problem from a different point of view. In a double-blind study, aspirin was compared to the narcotic analgesic meperidine in patients with post-operative pain ranging from "mild" to "severe." They concluded that aspirin was preferred at the milder intensity of pain while meperidine was preferable at the severe pain levels (Ref. 11). However, these same researchers in another double-blind study in patients with pain following gynecological surgery could not differentiate meperidine, aspirin and placebo "in the patient population as a whole" but could distinguish them when patients were classified as to the initial severity of their pain (Ref. 12). This latter study could have been insensitive if the pain intensity had not been considered and illustrates one of the inherent difficulties in analgesic evaluation.

Moertel et al. (1971) have evaluated the analgesic effect of 650 mg aspirin as compared with 60 mg codeine sulfate in patients with pain due to unresectable carcinoma (cancer) and found that pain relief was obtained in a significantly greater percentage of those patients receiving codeine than those receiving aspirin (Ref. 14).

Moertel et al. (1972) compared 650 mg aspirin to 250 mg metamizole acid, 300 mg acetaminophen, 650 mg meperidine, 650 mg codeine, 65 mg promazine, 75 mg ethoheptazine, and placebo all given orally to patients with pain due to unresectable cancer (Ref. 15). They concluded that aspirin was "superior to all agents tested."

Recently, Moertel et al. (1974) studied aspirin as a single agent and in combination. Aspirin 650 mg again proved significantly better than placebo. Neither 32 mg pentobarbital nor 65 mg caffeine appeared to increase efficacy in patients with pain (Ref. 16). However, adding 65 mg codeine, 25 mg pentazocine, or 9 mg oxycodone did significantly increase pain relief (Ref. 15).

While the effectiveness of aspirin is undisputed, there are limitations to its use which must be kept in mind. There are wide individual variations in response to all analgesics, and while aspirin is effective in relieving a variety of pain intensities, it is only of limited value in relief of severe pain.

The Panel recognizes that pain is only a symptom of an underlying pathological state and if it is severe or persists, medical attention should be sought. Thus, it finds the following warning necessary.

Do not take this product for more than 10 days. If symptoms persist, or new ones occur, consult your physician.

References


II. has reviewed the metabolism of aspirin
is discussed below. The Panel
labeling can be established to provide for
Persons with a history of blood coagula-
siderations and has summarized "them
ADVERSE EFFECTS ON THE GASTROINTESTINAL TRACT
The drug may potentiate peptic ulcer,
Aspirin causes an increase in occult
ADVERSE EFFECTS ON HYPERSENSITIVE INDIVIDUALS
Aspirin produces allergic and ana-
ADVERSE EFFECTS DURING PREGNANCY
Aspirin interferes with maternal and
ADVERSE EFFECTS ON THE CENTRAL NERVOUS SYSTEM
Aspirin when taken in overdose pro-
ADVERSE EFFECTS ON THE KIDNEY
Aspirin may rarely cause an increase of
ADVERSE EFFECTS ON THE LIVER
High doses may produce a reversible hepatic dysfunction.
ADVERSE EFFECTS OF CONCOMITANT USE WITH OTHER DRUGS OR BY PERSONS WITH CERTAIN DISEASE STATES
Aspirin interferes with some anticoagu-
ADVERSE EFFECTS RESULTING IN IRON DEFICIENT ANEMIA
Aspirin used chronically may cause a persistent iron deficient anemia.
(I) Adverse effects on the blood. In
of aspirin in overdose produces a change in the bleeding time which is ing time and possibly other effects such as fibrinolysis (Ref. 1). (a) Decrease in prothrombin production. High doses of aspirin and salicylic acid (6,000 to 10,000 mg daily) taken for several days can cause hypoprothrombinemia, i.e., a decrease in the amount of prothrombin (blood clotting factor II) in the circulating blood (Refs. 1 and 4) which may be reversed by vitamin K
ANnormal bleeding. In addition to the well-known association between aspirin ingestion and gastro-
ADVERSE EFFECTS ON THE NERVOUS SYSTEM
ADVERSE EFFECTS ON THE LIVER
ADVERSE EFFECTS OF CONCOMITANT USE WITH OTHER DRUGS OR BY PERSONS WITH CERTAIN DISEASE STATES
Aspirin interferes with some anticoagu-
ADVERSE EFFECTS RESULTING IN IRON DEFICIENT ANEMIA
Aspirin used chronically may cause a persistent iron deficient anemia.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
Other analgesic drugs which show marked inhibition of platelet aggregation include indomethacin, ibuprofen, mefenamic acid, and acetylsalicylic acid, or phenacetin (Ref. 23). The importance of the platelets as the first line of defense in hemostasis has been established in recent years (Refs. 24, 25). Bleyer and Breckenridge have studied which facilitates platelet aggregation aspirin therapy, rather than vascular mechanisms other than platelet plugs, to stop bleeding. This histological picture is characteristic of acute gastritis and duodenitis which gastroenterologists state is most likely associated with recent aspirin in- gestion and subsequent gastrointestinal bleeding has been reported following a 3-day course of aspirin administration to patients with chronic conditions which many hematologists state occurs most often not from ulcers but from inflamed mucosal tissue which is partially deme- ned of surface epithelium exposing engorged, hyperemic and dilated capil- laries in the underlying lamina propria. This histological picture is characteris- tic of acute gastritis and duodenitis which gastroenterologists state is most likely associated with recent aspirin ingestion and subsequent gastrointestinal bleeding has been reported following a 3-day course of aspirin administration to patients with chronic conditions which many hematologists state occurs most often not from ulcers but from inflamed mucosal tissue which is partially deme- ned of surface epithelium exposing engorged, hyperemic and dilated capil- laries in the underlying lamina propria. This histological picture is characteris- tic of acute gastritis and duodenitis which gastroenterologists state is most likely associated with recent aspirin ingestion and subsequent gastrointestinal bleeding has been reported following a 3-day course of aspirin administration to patients with chronic conditions which many hematologists state occurs most often not from ulcers but from inflamed mucosal tissue which is partially deme- ned of surface epithelium exposing engorged, hyperemic and dilated capil- laries in the underlying lamina propria. This histological picture is characteris- tic of acute gastritis and duodenitis which gastroenterologists state is most likely associated with recent aspirin ingestion and subsequent gastrointestinal bleeding has been reported following a 3-day course of aspirin administration to patients with chronic conditions which many hematologists state occurs most often not from ulcers but from inflamed mucosal tissue which is partially deme- ned of surface epithelium exposing engorged, hyperemic and dilated capil- laries in the underlying lamina propria. This histological picture is characteris- tic of acute gastritis and duodenitis which gastroenterologists state is most likely associated with recent aspirin ingestion and subsequent gastrointestinal bleeding has been reported following a 3-day course of aspirin administration to patients with chronic conditions which many hematologists state occurs most often not from ulcers but from inflamed mucosal tissue which is partially deme- ned of surface epithelium exposing engorged, hyperemic and dilated capil- laries in the underlying lamina propria.
proposed rules


(7) Menon, L. S., "Aspirin and Blood Fibri


(14) Lessing, J. L., P. Medon and L. Wagner, "Influence of Acetylsalicylic Acid/Sa


(16) Evans, G. M. A. Packham, E. M. Nish


(29) Rapaport, S. L., letter solicited by the Panel April 5, 1974 is included in OGC Vol. 030150.


(46) Adverse effects on the gastrointesti nal tract. Aspirin has several adverse effects on the gastrointestinal tract. These range from relatively mild effects such as gastric distress (mimic stomach pain), an increase in urinary tract symptoms, superficial mucosal irritation and minor occult (un seen) bleeding, to less frequent but more serious effects such as mucosal erosion, ulceration or life-threatening massive bleeding from a variety of gastrointestinal sites. The Panel concludes that all products containing aspirin should include the labeling warning, "Caution: Do not take this product if you have peptic ulcers or bleeding problems except under the advice and supervision of a physician.

The direct and indirect roles of aspirin in producing or potentiating these different types of mucosal damage or bleeding in the gastrointestinal tract are complex and have been controversial. Disagree ment, in part, has been due to the many interacting variables acting singly and to the disease processes involved.
Disease variables of interest relative to safety and labeling include the increased incidence, and severity of adverse effects associated with aspirin use, the site and mechanisms involved and whether aspirin causes, potentiates or exacerbates particular types of gastrointestinal conditions. Important drug variables considered by the Panel include the usual dose required to produce these effects, and whether the effects involve acute (1 to 5 days) or chronic (several months) use of aspirin. Particular attention was given to claims that adverse effects may be reduced by a particular type of dosage form such as buffered tablets or highly buffered effervescent solutions. Buffered aspirin has not decreased the incidence of minor effects but not serious disorders, such as massive bleeding.

The Panel concludes that aspirin should not be used by individuals with a recent history of peptic ulcers or gastrointestinal bleeding because of the increased incidence of gastrointestinal bleeding in such individuals following acute and chronic aspirin ingestion. Furthermore, because recurrent gastric distress caused because of chronic aspirin use frequently occurs in patients with peptic ulcers as compared to normal subjects. Roth states that dyspepsia occurs in about 7 percent of normal subjects, 10 percent of rheumatoid arthritis patients and 30 percent of peptic ulcer patients. Although individuals with an active peptic ulcer are not unusually susceptible to aspirin-induced occult bleeding, they do have an increased susceptibility to dyspeptic symptoms.

The Panel concludes that by merely stating that aspirin (and salicylic acid) cause, potentiates or exacerbates peptic ulcer, or dyspepsia, it may be possible to warn as many as 80 percent of the high risk population.

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vided significantly higher blood salicylate levels (p is less than 0.001) than the rectal route (Ref. 31).

In a study reported by Cacchillo and Hassler (Ref. 32), 11 male volunteers were administered 650 mg aspirin in one of three different types of suppository bases on 1 day for 3 successive weeks. On the fourth week, 650 mg aspirin (tablets) was given orally to compare the oral route with the rectal route. The three suppository bases were cocoa butter, Carbowax and glycerinated gelatin. There was virtually no rectal irritation from aspirin suppositories formulated with cocoa butter and Carbowax as the bases. Glycerinated gelatin based suppositories showed a high incidence of prolonged burning pain, and the subjects evidenced a very strong desire to expel the suppository. There was no statistically significant difference between the absorption of aspirin orally and the absorption of aspirin from the Carbowax base only. The authors state that "individual studies must be undertaken to determine for each drug the base best suited for its absorption." In this study, Carbowax used with two bases, not only showed that "the rectal dosage given is equivalent to the oral, as a high degree of absorption through the rectal mucosa" occurs, but also that "little or no irritation" occurred.

The rate of absorption of aspirin rectally was related to the incidence of irritation in a study by Borg, Ekenved, Elfosson and Sjogren (Ref. 33). They formulated suppositories with two neutral triglyceride mixtures as the bases, i.e., Wittegels H55 with a melting range of 33.5° to 38.6° C and Wittegels B75 with a melting range of 37° to 39° C. Male volunteers were administered 750 mg and 1,000 mg aspirin in these formulations in two studies to investigate the absorption of aspirin from the suppositories. In another study, the investigators administered the two aspirin suppository formulations on the first 2 days of the week for 12 successive weeks. On the fourth week, the two suppositories daily, 8 hours apart, was administered. There was a difference in the rate of absorption of aspirin from the two bases. It was found that a rapid absorption of aspirin was associated with a high incidence of side effects. Reducing the rate of absorption by changing the suppository base, reduced the intensity and frequency of the side effects. The side effects consisted of burning pain, blood in the feces, diarrhea and tenesmus. The authors point out that with the use of bases giving reduced absorption and reduced side effects, however, the amount of drug absorbed from suppositories "will be highly dependent on the length of time the patient retains the suppository."

(3) Stomach mucosal damage. Aspirin has a direct effect on mucosal tissue which is not dependent on the presence of hydrogen ion, bile or other cellular irritants associated with peptic ulcer (Ref. 40). Aspirin particles or concentrated solution produces lesions in the mucosa of the mouth, stomach, rectum and probably most other mucosal tissue (Refs. 6 and 28). Aspirin tablets placed directly on the gastric mucosa of anesthetized cats initially produced coagulation of mucus and opacification of the adjacent gastric mucosa, similar to the appearance of the buccal (mouth) mucosa to aspirin (Ref. 6). These changes were attributed to coagulation of the mucus layer and desquamation (Ref. 8). Multiple small vessel lesions showed focal necrosis with underlying secondary capillary damage. The direct mucosal desquamation and focal necrosis produced by aspirin has been observed in man by gastroscopic observations (Refs. 23, 24 and 34), during surgery (Refs. 1, 2, and 6).

The mucous opacity noted after aspirin irritation is related to epithelial exfoliation. Cellular exfoliation can be measured by increased DNA content in the gastric fluids since DNA is found only in cells and therefore reflects sloughed or damaged mucosal cells (Ref. 8). Accumulation of DNA in gastric fluid occurred in about 10 minutes in 9 of 12 subjects receiving aspirin (Ref. 8) which is similar to the percent of subjects showing direct irritation to aspirin in the gastroscopic studies of Douthwaite and Lintott (Ref. 23).

The direct observations by gastroscopic effects of aspirin on the gastric mucosa (Ref. 38) in rabbits and cats are similar to the findings of Burger, Eberhart, Gross, Hassler and Wert (Ref. 38) who have provided basic principles which have been substantiated by many investigators during the past 30 years. Specifically, gastroscopic observations of 16 patients demonstrated the following: In 80 percent of the patients, a local inflammatory reaction of the gastric mucosa was observed ranging from slight hyperemia to submucous hemorrhage; and the occurrence and severity of the reaction was not a function of the brand of aspirin, the acidity of the stomach or the prior appearance of condition of the gastric mucosa. Patients with hyperchlorhydria (excessive acid secretion) had both positive and negative direct irritation responses. Responses were seen in patients with 16 hospital cases (40) of hyperchlorhydria (hydrochloric acid deficiency) and achlorhydria (absence of hydrochloric acid). Therefore, gastric acidity is not essential for initial direct irritation. Marked hyperchlorhydria in the absence of hemorrhage (hemorrhagic erosive gastritis) occurred in 1 of the 16 patients. Salicylic acid also caused direct gastric irritation but was less severe. Contact with 0.2 percent aspirin solution for 10 minutes did not have a direct effect on the gastric mucosa.

The initial effects of aspirin, such as mucus destruction, epithelial desquamation, inflammation and focal necrosis, affect the appearance of small well-demarcated erosions. This phase is not related to vascular damage or bleeding. It is apparently not dependent on the presence of gastric acid. Progression to visible hemorrhage may be dependent on local effects of gastric acid according to Davenport (Refs. 35 and 36) and/or possibly aspirin (Ref. 36).

Both found that phenacetin and acetaminophen have no direct irritating effect on the gastric mucosa (Ref. 6). However, phenacetin is claimed (but not proven) to slightly increase occult bleeding (Ref. 37), perhaps indicating that the two events are not necessarily related.

Acid-mediated erosive gastritis. In the stomach, the direct effect of aspirin or salicylic acid after being absorbed into the mucosal cell renders the cell more permeable to the hydrogen ions of the stomach (Refs. 33, 39, and 43). Absorption of aspirin or salicylic acid into the mucosal cell causes increased permeability via-breakdown of the cell barrier, which normally protects the submucosal capillary blood vessels. Excess backflow of hydrogen ion into the cell further damages the cell, causing erosion (acute erosive gastritis). Excess hydrogen ions can also pass into the space just below the surface cell (lamina propria), which contains an extensive network of capillary blood vessels. Hydrogen ions can initiate capillary damage and subsequently, minor bleeding occurs into the lumen of the stomach (Refs. 35 through 41, 44, and 45). This mechanism, referred to as the Davenport mechanism has been extensively studied in animals (Refs. 35 through 41, 44, and 45). Many investigators believe that it is a major factor in hemorrhagic erosive gastritis and aspirin has other gastrointestinal effects of aspirin from occult bleeding to hemorrhagic erosive gastritis to major gastrointestinal hemorrhage are all related to this single mechanism involving the back diffusion of acid (Ref. 48). As a corollary, it has been proposed that any preparation which neutralizes gastric acid during absorption will obviate the danger of severe gastrointestinal damage and massive bleeding (Ref. 47).

The Panel concludes that the acid-mediated gastric erosion induced by aspirin is undoubtedly an important factor in some adverse effects of aspirin on the gastrointestinal tract. It is probably associated with increased occult bleeding following single and multiple doses of aspirin. It may contribute at least in the beginning stages of aspirin-induced gastric ulcer caused by chronic doses of aspirin (Ref. 48). It is also probably a factor in hemorrhagic erosive gastritis directly initiated by multiple doses of aspirin. In this case it may initiate major bleeding. However, as will be noted in subsequent sections, alcohol and other factors which can initiate hemorrhagic erosive gastritis and aspirin has other effects independent of gastric acid which may be of equal or greater significance in contributing to massive gastrointestinal bleeding.

(2) Other mechanisms of aspirin damage. The Panel agrees that there is very good evidence in both animals and man that the Davenport mechanism is one important effect of aspirin. However, to conclude that this mechanism is the only effect of aspirin on the gastrointestinal tract and thus the only basis

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
for aspirin's role in initiating, exacerbating, potentiating or facilitating gastrointestinal pathologies is not consistent with current experimental data and clinical studies.

I. Additional factors in the Davenport mechanism. According to the Davenport theory, the absorption of unionized aspirin or salicylic acid into the cell carries hydrogen ion across the barrier into interstitial space where the pH is higher, whereas aspirin or salicylic acid are ionized and the hydrogen ion is dissociated. Hydrogen ion is thought to cause the release of vasoactive substances such as histamine from mast cells, in the lamina propria, which initiates capillary bleeding. If the hydrogen ion flux associated with transport of the acids were the only factor, one would expect salicylic acid to cause greater occult bleeding than aspirin since it is more rapidly absorbed. Leonards and Levy (Ref. 49) have shown that salicylic acid is more rapidly absorbed than aspirin in man, but it produces significantly less occult bleeding. Mean occult blood loss in 13 subjects was 6.3 ml, 1.9 ml, 1.2 ml and 0.7 ml for aspirin, sodium salicylate, salicylic acid, and sodium salicylate with buffer, and control respectively.

An explanation for the differences between aspirin and salicylic acid is that the direct cellular effects of aspirin and salicylic acid interfere at different concentrations with biochemical cellular process (Ref. 50) which affect the hydrogen ion barrier. Lower concentrations of aspirin are needed to initiate cellular dysfunction. Indeed the effective concentrations of these agents are consistent with the direct mucosal effects seen in nonacid mucosal cells (mouth).

However, this would not explain why several anti-inflammatory agents cause gastric erosions and massive gastric bleeding but do not affect the hydrogen ion barrier and vice versa.

II. Relationship between aspirin damage and bleeding. Studies using the gastrectic potential difference which is the most sensitive way to measure changes in the hydrogen ion barrier in man show that phenylbutazone and indomethacin in usual doses do not damage the hydrogen ion barrier (Ref. 51). However, they both produce major gastrointestinal bleeding and gastric ulcer (Refs. 52 and 53). These agents do not generally increase occult bleeding (Refs. 53 and 54) indicating the occult bleeding may involve the Davenport mechanism but not massive bleeding.

Conversely, some agents may affect gastric potential but do not cause bleeding. Indeed this was recognized by Davenport (Ref. 40) who stated the other side of the coin: "why does bleeding occur during back diffusion following salicylate injury and not during comparable diffusion after many other forms of injury." Bile can cause changes in the barrier at neutral pH which is said to be augmented by the effect of aspirin (Refs. 40 and 55). Some discrepancies can be resolved by considering additional direct and indirect effects of aspirin and other agents on mucosal blood flow.

III. Vascular effects. In contrast to the Davenport mechanism, which assumes the initial effect of aspirin is on the mucosal cell mediated through hydrogen ion possibly by causing release of histamine with secondary vascular involvement, there are several types of hemorraghic erosive gastritis the reverse occurs where the initial effect is on the mucosal vasculature.

Weiss et al. (Ref. 10) state that the primary cause of direct vascular injury of the capillaries in the lamina propria followed by capillary hemorrhage and hypoxia (deprivation of oxygen). It may also lead to necrobiosis of the neck cells and exfoliation of the gland.

It is now believed that two hemorraghic erosive gastritis are caused by factors which directly initiate histamine release from the mast cells in the lamina propria as opposed to the hydrogen ion mediated release in the Davenport theory (Ref. 39). These factors may be involved in "stress ulcers", and other gastric lesions of the initial mechanism, whether hydrogen ion or stress, the common denominator is initiation of histamine release from the mast cells in the mucosal capillary region (Ref. 40). Both initial vascular and initial vascular or other factors may be involved in "stress ulcers", and other gastric lesions of the initial mechanism, whether hydrogen ion or stress, the common denominator is initiation of histamine release from the mast cells in the mucosal capillary region (Ref. 40).

Local capillary blood flow can apparently be affected by many diverse factors. The mechanism by which vagotomy decreases gastric bleeding may not be a result of decreased gastric acid as commonly stated but by a shunting of blood flow leading to hypoxia and a secondary cellular effect (Ref. 40).

Local capillary blood flow can apparently be affected by many diverse factors. The mechanism by which vagotomy decreases gastric bleeding may not be a result of decreased gastric acid as commonly stated but by a shunting of blood flow leading to hypoxia and a secondary cellular effect (Ref. 40).

(c) Occult bleeding. Occult (unseen) bleeding is a common predictable occurrence related to normal aspirin ingestion. The average person (70 percent of the population) taking one or two tablets of aspirin 3 or 4 times daily will lose from 2 to 5 ml of blood per day into the stools due to the direct effect of aspirin on the gastric mucosa (mucous membrane of the stomach). Some individuals, about 10 percent of the population, may lose as much as 10 ml daily (Ref. 57). Occult blood loss is not decreased by food although aspirin dyspepsia is (Ref. 58).

This minor occult bleeding is not, usually, clinically significant except in those individuals taking aspirin for long periods of time who are anemia-prone or have bleeding tendencies (Refs. 49, 59, and 60).

The Panel has discussed the association of aspirin with iron deficient anemia elsewhere (see part III, paragraph B.1.a. (2) (d) below—Adverse effects resulting in iron deficient anemia). The mechanisms involved in occult bleeding have been extensively studied in animals (Ref. 26) and to a lesser extent in man (Ref. 61). There is general agreement among most authorities that the use of radioactive tagged red blood cells (Ref. 57). Therefore, there are many studies and reliable data available on the relationships between occult stomach bleeding and different types and formulations of analgesics (Ref. 58).

There is good evidence that the addition of sufficient buffering to decrease gastric acidity and increase the pH of the gastric contents will significantly reduce, but not necessarily eliminate, occult bleeding. However, highly buffered aspirin preparations will increase occult bleeding in normal subjects if given as multiple doses for 2 to 3 days (Ref. 63).

In a few susceptible individuals who are otherwise apparently normal any aspirin preparation including highly buffered aspirin solutions, will greatly increase occult bleeding (Ref. 63).

While these individuals with unusual susceptibilities may provide some insight into the factors related to clinically important massive occult bleeding, the average occult bleeding following aspirin ingestion in normal individuals or in individuals with peptic ulcerer currently has no relationship to massive bleeding (Refs. 6 and 9).

There appears to be no difference between the average increase in occult bleeding in normal individuals and massive bleeding.
PROPOSED RULES

never been shown. Occult bleeding and massive gastrointestinal hemorrhage should be considered as two distinct clinical entities (Refs. 7 and 8). The failure to recognize this difference has been stated to be responsible for much of the confusion in the literature (Ref. 8). Occult bleeding is a predictable occurrence in most normal people. Massive bleeding after small doses of aspirin than normal subjects. These subjects, however, do have a greater propensity for recurrence of massive bleeding (Refs. 7 and 10).

Persons with active peptic ulcer (Refs. 7 and 8) or persons who have recently experienced a massive gastrointestinal hemorrhage (Refs. 27 and 43) do not necessarily relate aspirin causes ulcer in animal models; direct observation of isolated cases in man; several recent well-controlled studies (in which disease-induced bleeding and normal ulcers were not mixed) demonstrated that increased gastric ulcer incidence in a population in which increased chronic use occurred due to subclinical symptoms or variabilities of the lesion are different than in aspirin users than nonaspirin users; and evidence that the site of the ulcer lesion can be affected by the dosage form used.

The Boston series (Ref. 84) conservatively estimated that 10 out of every 1,000 aspirin users would develop a nonbleeding gastric ulcer requiring hospital admission. This study estimated that one-eighth of all gastric ulcers were related to aspirin and Cameron found one-third of all new non-bleeding gastric ulcers are caused by chronic aspirin ingestion (Ref. 19).

Jorgensen and Gyllenborg (Ref. 85) determined the life incidence of peptic ulcer to be 9.2 percent in a sample of 5,240 men aged 40 to 59 in Copenhagen and reported a relative risk of 2.2 forhh in the U.S. In a one year followup study on 4,753 males the year incidence of peptic ulcer was 1.2 percent. Only 15 percent of these newly diagnosed ulcer cases were associated with aspirin. Thirty percent of subjects ingested aspirin regularly compared to 16 percent of controls (p is less than 0.02). In only one of these subjects was aspirin taken for ulcer symptoms.

It can be estimated that 16 percent of the ulcer cases were associated with aspirin which is equivalent to a 9 percent increase in the incidence of peptic ulcer. This was reported in 1961 by Brown and Schneider (Ref. 86) and in 1970 by Roth (Ref. 6). Brown and Schneider (Ref. 86) estimated the life incidence of peptic ulcer to be 3.6 percent in the age group 50 to 59. This is similar to the estimate given by Levy of 10 per 100,000 of all adults taking aspirin since the incidence in women and younger adults would be lower. This total incidence of aspirin-related gastric ulcer may be higher than generally assumed.

There appears to be almost universal agreement that aspirin should not be used in persons with peptic ulcer, particularly those with gastric ulcers. Cameron (Ref. 89) states, "...the evidence presented suggests that patients with gastric ulcer should be urged to avoid aspirin." Similar warnings have been urged by Roth (Ref. 6), Brown and Mitchell (Ref. 86), Schneider (Ref. 24), and Weiss (Ref. 10). Acute use of aspirin can precipitate massive hemorrhage in gastric and duodenal ulcer patients. The mortality of acute hemorrhage in patients two distinct clinical entities (Refs. 7 and 8). The failure to recognize this difference has been stated to be responsible for much of the confusion in the literature (Ref. 8). Occult bleeding is a predictable occurrence in most normal people. Massive bleeding after small doses of aspirin than normal subjects. These subjects, however, do have a greater propensity for recurrence of massive bleeding (Refs. 7 and 10).

Watson and Piersen (Ref. 64) in 1961 showed that occult bleeding was not greater in persons taking anticoagulants even though prothrombin activity was greatly reduced. Massive bleeding, however, has been associated with hypoprothrombinemia resulting from high doses of aspirin. See part III. paragraph B.1.a.(2) Decrease in prothrombin production. The amount of occult blood lost is less in individuals who have atrophic gastritis (Refs. 6, 61, and 65) or less frequently than in normals, presumably because these patients have decreased gastric acid. But patients with atrophic gastritis are often involved in aspirin-induced massive bleeding and are at much greater risk of bleeding following aspirin than the normal population (Refs. 61 and 65).

The Panel concludes that occult bleeding resulting from aspirin ingestion appears to have very little correlative or predictive value in the diagnosis or study of the major clinically important gastrointestinal effects produced by aspirin such as ulceration and massive bleeding.

1. Gastric ulcers. The Panel concludes that chronic use of aspirin may directly cause gastric ulcers (Refs. 16 through 19 and 68). Several of these studies show that chronic use increases significantly the incidence of gastric ulcers but not duodenal ulcers (Refs. 6, 61, and 65). Chronic use of aspirin is associated with an increased incidence of uncomplicated nonbleeding ulcers, bleeding from ulcers and perforated gastric ulcers (Refs. 16, 86, and 87). Epigastric pain is common in all of these cases. Continued use of aspirin can delay ulcer healing even though ulcer therapy is started (Ref. 18). Discontinuation of aspirin leads to rapid recovery (Refs. 3 and 18). Beneficial effects of aspirin can re-activate gastric ulcer (Ref. 17).

2. Acute use of aspirin may activate symptoms of both gastric and duodenal ulcers. The symptoms and signs include both epigastric pain and massive gastrointestinal hemorrhage.

The role of acute aspirin use in the exacerbation of existing peptic ulcers has been noted by many authors over the past twenty years (Refs. 16 through 19 and 66 through 86). Evidence that chronic use of aspirin will increase the incidence of gastric ulcers has not been widely appreciated. In the opinion of the Panel a causal role of chronic aspirin use and increased incidence of peptic ulcer is supported by several types of evidence. These include: (1) the well documented fact that aspirin causes ulcers in animal models; (2) direct observation of isolated cases in man; several recent well-controlled studies (in which disease-induced bleeding and normal ulcers were not mixed) demonstrated that increased gastric ulcer incidence in a population in which increased chronic use occurred due to subclinical symptoms or variabilities of the lesion are different than in aspirin users than nonaspirin users; and evidence that the site of the ulcer lesion can be affected by the dosage form used.

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particularly in women, provides evidence for a causal relationship between aspirin, usually in combination, and chronic peptic ulcer. This population is significant from an epidemiologic point of view not only because it comprises a high percentage of chronic, daily aspirin use but also the significantly greater incidence of daily use by women compared to men, first noted by Billington in 1969 (Refs. 71 and 72). The authors state that aspirin therapy by women who take analgesic compounds is clearly for other than gastrointestinal symptoms. If increased chronic use of aspirin does result in a higher incidence of gastric ulcer, then this effect should be clearly evident in the Australian population. A correlation between increased analgesic use and increased incidence of ulcer was shown by Duggan and Johnson (Ref. 74) and confirmed by several others (Refs. 16, 17, 19, 78, 77, and 78). It is possible that phenacetin, an ingredient in almost all abused analgesic combinations, contributes to gastric ulcer. However, phenacetin alone does not have a direct damaging effect on the gastric mucosa (Ref. 6). Furthermore, ulcers are rare in patients taking phenacetin compounds not containing aspirin, even though kidney disease continues to develop (Ref. 72).

It is possible, however, that the combined effect of phenacetin and aspirin may be greater than aspirin alone. The same reasons discussed later in the section on the effects of aspirin on the kidney. (See part III: paragraph B.l.a. (2) (vi) — in the same study, Douglas and Johnson of Australia (Ref. 74) reported that 90 percent of 73 chronic gastric ulcer patients took a proprietary compound containing aspirin, phenacetin and caffeine. Most patients were chronic headache sufferers with pain predating the ulcer and were daily users of analgesic compounds containing aspirin. Compounds with phenacetin (or salicylamide) and caffeine were preferred by over 50 percent of this group. The usual reasons for use given by chronic users were headache (41 percent), arthritis (21 percent), and indigestion (7 percent).

Gillies and Skyring (Ref. 77) in an interview study found a statistically significant association between chronic use of high doses of aspirin and the incidence of gastric ulcer. Fifty-seven percent of patients with active gastric ulcer had taken aspirin daily compared to 22 percent of controls. In earlier case-control studies, Gillies and Skyring (Ref. 77) found a significant correlation between high intake of aspirin and gastric ulcer but not indigestion. The authors state that aspirin use was higher among women than men, but the difference was not statistically different (p is greater than 0.05) from controls.

Duggan and Chapman (Refs. 81 and 82) found a correlation between the incidence of gastric ulcer in women and the consumption of large amounts of aspirin, mainly as analgesic tablets. Within 4 years, all patients taking analgesic tablets had developed a headache. No such correlation for duodenal ulcer in either sex or gastric ulcer in males was found. Duggan (Ref. 82) followed all patients with acute perforated peptic ulcer in an Australian hospital over a 4-year period. The proportion of women in this series was very high (24 percent) compared to the usually very low incidence of gastric ulcer in women in British literature. The association between the use of high doses of aspirin over prolonged periods and the incidence of gastric ulcer was highly significant statistically, particularly for the women.

In men, 25 percent had a high intake of aspirin and 45 percent of ulcer patients took no aspirin. In the women, 62.5 percent had a high intake of aspirin and 25 percent took no aspirin. The authors state that aspirin abuse is the environmental factor responsible for the excess of gastric ulcer in middle-aged Australian women and was not related to whether or not the patients took aspirin.

In a further study, Duggan (Ref. 90) analyzed the prognostic factors of 1,634 patients with acute gastrointestinal hemorrhage and found 66 percent of the group with chronic ulcer and 25 percent involved an acute lesion. The total mortality was 11 percent. There was a statistically significant association between gastric ulcers with matched controls for chronic aspirin use. These patients had the worst prognosis. However, the reason for the poor prognosis probably reflects habituation of the individuals to the APC compound used, or gastric ulcer patients to the aspirin taken by women in Australia. In other series, aspirin-induced gastric ulcers healed rapidly with a good prognosis when aspirin was withdrawn (Ref. 19).

In the Duggan study the overall mortality for all forms of major gastrointestinal hemorrhage was 11 percent. The mortality of peptic ulcer patients who had gastrointestinal hemorrhage was 8.5 percent and was not related to whether or not the patients took aspirin.

(iii) Case-control studies with controlled drug intake. There have been three case-control studies in gastric ulcer patients that have been designed to avoid bias due to analgesic drug intake related to gastrointestinal pain. Cameron (Ref. 19) in a prospective study found that chronic aspirin use (15 tablets per week for 1 month or more) was associated with gastric ulcer in 53 percent of 61 patients compared to 10 percent of controls. When aspirin was given to ulcer patients for their symptoms, the ulcer patients were excluded, 45 percent of 40 ulcer patients took aspirin. The difference between ulcer cases and control subjects was highly significant statistically. When the same correlation was applied to duodenal ulcer patients only 16 percent of the remaining 26 duodenal ulcer patients were regular aspirin users, whereas this was not statistically different (p is greater than 0.01) from controls.

(iv) Characteristics of aspirin-related gastric ulcer lesions. Aspirin-related gastric ulcer patients who were taking aspirin had lesions which are generally of the same shape, size and appearance as in nonaspirin ulcer patients. However, the location and distribution of these lesions differed from those in the stomach and the condition of the surrounding mucosa appear to be different. Interestingly, the distribution of aspirin lesions is apparently a function of the dosage form as well as the drug. By far the most serious adverse effect of the action of aspirin on the gastro-intestinal tract is massive upper gastrointestinal bleeding, which can be life-threatening (Ref. 87), often requiring surgical intervention and which also has a high mortality risk (Ref. 87). The mechanisms and factors involved in massive gastrointestinal bleeding are not completely understood. It is a relatively rare event which in most cases does not ap-
pean to be predictable relative to the dose or frequency of use of aspirin.

Although the incidence of massive bleeding is low, relative to the frequency of aspirin use, the total occurrence is not insignificant. Three different recent reports from the Boston Collaborative Surveillance program and incidence figures support this. It appears that the number and severity of adverse effects on the gastrointestinal tract produced by aspirin are quite significant (Refs. 92, 99, and 101). In a recent survey, aspirin was the second most frequent drug involved in adverse effects that were serious enough to require hospitalization. Two out of every 1,000 hospital admissions were attributed to aspirin. Massive bleeding was second only to digitals intoxication as the most frequent cause of drug-induced hospital admission, and aspirin products were involved in over 60 percent of the cases (Ref. 92). Of greater significance is the fact that the mortality rate associated with this condition is high (Ref. 92). Death occurred in 16 percent of all patients with gastrointestinal bleeding including those associated with aspirin ingestion (Refs. 15 and 16). Even greater mortality rates are involved in those patients requiring surgery to stop bleeding (Ref. 87).

Miller (Ref. 93) also compared the incidence of adverse reactions in 1,615 hospitalized patients receiving usual doses (300 to 600 mg aspirin in 70 percent of patients). The incidence of gastric distress such as heartburn, indigestion, nausea, vomiting was only 1.9 percent. The incidence of gastrointestinal bleeding, including hematemesis and epistaxis, was 0.7 percent (12 per 1,615) of all patients receiving aspirin (47 per 1,000).

A third report by Levy (Ref. 94) estimated the frequency of major gastrointestinal hemorrhage that was unrelated to any known predisposing factors such as ulcers, gastritis. The incidence of gastrointestinal bleeding in regular aspirin users was estimated at 25 per 100,000 (0.25 per 1,000).

The very low figure in the third study is undoubtedly an underestimate due to the design of the study, which is discussed below.

Numerous clinical studies have indicated that from 30 to 80 percent of all persons (Refs. 4, 22, 85 through 87, and 94 through 101) entering the hospital for massive gastrointestinal bleeding have taken aspirin within the past 24 to 72 hours. Recent epidemiological studies conclude that acute use of aspirin is causally related to massive bleeding (Refs. 84 and 93). The Panel believes that aspirin can potentiate bleeding in patients having a variety of gastrointestinal lesions including acute erosive gastritis (Refs. 15 and 102), chronic atrophic gastritis, stress ulcer, gastric ulcer (Refs. 19, 79, 82, and 84), duodenal ulcer (Ref. 84) and duodenitis (Ref. 69).

There are now convincing studies which indicate that aspirin is a definite factor associated with increased incidence of severe gastrointestinal hemorrhage in susceptible individuals. Therefore, the Panel concludes that the labeling should include the warning, "Use of aspirin is contra-indicated if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician."

(i) Evidence for aspirin causation in major gastrointestinal hemorrhage

In establishing a causal relationship between a drug and a disease, criteria that a drug causes a disease must be identified; when a mechanism involving the drug can be established, consistent with all data, or by identification of a particular high risk group.

The possibility of comparing the incidence of aspirin use and the incidence of bleeding from different types of lesions is dependent upon the diagnostic procedures used such as x-ray, laparotomy, gastroscopy and histological examination of biopsies. Radiological (x-ray) methods detect chronic ulcers but not erosions or acute (superficial) ulcer. Depression of the gastric mucosa requires gastroscope examination or, occasionally, observation during surgery. More recently it has been established that acute hemorrhagic gastritis associated with aspirin ingestion is one type (incomplete gastritis; atrophic, hyperfunctional etc.) which can only be established if biopsies of mucosa are examined microscopically. Even the histological studies involving single biopsies may miss some types of lesions.

(ii) Direct observation of bleeding in subjects

Hemorrhagic erosive gastritis has been observed in aspirin studies designed to test other responses. In a few cases, bleeding was severe enough to require surgery. Bleeding erosions containing fragments of aspirin tablets have been reported (Ref. 6). A representative case was described by Roth (Ref. 6) who described an example illustrative of massive hemorrhage secondary to aspirin use. Surgical intervention was necessary and revealed two 1-cm round lesions (the size of the tablet). The appearance of the lesions resembled acute focal hemorrhagic gastritis including desquamation of surface epithelium and capillary breakdown in the focal area.

The authors state that there could be no doubt about the causative relation of aspirin to the punched out bleeding erosions but questioned the persistent bleeding from two small erosions involving only capillary breakdown. They concluded that occasional massive bleeding probably requires the local effect to initiate the bleeding but also some undefined effect such as hyperresponsiveness or a capillary or coagulation defect.

Several of the authors have observed mucosal erosions and hemorrhage associated with aspirin particles by gastrointestinal examination (Ref. 23) and during surgery (Ref. 33). Correlation of individual bleeding response with variable drug intake. Individual cases showing reversible susceptibility to bleeding when aspirin is increased or withdrawn are given by Weiss (Ref. 10), Hurst (1 case) (Ref. 34), Kelly (3 cases) (Ref. 85), Waterson (Ref. 103), and Brown and Mitchell (Ref. 86).

Because aspirin is frequently taken by patients for symptoms of their gastrointestinal disease, it is particularly critical to evaluate this potential bias in all studies showing an increased incidence of aspirin use associated with a particular disease condition. There, are several studies, however, in which the available information clearly shows that the drug was not taken for symptoms related to the disease condition. The control group was matched for all important variables except bleeding (Refs. 2, 22, 84, and 85).

Because gastric distress is such a common component of gastrointestinal disease, in some studies all cases of acute upper gastrointestinal hemorrhage in individuals with a known history of gastrointestinal disease were included as possible cases involving aspirin as a causal factor. Gastric pain associated with peptic ulcer or contributory factor (Refs. 2 and 84). These studies do not consider the important possibility that aspirin taken either for unrelated reasons or for the chronic gastric pain associated with peptic ulcer or gastritis will initiate bleeding from existing lesions.

(iii) Case-control studies eliminating bias due to drug use for gastrointestinal symptoms

Langman (Ref. 104) has reviewed several of the case-control studies concluding that a relationship between aspirin and major gastrointestinal hemorrhage was evident but could not be shown to be a causal relationship. A causal relationship could not be shown because it could not be ruled out that aspirin may have been taken for symptoms of massive bleeding. The Panel believes that some of the criticisms of the control groups, made by Langman, were possibly appropriate but also some were arbitrary and not based on any substantive evidence known to the Panel. Furthermore, the fact that the percent of persons taking aspirin in the case group was greater than that in the control of the different types of studies is important since it is highly unlikely that a systematic bias would be involved for all groups in all the studies (Refs. 4, 10, 22, 84 through 87, 90, 92, and 94 through 101).

The choice of Alvarez and Summerskill (Ref. 23) in using dyspeptic patients as controls was criticized by Langman (Ref. 104) because these patients may have been warned by their physicians not to take aspirin. In the Panel's opinion this criticism is not valid because the patients
were carefully matched and the "case" group is just as likely to have dyspepsia and be women as their physician; and dyspeptic patients are probably the best possible control group to assure that the control group would have the same likelihood of taking the drug for symptoms as the case group. A well-controlled study by Needham et al. (Ref. 95) was designed to meet the criteria described by Langman. They found a relationship between short-term use of aspirin (within 72 hours of hospital admission) and massive upper gastrointestinal bleeding. A second study was carefully ruled out bias from aspirin being taken for symptoms, a retrospective case-control study of 16,468 patients carried out by the Boston Collaborative Drug Surveillance Program found an association of "heavy" aspirin use (used for 4 or more times a week for 12 weeks) with non-bleeding stomach ulcer and major upper gastrointestinal bleeding in the absence of known predisposing conditions (Ref. 86).

In the Boston study it was estimated that the incidence rate of hospital admissions for gastrointestinal bleeding in individuals without known predisposing conditions, or evidence of intestinal ulcer, and not taking aspirin, is 11 to 13 per 100,000 per year. The incidence rate in heavy aspirin users was twice as high, being about 28 per 100,000 per year. The yearly incidence-rate of new cases of nonbleeding stomach ulcers in individuals not taking aspirin was 100,000 per year. In heavy aspirin users the rate is about four times higher, 13 per 100,000 per year. Both of these differences were statistically significant. Thus, the increase in admissions for new massive gastrointestinal bleeding, excluding intestinal ulcer, and stomach ulcers that might be attributed to heavy use of aspirin would be about 25 per 100,000 per year. The author concludes that these data are consistent with a causal relationship between regular "heavy" use of aspirin and major upper gastrointestinal bleeding in nonbleeding stomach ulcers. It should be noted that 15 percent of the total patients admitted to the hospitals used aspirin at least once a week for 3 months and 6.3 percent took aspirin four or more times a week for 3 months.

The estimated involvement of aspirin is probably conservative in the Boston study since it involved only new cases. It unfortunately does not provide information on a critical point of concern to this Panel, i.e., the possible increased risk of aspirin use in patients with a history of bleeding in the past. It also does not provide information regarding the possible role of aspirin effects on the blood clotting mechanism which might potentiate bleeding from existing intestinal ulcers since this group was excluded from the study. The authors state:

"It is worth emphasizing that this study provides no information on the relation of aspirin to gastrointestinal bleeding in patients who have predisposing conditions such as established chronic peptic ulcer disease. Evaluation of such cases, in a case-control study, could be virtually impossible since there would be no satisfactory way to determine the influence of the disease itself on aspirin use."

The Levy study clearly underestimated the true incidence (Ref. 1). It did not take the case-control design into account to eliminate individuals who may have taken aspirin for the gastrointestinal symptom. Even this does not include those individuals who take aspirin for gastric distress which then precipitates bleeding from primed sites. Of the total number of cases of peptic (stomach) ulcer (517) and upper gastrointestinal bleeding (467) only 243 cases were used in the study. 356 cases were excluded from the study because of a history of stomach ulcer or stomach surgery and an additional 78 cases were excluded because bleeding occurred after admission. Furthermore, this study did not examine the possible effect of one time or short term ingestion of aspirin on massive bleeding since only chronic use was studied. It is important to realize that while the study does prove that there is a causal relationship between chronic or heavy use and massive bleeding, it does not prove that only chronic use of aspirin will produce ulcer or gastric bleeding. The study was designed such that only chronic aspirin use was studied. Any individual who had one or more strokes of bleeding on aspirin was excluded. All other studies of gastrointestinal hemorrhage have examined only acute use of aspirin, usually only 24 to 72 hours prior to bleeding. The association between bleeding and "heavy regular" use (more than 3 times per week) may simply reflect the higher probability of aspirin being ingested during the period of gastric susceptibility even though only a few doses were actually necessary to potentiate the bleeding episode.

It is also of possible significance that the Boston Collaborative Drug Surveillance Study found no evidence of an association between aspirin ingestion and newly diagnosed cases of uncomplicated non-bleeding intestinal ulcer. In the study, the incidence rate was 7.8 percent per 100,000 per year for heavy users of aspirin compared to 6.9 percent of controls. In the 43 patients with newly diagnosed duodenal ulcer who had major bleeding 11.8 percent were heavy aspirin users compared to 6.9 percent of controls which was not statistically significant. However, this trend of an increased incidence of bleeding in duodenal ulcer patients taking aspirin was found to be statistically significant in the study of Needham et al. (Ref. 95). Chapman and Duggan (Ref. 79) in 1963 also found a relationship between chronic aspirin use and the ingestion of a combination product that contained aspirin, phenacetin and caffeine (APC), and the incidence of peptic ulcer and no association between duodenal ulcer (intestinal ulcer) and analgesic consumption. Prepyloric ulcers (ulcers near the exit valve of the stomach) were found in an abnormally high incidence in aspirin users. The association of aspirin with ulcers was highly significant, supporting the concept that aspirin abuse is a cause of chronic peptic ulcer and is the environmental factor responsible for the observed high incidence of ulcer disease in middle-aged women in eastern Australia (Ref. 88).

(2) Difference between case and control in the frequency of duodenal hemorrhage and the time between aspirin ingestion and response. Unfortunately the details of aspirin consumption in patients with major gastrointestinal bleeding has not been given in most studies. The carefully done prospective study of Alvarees and Summerskill (Ref. 22) does provide some useful information in this regard. These workers carefully noted the exact time and reason for aspirin ingestion in 103 consecutive patients in order to determine if the drug was taken as a result of the bleeding rather than being the precipitating factor. The control group of dyspeptic patients with no bleeding were matched for sex but not age. The differences in age, however, are small and insignificant relative to the study. The data were analyzed by the same method drawn from their data. First, the difference in the time distribution provides additional support for aspirin as a causative factor in hemorrhage.

Second, the effect of aspirin in producing hemorrhage is acute. If one plots these data as the cumulative frequency of aspirin use, relative to total use, for the entire study, one can clearly see that the probability of aspirin ingestion being associated with gastric bleeding declines exponentially with time. The majority of patients who bleed took aspirin within 2 days of bleeding.

(3) Characteristics of lesions. (1) Bleeding in peptic ulcer patients. Peptic ulcer patients do not show increased occult bleeding after aspirin (Refs. 8 and 9) but aspirin does increase the incidence of massive bleeding in both gastric and duodenal ulcer patients. Weiss (Ref. 10) states that patients with peptic ulcer disease are unlikely to show gastrointestinal bleeding.

When bleeding occurs it often occurs from other sites rather than from the healed or active ulcer (Ref. 15) found to occur from the ulcer directly (Ref. 102).

Gastro-duodenal hemorrhage following the taking of aspirin is more often due to superimposed acute erosive gastritis than to bleeding from the actual ulcer (Ref. 2).

Several recent studies indicate that acute use of aspirin will cause bleeding in the gastric and duodenal ulcer patient (Refs. 95, 104, and 105). Furthermore, recent studies establish that the gastrointestinal bleeding associated with aspirin is increased by alcohol consumption (Refs. 104 and 105). In these studies the increased effect of alcohol was often statistically demonstrated only in duodenal ulcer patients and not in the gastric ulcer and duodenal bleeding patients (Refs. 95 and 104). The fact that aspirin causes only gastric ulcer
It should be noted that the chronic aspirin-related gastric ulcer is not necessarily a bleeding ulcer. Only 3 of the 61 gastric ulcer patients studied by Camer- oster had hypersensitive reactions in the previous 6 months (Ref. 19). The occurrence of acute lesions associated with patients with chronic peptic ulcers is not necessarily dependent upon aspirin ingestion alone. Ingestion of aspirin by patients who were not taking aspirin. Furthermore, the nature of the acute lesions depends upon the probable inciting factors such as stress or alcohol. However, the majority of bleeding associated with lesions in acute gastritis involves patients taking aspirin. It appears that aspirin can potentiate bleeding from acute lesions regardless of whether it initiates the lesion. These lesions are usually the type designated as erosive gastritis.

Hemorrhagic erosive gastritis. Hemorrhagic erosive gastritis is characterized by gastric mucosal hemorrhage from small superficial discrete lesions. Unlike ulcers they do not penetrate beyond the muscular layer (lamina muscularis mucosa) just below the lamina propria (Ref. 15). These lesions are too small to be seen by radiographic examination and are generally detected only by rectal observation at the time of gastroscopy during surgery. In studies in which gastroscopic examinations were not performed this lesion is probably included in the "cause unknown" category. Furthermore, these lesions may not be observed if gastroscopy is performed several days after bleeding as they frequently disappear rapidly (24 to 48 hours). The incidence of gastric mucosal erosions and hemorrhage have been associated with a variety of diseases, including infections, following gastric and nongastric surgery and trauma (brain injury) (Ref. 15). Although the occurrence of hemorrhagic erosive gastritis has been associated with a variety of disease states, alcohol and aspirin alone or together are the most frequent identified as the precipitating agents (Ref. 61).

Sugawara, Lucas and Wait (Ref. 105) followed 132 patients with acute erosive gastritis (46 after sepsis or trauma, 40 after alcohol intake and 8 after aspirin ingestion). They were studied by serial gastrointestinal and photography using fiberoptic endoscopes. The color, size, shape and distribution of mucosal changes were recorded during early healing phases, and these changes were correlated with microscopic studies. Mucosal changes in the trauma-sepsis group (stress "ulcer") with mainly black based erosions, were usually restricted to the parietal cell mucosa and were mainly on the greater curvature near the fundus.

Mucosal changes in the alcohol group were more evenly distributed throughout the stomach. It was found that 17 of 40 patients who had duodenal ulcer had duodenal ulcer. Red based erosions were the main lesion in this group. Aspirin erosions were more frequent in the body, but were also seen throughout the stomach. An unusual number of patients developed superficial white based ulcerations after aspirin.

Dagradzi et al. (Ref. 15) state that the stress and causative factors in hemorrhagic erosive gastritis are similar regardless of the nature of the inciting agent. They undergo the same course of healing and the clinical spectrum is the same.

There are some differences related to the inciting agent. These differences are exemplified by the series of 106 patients with bleeding from hemorrhagic erosive gas- tritis. The bleeding in 80 percent of the cases was associated with the ingestion of aspirin and/or alcohol just before the bleeding. In 10 percent of the cases, no determinant could be established. In most cases, aspirin was taken acutely, 2 to 3 days prior to bleeding for pain unrelated to gastric condition. Gastric distress occurred frequently in the aspirin group and was seen in 71 percent. Gastric distress occurred in 33 percent of the aspirin group but only in 5 percent of the alcohol group. The peptic ulcer was present in 50 percent of the aspirin-related group and only 4 percent of the alcohol group. However, the frequent gastric distress in the aspirin group was unrelated to the presence or absence of ulcers.

Rats and Siegel (Ref. 14) reported that bleeding from acute erosions outnumber acute ulcers as a source of bleeding by 7 to 1, respectively. They described the typical acute gas- tric lesion as having denudation of superficial epithelium sheared at the neck of the glands with variable hemorrhage in the capillary rich area of the neck. These authors propose that a variety of agents may cause hem- orrhagic erosive gastritis through the same mechanism. A variety of inciting agents may cause release of histamine from mast cells in the lamina propria. They state, "it seems probable that many pathways lead to degradation of the histamine which must occur in the area about the neck of glands and that capillary injury results whatever the initiating stimulus. Capillary permeability increases, leading to hemorrhage at the neck with tissue anoxia, amputation of superficial epithelium and gross hem- orrhage following."

The importance of stress as a precipi- tating factor for erosive gastritis has been suggested by several authors (Refs. 14, 94, and 96).

The more recent studies of Gelzayd and Gelfand and Gelzayd, Gelfand, and Rinaldo (Refs. 106 and 107) show that aspirin and alcohol may often be involved in duodenitis (inflammation of the intestine) rather than duodenal (in- testinal) ulcer. Thirty-two patients had a variable history of epigastric pain (mainly dyspeptic), nausea, vomiting, and hematemesis (passage of blood by vomiting) or melena (passage of blood through the stools). Only three of these people had had a duodenal ulcer. Hemorrhagic duodenitis (bleeding resulting from intestinal inflammation) was present in eight patients with anemia and severe enough in four patients to require transfusion.

These bleeding episodes involve sites of bleeding which would not be decreased by high-dose aspirin in solution since the primed site is already existing. Thus, there is no rationale for using buf- fered or highly buffered aspirin for con- current symptoms of headache and diar- rhea. Indeed, the Panel believes it is contraindicated. The Panel has discussed the labeling of such products elsewhere in this document. (See part VI, paragraph B.1.d. below—Label- ing claims for marketed products containing analgesics combined with anti- acid or buffering ingredients.)

Those who contend that the systemic effect of aspirin is negligible relative to the association of aspirin to massive bleeding have usually made the assumption that the systemic effect must cause bleeding rather than potential ex- isting bleeding group and which carries pre- sent information regarding the effect of aspirin on platelet function, it is clear that aspirin will not initiate bleeding on the primary level. However, aspirin is unlikely to potentiate bleeding from all types of bleeding sites. Most authori- ties agree that reduced platelet function will be important only when there is established bleeding potential in the capil- lary level. It is of significance that the unique vasculature of the gastrointestinal tract and the importance of capil- lary blood flow to the lamina propria is the primary factor in acute hemorrhagic erosive gastritis or duodenitis. It is in these situations that aspirin is most frequently involved, accounting for 50 to 60 percent of all cases of massive bleeding from these sites. There are few situations in the body other than gastroin- testinal erosions where extensive existing damage to mucosal tissue would involve extensive capillary networks. The capil- lary bed in the tonsillar region is one such case, however, and as might be ex- pected, bleeding associated with aspirin ingestion does occur, massive bleeding from this site can and does take place following aspirin ingestion. It should be clear that aspirin is not acting through the Davenport (hydrogen ion mediated bleeding) mechanism.

In summary, the Panel finds that massive gastrointestinal bleeding frequently is associated with acute aspirin ingestion by patients who have existing duodenal ulcers or highly buffered aspirin for con- current symptoms of headache and diar- rhea. Indeed, the Panel believes it is contraindicated. The Panel has discussed the labeling of such products elsewhere in this document. (See part VI, paragraph B.1.d. below—Label- ing claims for marketed products containing analgesics combined with anti- acid or buffering ingredients.)

The importance of stress as a precipi- tating factor for erosive gastritis has been suggested by several authors (Refs. 14, 94, and 96).

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they are not under arteriolar control (Ref. 14); massive bleeding is more frequently observed in individuals who have inborn clotting deficiencies. While hemophila has long been recognized to be a condition which is a contraindication to aspirin use, other clotting deficiencies which are less severe have been detected because of the diffuse nature of the bleeding. Therefore, those patients who might bleed would obviously be at great risk from gastrointestinal bleeding. The clotting deficiency which is through, and therefore requiring, available direct cellular damage mediated by plasminogen activator. Cytotoxic mediators of aspirin since the combination of aspirin and heparin (Ref. 10) has been shown to be effective in reducing bleeding in the blood stream can promote or increase bleeding, all preparations containing aspirin regardless of formulation should bear a warning: 'Caution: Do not take this medicine if you have any of the above conditions.'

(2) Interaction with alcohol. Another aspect of the gastrointestinal bleeding problem is the evidence in recent studies of a synergism between alcohol and aspirin's ability to cause such gastrointestinal bleeding. In a study which was also designed to overcome the problems outlined, Needham et al. (Ref. 95) found a definite association between the acute use of aspirin (178 mg in 72 hours of hospital admission) and massive upper gastrointestinal bleeding, and evidence of a synergism between alcohol and aspirin in the association with gastric bleeding. It is of significance that in this study the separate diagnostic groups, i.e., duodenal and gastric ulcer, gastritis, etc., only the duodenal group showed a high significance in the synergistic effect of aspirin and alcohol in terms of an increased incidence of bleeding. While this may be because of the low numbers of patients in the other categories, e.g., gastritis, it is important to note that acute ingestion of aspirin had a significant effect on duodenal bleeding and a synergistic effect with alcohol in bleeding from duodenal ulcers even though there is present no evidence that even chronic aspirin usage is innocuous to individuals who have been bleeding duodenal ulcers (Ref. 86). This gives support to the hypothesis that aspirin may support or potentiate bleeding from gastrointestinal lesions even though aspirin alone may not initiate the lesion.

It is also significant that in this study alcohol alone did not increase the risk of bleeding, but did potentiate the effect of aspirin. The results of this study revealed that 13 percent of the total number of patients who took aspirin for stomach pain and 4 percent for hangover. The authors conclude that on the basis of these findings, while a good case for warning the public of the dangers of aspirin since the combination of headache and upset stomach are often related to alcohol ingestion and might be a frequent reason for use of aspirin.

(4) Formulation effects. Some authorities claim that the mechanism involved with major gastrointestinal bleeding is the same as occult bleeding, i.e., involving direct cellular damage mediated through, and therefore requiring, available hydrogen ion (Ref. 22). As a corollary to this hypothesis, it has been claimed that highly buffered aspirin preparations which do not bleed would also obviate major bleeding (Refs. 37 and 47). While the direct acid-mediated gastric erosion may undoubtedly contribute, or even in some cases be the only mechanism involved, it is clear that this is not the only, and in fact, probably not the most important mechanism involved in aspirin-induced massive bleeding. There are several lines of reasoning to support this conclusion. Mucosal membrane damage to the stomach produced by direct contact with aspirin and occult bleeding which does not bleed under given experimental conditions. Increased occult bleeding is observed in about 70 percent of the normal population of therapeutic doses (Ref. 108). Massive bleeding has not been simulated in the laboratory and occurs sporadically and unpredictably in the aspirin-taking population.

Even though the locally applied aspirin solution decreases the average occult bleeding loss in most studies (Ref. 75), frequently in these studies using highly buffered aspirin, one or two subjects who have been highlighted in solution have sporadic, large increases in gastric bleeding. These "atypical responders" or "outliers" have occult bleeding losses which are often significantly greater statistically than the average for all subjects in the study (Ref. 77). Studying occult bleeding without regard to the unusual excessive bleeding or eliminating these "outliers" from the study begs the issue that perhaps decreases blood loss and probably ignores the very type of exaggerated bleeding which characterizes massive bleeding.

Locally applied aspirin produces massive bleeding from capillary beds of tissue which do not secrete hydrochloric acid such as the connective tissue, the tongue, and the skin. See Part J. B.I.A. (2) (1) above—Mucosal erosion of the mouth, particularly following tonsillectomy when abraded oozing tissue is involved. Enteric-coated aspirin products designed to release aspirin in the intestine where the acidity is low, produce significantly increases in occult gastrointestinal bleeding, particularly in individuals who are more prone to such bleeding, e.g., the elderly (Ref. 1).

The Panel recognizes that a direct correlation between a reduction in occult bleeding and a reduction in occasional massive gastrointestinal bleeding has never been demonstrated.

Chronic aspirin ingestion appears to increase the incidence of stomach ulcers to a greater extent than duodenal (intestinal) ulcers presumably due to the hydrochloric acid effect in the gastric mucosa (mucous membrane of the stomach) which then becomes to be implicated in massive bleeding associated with duodenal ulcer patients to the same or greater extent as patients with stomach ulcers or erosive gastritis (stomach inflammation) (Ref. 79). This supports the hypothesis that the effect of aspirin on massive bleeding may not be dependent on the extent of those factors related to direct mucosal damage in the stomach.

While the Davenport mechanism may contribute to or even in some cases initiate massive bleeding, it is not clear not to be the only mechanism involved.

For the various reasons discussed above, the Panel concludes that because aspirin after it has been absorbed into the blood stream can promote or increase bleeding, all preparations containing aspirin regardless of formulation should bear a warning: 'Caution: Do not take this medicine if you have any of the above conditions.'
PROPOSED RULES


The Panel finds that there is still considerable disagreement and there are unresolved questions regarding these important considerations, which can be drawn on the probable mechanisms involved and susceptible subgroups. These are complex and exceptions are numerous.

The second group involves aspirin or precipitate hypersensitivity reactions to aspirin, which differ in mechanism, in usual type of response and cross-sensitivities with other agents (Refs. 18 and 19). Current evidence suggests this group involves a nonimmunologic hypersensitivity mechanism possibly related to the effects of aspirin on inhibition of prostaglandin synthesis (Refs. 20 and 21). Cross-sensitivity between aspirin and other agents, such as salicylates, salicylic acid and acetaminophen are not usually show cross-sensitivities in this group (Ref. 20). Exceptions have been noted however (Ref. 19).

The Panel recommends that all products containing aspirin should be labeled with the warning: "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have any other known allergic reactions to aspirin." The Panel recommends labeling statements involved as-
stood by the majority of patients. It is sufficient to state that these relationships are not discernible and cannot be self-diagnosed by a lay person. Consequently, at this time, no statement would be any more meaningful to the user of aspirin than the general warning against its use by those known or likely to be hypersensitive to aspirin.

(d) Asthma. Asthma may range from mild brief severe and prolonged attacks and, rarely, deaths. Severe angioedema, bronchial asthma, cyanosis, asphyxia, coma and death within minutes have been reported in hypersensitive individuals (Refs. 1 through 4).

Conflicting figures are given in the literature regarding the incidence of aspirin hypersensitivity. Some authors believe that the incidence is much lower than commonly believed (Refs. 4 through 6). Objective measurement of skin tests with the function of the method of assessment (Refs. 8 through 13, 17, 22, and 23). Objective measurement of nephelometric reaction. They have been used to be an effective means of detecting sensitivity. There is some risk involved in challenge tests because deaths have been reported (Ref. 23). Skin tests have not been found to be an effective means of establishing sensitivity. There is some risk involved in challenge tests because deaths have been reported (Ref. 23).

McDonald et al. (Ref. 22) studied 42 asthmatic patients who had no history of asthma after taking aspirin (aspirin intolerant). Patients with an unequivocal history of asthma after taking aspirin (aspirin intolerant) were excluded from the study. Patients who had no history of asthma associated with aspirin were selected for aspirin challenge during a time when the patient's asthma was stable. A dose of 800 mg aspirin was given as two tablets that contained 200 mg magnesium hydroxide and 150 mg aluminum hydroxide per tablet and no aspirin, which were similar in size and appearance, were given as a control, in crossover fashion, to the same patients. Respiratory signs were measured by spirometry and a Jones Pulmonary, (1973) (Ref. 24). These results, combined with 14 patients with a history of intolerance to aspirin, yield a prevalence of aspirin intolerance of 6 percent in the asthmatic population studied by these investigators. The number of patients who were intolerant to aspirin showed a statistically significant increase in the presence of nasal polyps, chronic sinusitis and steroid dependence when compared to all new asthmatic patients examined during the 2-year period.

Many other authors have noted a particular hypersensitivity to aspirin in asthmatic patients with nasal polyps, chronic sinusitis and eosinophilia. In general, aspirin-induced asthmatics have not fitted the usual characteristics of the typical "allergic" patient. The allergic patient most familiar is one who when exposed to some allergen (eg, hay fever) develops "hay fever" watery and itchy eyes, runny nose (allergic rhinitis) and bronchospasm. Secondary symptoms may involve: urticaria, allergic asthma and, rarely, anaphylactic shock. Allergy of this type belongs to the so-called "immune" class of disease termed atopy (Type I, reagin-mediated allergic hypersensitivity). In this class of disease an antibody mediates the reaction. The 1G E class of immunoglobulins which has the peculiarity of attaching itself to a certain type of cell, mast cells in the tissues and basophils in the blood. With the arrival of the allergen and the antibody attached to these cells occurs and leads to the release of active substances such as histamine which in turn cause the symptoms we call "allergic." In contrast to the atopic group, most aspirin-sensitive asthmatics do not have any of the usual indications of an immune response (Ref. 15).

Jaffe and Pollak (Ref. 16) stated that aspirin-sensitive asthmatics are usually the Type II, intrinsic, nonallergic type (Refs. 17 and 24).

Falliers states that aspirin-sensitive asthmatics are usually the Type II, intrinsic, nonallergic type (Refs. 17 and 24).

Falliers has stated that aspirin-sensitive asthmatics are usually the Type II, intrinsic, nonallergic type (Ref. 22). Skin tests have not been found different from asthmatics not sensitive to the drug (usually Type I asthmatics).

Based on his study of 1,298 chronic asthmatics, between the ages of 15 to 16 years, the severity of asthma to aspirin were mainly the typical "abrupt-late-onset" intrinsic types with nasal polyps. He states that the majority of the atopic (reagin-mediated or Type I allergic hypersensitivity) are said to carry no greater risk of aspirin sensitivity than the general population. The distinguishing characteristics of the low risk patients were: allergy and, specifically asthma, atopic eczema, and rhinitis. In contrast to the large number of asthmatic adults who are sensitive to aspirin, approximately 10 to 20 percent, the number of asthmatic children who are allergic to aspirin is only about 2 percent, according to Falliers (Ref. 24). Falliers has pointed out that the label warning for aspirin should state, "some asthmatics (intrinsic nonallergic type) may react adversely and therefore should not use aspirin without medical advice." One difficulty of this suggestion is that many asthmatics may not know which category they are in and could not self-diagnose their condition. A second more important reason is that some aspirin-sensitive children do in fact have atopic characteristics. For example, five children with asthma induced by aspirin, Yangninger et al. (Ref. 25) found that four were then recognized by Falliers to be low risk. These four had no history of nasal polyps and were characterized by atopic constitutions including sensitivities to seasonal pollens, a family history of allergy and positive skin tests.

The mechanism involved in the intrinsic nonallergic aspirin-sensitive asthmatic probably includes the effect of aspirin on prostaglandin synthesis (Refs. 20 and 21). Polish workers recently demonstrated bronchoconstriction in patients with aspirin hypersensitivity after administration of five drugs which inhibit prostaglandin synthesis (Ref. 20 and 21). Indomethacin produced peak expiratory flow in all 11 patients tested after a dose of 5 mg. Therapeutic doses of indomethacin and flufenamic acid, 500 to 600 mg phenylbutazone produced a bronchoconstrictor effect in most patients. These five drugs all inhibited mesenteric prostaglandin synthesis. Salicylamides, benzydamine and chloroquine, did not inhibit prostaglandin synthesis and did not produce bronchoconstriction.

(e) Urticaria (dermal) hypersensitivity. Urticaria is usually "spontaneous" only by aspirin and not salicylate acid, both aspirin and sodium salicylate will exacerbate chronic urticaria in 20 to 25 percent of cases (Refs. 14 through 16).

Philis et al., using the rat mast cell feeding, which can be used to detect IgE immunoglobulin reactions, were able to distinguish between two groups of patients hypersensitive to aspirin (Ref. 19).

In contrast to aspirin-induced asthma, urticaria is usually "spontaneous" only by aspirin and not salicylate acid, both aspirin and sodium salicylate will exacerbate chronic urticaria in 20 to 25 percent of cases (Refs. 14 through 16).

The American Academy of Allergy in 1973 (Ref. 26) approved the following resolution:

While recognizing that acetylsalicylic acid (aspirin) is a valuable drug, the American Academy of Allergy recommends that a formulation containing aspirin in a dose of not more than 325 mg should be marketed only by a company who has stated that the formula promoting the formulation should clearly indicate that the preparation contains aspirin and that aspirin can be harmful to some persons.
The Panel is in agreement with this resolution.

In summary, since aspirin has long been recognized to produce allergic type reactions in hypersensitive individuals, the Panel recommends that all products containing aspirin should be labeled with the warning: "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician."

REFERENCES

(1) Reed, E. N., "Idiosyncrasy to Aspirin (Acetylsalicylic Acid)," Journal of the American Medical Association, 72:14, 1914.

PROPOSED RULES

In summary, since aspirin has long been recognized to produce allergic type reactions in hypersensitive individuals, the Panel recommends that all products containing aspirin should be labeled with the warning: "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician."

Moreover, since aspirin has long been recognized to produce allergic type reactions in hypersensitive individuals, the Panel recommends that all products containing aspirin should be labeled with the warning: "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician."

The Panel has reviewed the effects of aspirin on various aspects of pregnancy as studied and extensively reported in the literature. The investigations on the effects of aspirin ingestion during pregnancy have been found on the following aspects: Teratogenic effects (malformation of offspring); the incidence of stillbirths and neonatal deaths (deaths at or shortly after birth); the effect of aspirin ingestion on the length and duration of pregnancy and parturition time (length of labor and delivery); and the impairment of hematostatic mechanisms by aspirin (bleeding on the mother as well as on the newborn infant).

In the discussion below, the Panel has elected to separate and review the available data according to the above effects. Teratogenic potential and fetal lethality will be discussed in terms of both animal studies and human retrospective and prospective studies. Secondly, prolongation of the duration of pregnancy and parturition time in animals and in human retrospective studies will then be summarized. Lastly, the effects on maternal and newborn hematostatic mechanisms will be discussed. The Panel's conclusions and recommendations.

(a) Teratogenic potential and fetal lethality. (1) Animal studies. Workun and Takacs (Ref. 1) reported that the first dose of methyl salicylate and sodium salicylate were teratogenic in rats. The drugs were administered to pregnant rats subcutaneously from days 9 to 11 of pregnancy. However, the doses used, on a weight basis, much greater than the therapeutic doses used in man. Females received either single subcutaneous injections of methyl salicylate in doses of from 0.1 to 0.5 mg (the mg/kg dose was not specified) or sodium salicylate in doses of 60 to 180 mg (maximum 300 mg/kg based on the assumption of a 0.2 kg rat). In addition, the teratogenic doses (12), the effect of malformations) were found to be quite close to doses lethal to the embryo (developing offspring) and toxic to the mother (Ref. 1). Larsson, Bestrom and Eriksson (Ref. 2) in 1966 showed that large doses of salicylates, 10 mg (maximum 500 mg/kg based on the assumption of a 0.02 kg mouse) sodium salicylate, administered intramuscularly to pregnant mice induced a high incidence of malformations. A feature of particular interest was that these malformations occurred either in vascular (blood vessel) or skeletal tissues both know to contain acid mucopolysaccharides. The authors hypothesized that the teratogenic effects of salicylates in mice were related to the inhibition of mucopolysaccharide synthesis and suggested that the embryos seemed to be more sensitive when the injections were given on the 12th and 13th day of gestation.

Larsson and Eriksson (Ref. 3) in 1966 investigated the effects of time of administration of salicylates to pregnant mice on the incidence of fetal death and fetal resorption. They compared two mouse strains identified as A/Jax and CBA strains and found that they had a low teratogenic susceptibility. Sodium salicylate, 500 mg/kg of body weight, was given intramuscularly in a single dose on one specific gestation day (either day 9, 10, 11 or 12). The A/Jax and CBA strains and to their reciprocal crossings. It was found that the fetal resorption rate increased steadily the later in pregnancy the salicylate was administered. The authors hypothesized that the teratogenic potential of salicylates in late pregnancy. Vascular anomalies were studied and it was noted that the highest incidence of vascular anomalies occurred after injection of sodium salicylate on the 15th day of gestation, whereas anomalies of the ribs and vertebrae showed the highest incidence after injection. The authors suggested that in drug tests for teratogenic potential, the drug should be given after the period of organogenesis and that special attention should be focused on fetal lethality.

Eriksson (Ref. 4) in 1970 studied the results of teratogenic potential of administration of sodium salicylate on fetal mouse damage as well as a possible protection against such damage when pentobarbital was given as a pretreatment. There was little or no effect on the fetus when a dose of 150 mg/kg of body weight was administered to the mother on day 17 of pregnancy. At a dose of 500 mg/kg of body weight given to the mother on day 16, death occurred in 70 percent of the fetuses. Subcutaneous and subcapsular liver hemorrhages were found in 39 and 15 percent of the living fetuses, respectively. Cardiomegaly and mucosal hemorrhage in the stomach was seen in 22 percent of the surviving fetuses. When a dose of 750 mg/kg was administered, four out of ten pregnant females died within 24 hours. Five of the remaining six pregnant females gave birth before being sacrificed and the fetal lethality in one litter was 100 percent. When 75 mg/kg pentobarbital was given intraperitoneally to pregnant mice, results similar to those administered to pregnant mice on the 9th day of gestation. At a dose of 500 mg/kg of body weight given to the mother on day 16, death occurred in 70 percent of the fetuses. Subcutaneous and subcapsular liver hemorrhages were found in 39 and 15 percent of the living fetuses, respectively. Cardiomegaly and mucosal hemorrhage in the stomach was seen in 22 percent of the surviving fetuses. When a dose of 750 mg/kg was administered, four out of ten pregnant females died within 24 hours. Five of the remaining six pregnant females gave birth before being sacrificed and the fetal lethality in one litter was 100 percent. When 75 mg/kg pentobarbital was...
administered on days 15 and 16 of gestation followed by 500 mg/kg salicylate on day 17, fetal death was significantly decreased. Although these observations are interesting, it must be noted that these again extremely high doses were used since the LD₅₀ for females of the strain used (A/Xax) was determined to be 760 mg/kg of body weight.

Studies in rhesus monkeys by Wilson (Ref. 5) have shown that doses of aspirin five to six times higher than the teratogenic doses used in rodents produced embryotoxic effects and fetal malformations. It should be emphasized that the daily dose of 500 mg/kg was considerably in excess of that already been emphasized, on a weight basis the doses used in the animal studies were excessively high and approached or were at lethal levels in comparison to the usual human adult dosage. Not only were these doses at lethal levels for the animals, but considering that the lethal dose for man ranges from 400 to 600 mg/kg, the animal doses were also at levels that would be lethal to human beings. Different species and different gestations in animals have also considerably in excess of that likely to be used therapeutically in pregnant women.

According to Wilson (Ref. 6), this "margin of safety" has been made less secure by the observation of Kimmel and Schumacher (Ref. 7) that the teratogenic potential of a given dose of aspirin in rats can be appreciably increased by the concurrent administration of benzoic acid, a widely used food preservative. Levy, Amsel and Elliott (Ref. 8) have shown that benzoic acid elevates salicylate blood levels in man by vates salicylate blood levels in man by approximately 80 per cent that of aspirin alone. When pregnant mice were given lower doses, such as a dose of 150 mg/kg, there was little or no adverse reaction. As noted above, the panel also considered the dose of aspirin recommended by the Panel for an average woman is approximately 70 mg/kg, about one-half the dose in mice 150 mg/kg. The potential for extrapolation from animal data, to humans is not always a matter of direct arithmetic and conversion of doses on a mg/kg basis. It is a well-known fact in toxicological assessment that species vary in the susceptibility to toxic agents and often it is required by government agencies that doses 10 or 50-fold of those intended for human use be used in animals for the assessment of toxic potential.

This interspecies variation could be due to susceptibility of the target organ (or growing embryo) or to differences in absorption, metabolism, distribution or excretion. Differences in metabolism are extremely common.

(2) Human studies. Studies related to the use of salicylates by pregnant women were reviewed by the Panel to make an assessment of the therapeutic benefit. Obviously, ethical and moral reasons preclude specially designed randomized studies that would examine the effects of salicylates on pregnancy. The Panel also had to review retrospective studies, i.e., previous clinical experience or statistical records which are subject to many valid criticisms and from which conclusive evidence cannot be definitively drawn. Several retrospective studies in humans attempting to determine if a correlation exists between aspirin ingestion and fetal malformations have been reported in the literature. A retrospective survey of malformed infants resulting from 833 pregnancies during the period between 1964 to 1966 was performed in Wales by Richards (Ref. 10). The mothers of the malformed infants were matched with an equal number of controls, women who had given birth to normal infants. The findings were based on interviews in the homes of each mother of a malformed infant and her matched control. In addition to the retrospective nature of the study, the dosages of salicylates, the duration of treatment, and the medical histories of the mothers do not mention the significance of this factor. These data indicate that, in rats, the combination of food restriction and aspirin affected fetal development more than did aspirin alone.

In summarizing the animal studies as they might be related to humans, several important points should be noted. As already been emphasized, on a weight basis the doses used in the animal studies were excessively high and approached or were at lethal levels in comparison to the usual human adult dosage. Not only were these doses at lethal levels for the animals, but considering that the lethal dose for man ranges from 400 to 600 mg/kg, the animal doses were also at levels that would be lethal to human beings. Different species and different gestations in animals have also considerably in excess of that likely to be used therapeutically in pregnant women.

The author concluded that the results of the investigation "suggest that either salicylates have a teratogenic effect or that the conditions for which they are given have such an action." It should be noted that in addition to salicylates, other drugs had been taken by some of the women during pregnancy such as antibiotics, sulfonamides, steroids, sedatives, iron, oral contraceptives, vitamins, etc. However, the women taking salicylates did not all take these various drugs.

The retrospective study included a statistical evaluation of each drug administered to the mothers to determine whether there was a statistically significant relationship between the drug and the malformed found in the infants. The author acknowledged that there are several limitations to a retrospective study that cannot be overlooked, and that "a large number of tests of significance were performed and many of these apparently significant differences could have arisen merely by chance." The author performed a total of 1,026 tests of significance and indicated that of the 101 tests that showed statistical insignificance, he considered that 51 of these statistically significant results could have occurred merely by chance.

In reviewing the study, the author acknowledges limitations to a retrospective study including the fact that the results may be affected by bias in the part of the interviewer or the mother; events, drugs and dosages may have been forgotten; emphasis was placed on the whole of the trimesters, whereas the critical periods of development are short and occur at different times for different organs; and lastly that since a large number of tests of significance are performed, many of these apparently significant differences could have arisen mainly by chance. The Panel recognizes these deficiencies and especially the fact that the statistical analyses were not planned in advance of the study. It is also important to note that the study was not designed specifically to evaluate the effects of salicylates on the drugs, but to evaluate the effects of these and other drugs on congenital malformations and environmental influences in pregnancy. Many factors besides drugs were evaluated such as weight, nutrition, smoking and diet habits, employment, accommodations, water supply, etc.
Nevertheless, the Panel concludes that regardless of the circumstances, the Panel views the content of the draft document as very important. Namely, the fact that Richards found many statistically significant differences between cases and controls, those of greatest interest being: (i) Use of salicylates, (ii) certain other drugs (antimetics) and (iii) the effects of diet in the first trimester considered to be unimportant. Of significance to this Panel, the author found that the taking of salicylates in the first trimester resulted in the following significant differences: Defects of the central nervous system (p is less than 0.01), miscellaneous defects (p is less than 0.05) and talipes (club foot) (p is less than 0.01) for all organ systems (p is less than 0.001).

In another retrospective study by Nelson and Forfar (Ref. 11) reported in 1971, the effects of drugs administered during pregnancy on the morphogenesis of the fetus was compared. Virtually all 1,369 of these women (1,333 out of 1,369) had taken one or more drugs during pregnancy, with the greatest use of salicylates in the abnormal group and 2.9 percent of mothers in the control group did not take any drug. Most mothers who had taken salicylates delivered normal infants. In the first 57 percent of the mothers took prescribed drugs and 65 percent OTC drugs. Aspirin was one of the drugs included. More specifically, the aspirin ingestion during pregnancy of 458 mothers of malformed infants was compared with the ingestion of aspirin by 911 mothers of normal infants. Of mothers delivering normal infants, 54.3 percent took aspirin during the entire period of pregnancy as compared with 62.2 percent of mothers delivering malformed infants. This was reported to be a statistically "highly" significant difference (p is less than 0.001).

Approximately 50 to 60 percent of the mothers of the malformed infants and also the mothers of the normal infants had received different preparations during pregnancy. Approximately 15 to 20 percent of both groups of mothers had taken 6 to more than 10 drugs during pregnancy. The drugs consisted of analgesics, anesthetics, antimetics, antibiotics, appetite suppressants, barbiturates, bronchodilators, cough medicines, diuretics, hormones, hypnotics and tranquilizers, iron, sulphonamides and vitamins. Tests for significance had to be done for each class of drugs for the same groups of mothers. In the case of some drugs, the actual numbers were too small to show significant results which could not alone exonerate a drug from possible teratogenic effects. In other instances, although a greater number of mothers of malformed infants took a particular drug than in controls (and possible importance), this was not necessarily mean that the drug had a teratogenic effect.

Twenty-three different analgesic preparations had been used by the women. Statistical comparisons were made between the analgesics used during the whole of pregnancy, the first trimester and the first 14 and 56 days and all analgesics were further divided into major and minor abnormalities). The data showed that analgesics were used by a significantly high proportion of infants with "all" abnormalities during the whole of pregnancy and "all" abnormalities during the first trimester of pregnancy. The authors specifically note that aspirin should be avoided. A proportion of mothers of infants with "all and minor" abnormalities during the whole of pregnancy and "all" abnormalities during the first 56 days of pregnancy. The authors specifically note that aspirin should be avoided.

The data further showed no significant differences for aspirin for the first 14 and 56 days. However, there was a significant difference for the first 28 days of pregnancy. The authors concluded that any relationship between aspirin and congenital abnormalities should be kept in mind that this study had not been designed to detect any association with congenital abnormalities of the fetus were compared. Virtually all of these women (1,333 out of 1,369) had taken one or more drugs during pregnancy, with the greatest use of salicylates in the abnormal group and 2.9 percent of mothers in the control group did not take any drug. Most mothers who had taken salicylates delivered normal infants. In the first 57 percent of the mothers took prescribed drugs and 65 percent OTC drugs. Aspirin was one of the drugs included. More specifically, the aspirin ingestion during pregnancy of 458 mothers of malformed infants was compared with the ingestion of aspirin by 911 mothers of normal infants. Of mothers delivering normal infants, 54.3 percent took aspirin during the entire period of pregnancy as compared with 62.2 percent of mothers delivering malformed infants. This was reported to be a statistically "highly" significant difference (p is less than 0.001).
PROPOSED RULES

With regard to teratogenicity, there was no significant increase in malformed infants as compared to controls.

The authors concurred with the suggestions of Richards (Ref. 10) and Nelson and Turner (Ref. 11), stating that it may well be as suggested by those investigators "that teratogenicity is related to the illness for which salicylates were taken rather than a direct effect of the salicylates themselves." Turner and Collins (Ref. 14) did find that babies of mothers taking salicylates had a significantly reduced birth weight compared with controls. In addition, some babies were born with an abnormally reduced cord level of salicylates but this was not associated with hypoglycemia, bleeding or any other obvious clinical disturbance. It is interesting to note that there were more anomalies in the group of women who took salicylates intermittently rather than constantly which suggested to the authors that if there is any teratogenic influence this may be more related to fluctuating levels of salicylate than a constantly elevated level, Turner and Collins concluded, "Our findings do not support the suggestion that salicylates are teratogenic. In the study, which was conducted during the first 4 months of pregnancy prepared according to outcome, i.e., uniform malformations (CNS, cardiovascular, etc.) and nonuniform malformations (inguinal hernia and clubfoot), the data show that both aspirin exposure groups were similar to the unexposed group. The standardized relative risk approximated unity. The upper approximate limits (95 percent confidence limits) for uniform and major malformations in children who were heavily exposed to aspirin (Group I) were 1.08 and 1.11, respectively. The authors stated that "With regard to exposure to aspirin (heavily or not), the standardized relative risks of uniform and major malformations were 1.00 and 1.01, respectively, with approximate upper 95 percent confidence limits of 1.00 and 1.09."

As with other studies, criticisms were raised which could have obscured possible teratogenic effects. The authors commented in their discussion:

"First, chance may explain failure to detect relationships with some of the less common outcomes. Second, even though multiple logistic risk function analysis was used to simultaneously control a wide range of potential confounding factors, the possibility of negative confounding by undetected factors could not be ruled out. Third, a systemic bias in the data collection could have obscured an association. Certainly, observer bias was unlikely in this study because the information on drug exposure was collected before delivery. Fourth, some degree of underestimation of aspirin use was undoubtedly present, since the median time of the study was 21.6 weeks: some women may not have recalled taking aspirin during early pregnancy. However, the likelihood of underestimation among heavy users. In addition, misclassification of aspirin users as non-users would have had to be very common to completely obscure an actual association, because the non-exposed group was extremely large.

The data presented here are not in accord with two previous studies (Refs. 14 and 16). The striking differences between the study of Slone et al. and those of Turner and Collins (Ref. 16) and Turner and Collins (Ref. 14) are dramatic as it may appear at first sight. The studies in the American and Australian papers were widely different and probably the main difference lies in the definition of "heavy users" given in the U.S. study. The term "heavy user" as described by Slone et al. appears to be a misnomer as these authors were really studying three non-abusing populations and the outcome could have easily been predicted. A person who has taken eight aspirin or therapeutic dosages in any lunar month or in any of the first 4 lunar months can hardly be called a heavy user. However, it is noteworthy that Slone et al. (Ref. 16) concluded that the study gave no evidence that aspirin ingestion during pregnancy is associated with congenital malformations. They pointed out that from the statistical analysis the relative risk estimates for uniform malformations and for malformations and for mental retardation make it unlikely that substantial teratogenic effects would have escaped detection. Nevertheless, they were of the opinion that the possibility still remains that grossly excessive exposure to aspirin may be teratogenic. However, they referred to the study of Turner and Collins (Ref. 14) which in their view showed no effect. More importantly, Slone et al. concluded: "Based on a larger body of data, more conventional doses of aspirin as used by pregnant American women do not appear to cause malformations in their offspring."

(b) Prolongation of the duration of pregnancy and parturition (labor and delivery) time. Tuchmann-Duplessis et al. (Ref. 17) have reported that the mean duration of delivery was 9 minutes longer in the aspirin group than in the control group. In the aspirin group the mean duration of delivery was 7 minutes longer. This difference was not statistically significant.

Lewis and Schulman (Ref. 17) reported a 20 year retrospective study of 103 patients, most of whom had nonspecific collagen disease, taking doses of aspirin greater than 3,500 mg/day during the last 6 months of pregnancy in which comparisons were made with two control populations. The control populations were chosen as follows: The first control group consisted of 53 pregnant patients with rheumatoid arthritis, "nonspecific collagen disease", or degenerative musculoskeletal disease who were not taking aspirin or other compounds known to affect prostaglandin synthesis and not the result of the toxic effect of aspirin on the fetus in utero.

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The purpose of the study was to evaluate the influence of aspirin, an inhibitor of prostaglandin synthesis, on the duration of human gestation and labor. Prostaglandins are known to be capable of initiating uterine contractions. Lewis and Schulman indicate that their results support the view that prostaglandin metabolism may be an important determinant of the timing of the onset of spontaneous labor and of its duration. Patients taking aspirin had labors averaging 70 percent longer than those in the control populations.

Collins and Turner (Ref. 16) in an Australian study compared two groups of pregnant women who self-medicated with analgesics regularly, with a group of matched controls. One group of self-medicated women took analgesics in a powder daily (constant takers). A combination of aspirin, salicylamide, and caffeine was taken by 58 percent; 36 percent took a combination of aspirin, phenacetin, and caffeine; and 6 percent used either powder. The second group of self-medicated women admitted taking analgesics at least once a week throughout pregnancy (intermittent takers). Many of the constant takers had self-meditated with analgesics for many years and were "habituated" to analgesics. After the delivery of each patient in Group I (constant takers), the next Australian-born clinic patient to deliver a baby, who was matched for age, parity and gravity and after assurance that the patient had not taken analgesics, was used as a control. There were 63 patients in Group I, the same number in the control group and 81 patients in Group II. The major effects of regular salicylate consumption in pregnancy were found to be an increased frequency of anemia during pregnancy, a prolonged gestation, an increased incidence of complicated deliveries, a high incidence of antepartum and postpartum hemorrhage and transfusion at delivery and an increased perinatal mortality. The mechanism of the prolongation of gestation and labor by salicylates has been found to be related to the inhibition of the release of prostaglandins. Since one of the actions of prostaglandins is to stimulate uterine contractions, salicylates might be expected to delay the onset of labor and increase the length of labor. The Panel has summarized some of the findings of the authors in the following table:

### Results of study groups

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of gestation (days)</td>
<td>25.1±13.3</td>
<td>25.2±10.0</td>
<td>22.8±6.0</td>
</tr>
<tr>
<td>Length of labor (hours)</td>
<td>12.1±8.6</td>
<td>2.7±4.1</td>
<td>2.5±1.0</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>3.072±23.0</td>
<td>2.97±23.0</td>
<td>3.32±42.0</td>
</tr>
<tr>
<td>Estimated blood loss (ml)</td>
<td>310.0±153.0</td>
<td>214.0±114.0</td>
<td>233.0±25.0</td>
</tr>
</tbody>
</table>

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### Results of study groups

<table>
<thead>
<tr>
<th>Parameter measured</th>
<th>Group I</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia in pregnancy</td>
<td>14</td>
<td>12</td>
<td>28</td>
</tr>
<tr>
<td>Antepartum hemorrhage</td>
<td>24</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Postpartum hemorrhage</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Transfusion at delivery</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Mean duration of pregnancy</td>
<td>25.1±10.0</td>
<td>25.2±10.0</td>
<td>22.8±6.0</td>
</tr>
<tr>
<td>Duration ≥ 40 weeks</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Complicated delivery</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Cesarean section</td>
<td>12</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Stillbirths</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

The findings of the study in terms of stillbirths and neonatal deaths according to aspirin exposure during pregnancy are as follows:

### Stillbirths, Neonatal Deaths, and Mean Birth Weights Following Aspirin Exposure During Pregnancy

<table>
<thead>
<tr>
<th>Group</th>
<th>Exposed</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>Contained 1,516 heavily exposed mother-child pairs.</td>
<td></td>
</tr>
<tr>
<td>Group II</td>
<td>Contained 24,866 intermediate aspirin-exposed mother-child pairs.</td>
<td></td>
</tr>
<tr>
<td>Group III</td>
<td>Contained 14,956 non-aspirin-exposed mother-child pairs.</td>
<td></td>
</tr>
</tbody>
</table>
The findings demonstrate that in this study there is no evidence that aspirin taken in pregnancy is a cause of stillbirths, neonatal deaths or reduced birth weight. The fact that white children were associated with slightly reduced birth weight and for that matter neonatal deaths could have been in the authors' views due to chance. Opposite trends were evident in black children.

Criticism of the study by Sime et al. (Ref. 15) discussed above are equally valid here. However, it is the conclusion of Shapiro, et al. that "based on our data, we find no evidence that aspirin used by pregnant women in the United States is related to perinatal mortality or low birth weight." (c) Effects on maternal and newborn hemostatic mechanisms. (1) Interference with fibrinolytic mechanisms. In the study of Lewis and Schulman previously mentioned (Ref. 18), the average blood loss at delivery in patients in Group I, patients taking large doses of aspirin for at least 6 months of gestation, was 340±155 ml compared to 244±114 ml and 235±97 ml in the two control groups. This difference was found to be significant (p is less than 0.025) when the results were assessed using Student's t-test.

Collins and Turner (Ref. 16) also found that the incidence of antepartum hemorrhage, defined by the authors as "bleeding greater than a show, after 28 weeks gestation," and postpartum hemorrhage defined by the authors as "a blood loss of 600 ml of blood or more in the first 24 hours" was significantly increased (p is less than 0.001) when group I (constant takers) was compared to controls. In the same study, the authors also found that the incidence of patients having transfusions at delivery was markedly increased when pregnancy had increased cord-blood levels of salicylate, they did not show signs of clinical bleeding.

(2) Effect of aspirin on newborn hemostasis. Bleier and Breckenridge (Ref. 20) studied the effects of prenatal administration of aspirin on newborn hemostasis. Fourteen newborn babies who had been exposed to aspirin during the week prior to birth were compared to 17 children in whom aspirin had not taken aspirin. The two potential inducer drugs used in reactions detected were platelet dysfunction and diminished factor XII (Hageman Factor). In neonates born of mothers who had taken aspirin shortly before delivery, the slower rate of elimination of aspirin during pregnancy and found that although these infants had raised cord-blood levels of salicylate, they did not show signs of clinical bleeding.

(3) Salicylate exposure in the perinatal period. Studies demonstrating the presence of salicylic acid in newborn specimens have shown intraterine fetal exposure to aspirin or other salicylates. Umbilical cord sera from 272 consecutively delivered infants were examined for salicylate by Palmisano and Cassidy (Ref. 23). Salicylate levels were unexpectedly found to be above 1 mg/100 ml in 26 of the sera (9.5 percent). The degree of fetal exposure to salicylate was indicated by a mean concentration of 2.3 mg/100 ml with a range of 1.2 to 10.9 mg/100 ml in this group. The mean residual albumin binding capacity in these infants was significantly depressed (p is less than 0.03). The authors reported that unrecognized fetal exposure to salicylate was surprisingly common during late pregnancy. In view of comparable serum protein concentrations, the depression in the mean residual albumin binding capacity is unlikely to be related to different albumin concentrations between the positive sera and control sera samples. Since salicylate binds to albumin from its albumin binding sites (Refs. 24 and 25), this could pose problems in neonatal hyperbilirubinemia. The problem seems to be of such importance that Palmisano and Cassidy have proposed that blood salicylic acid measurements should be included in the clinical and management of neonatal hyperbilirubinemia (Ref. 23).

Turner and Collins (Ref. 14) had shown that the babies of 144 mothers who took salicylates for arthritis during pregnancy had increased cord-blood salicylate concentrations. Although maternal blood was not always collected immediately after delivery it was always taken while the mother was still in the labor ward and, as expected, when the maternal blood salicylate concentrations were high, so were the cord-blood concentrations. Unfortunately, because of the timing it was not possible to compare maternal and cord-blood levels directly but in most cases the cord-blood concentrations were higher than the maternal concentrations.

It has been previously shown that the concentration of salicylate in the blood of the infant is usually higher than that of the mother (Refs. 26 and 27). This has been interpreted as an indication that the fetus near birth has the pharmacokinetics of a "deep" compartment with respect to salicylate (Ref. 28).

Futhermore, another factor to consider is that the apparent volume of distribution for salicylate is higher in the neonate (300 to 650 ml/kg) than that for similar doses, on a body weight basis, in older children and adults, namely 200 ml/kg (Refs. 29 and 30).

In a recent report Garretson, Proctor, and Levy (Ref. 29) have described the placental transfer and kinetics of elimination of salicylates in an infant whose arthritic mother took 6.5 g/day aspirin during her entire pregnancy. The baby was born with a salicylic acid concentration of 25 mg/100 ml plasma. While salicylate elimination was slower than in normal adults, it was more rapid than in the newborn whose mother had taken aspirin shortly before delivery. The slower rate of elimination in this infant when compared to adults was described as due to immaturity of the glucuronidation pathway and immaturity of the renal excretory mechanism.

(d) Conclusions and recommendations. Any relationship regarding the possibility of any teratogenic effect of salicylates in pregnant women has come from retrospective studies which are indirect and are possessed with obvious shortcomings. As conducted, they do not unequivocally demonstrate a teratogenic effect. Some limitations of the study, as indicated by the authors themselves, are that they cannot distinguish between the effect of the salicylates and the effect of the condition for which the salicylates were taken. In those specific studies (Refs. 14, 15, 18, and 19), in which the delivery of women who had taken salicylates during pregnancy was directly observed, no relationship between salicylate therapy and congenicity was found. Even in a survey in which a comparison could be made between mothers of normal infants who...
had taken salicylates by prescription during pregnancy and mothers of malformed infants who had taken salicylates by prescription. In this difference was found that would demonstrate any relationship between salicylates and malformation in the offspring. Of particular significance in these retrospective studies, is the fact that the women in the study who had delivered malformed infants had taken several drugs other than salicylates, either alone or in addition to salicylates. This meant that many tests for significance had to be done during the statistical analysis to determine whether an association existed between the ingestion of a drug and the development of a malformation in an infant. The authors of the retrospective studies recognized these factors as limitations in the studies, and they state that because so many tests of significance were necessary some of the results of the tests may be due to chance. Some authors conclude that because so many tests of significance were necessary some of the results of the tests may be due to chance. Some authors conclude that because so many tests of significance were necessary some of the results of the tests may be due to chance.

References


(27) Ericson, "Salicylate-Induced Malformations in Rats," "Congenital Malformation of Congenital Malforma-


PROPOSED RULES

“early warning system” of overdosage is advantageous in that it alerts users to a potential hazard and thereby contributes to the safe use of aspirin.

However, it should be noted that approximately 1,100 deaths per year result from accidental poisoning by salicylates and congener (Ref 6). Until recently, over one-half the deaths have been of children under 5 years of age. This figure has recently declined to approximately one-fourth probably as a result of the introduction of safety closures for medicine containers and educational campaigns.

The Panel has included the following table which summarizes the total number of deaths of children under 5 years and the total number of deaths for all ages from accidental poisonings due to salicylate or congener for the years 1968 to 1974 (Ref 3):

<table>
<thead>
<tr>
<th>Year</th>
<th>Total deaths of children under 5 yrs</th>
<th>Total deaths of all ages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1968</td>
<td>61</td>
<td>120</td>
</tr>
<tr>
<td>1969</td>
<td>58</td>
<td>104</td>
</tr>
<tr>
<td>1970</td>
<td>48</td>
<td>107</td>
</tr>
<tr>
<td>1971</td>
<td>44</td>
<td>105</td>
</tr>
<tr>
<td>1972</td>
<td>46</td>
<td>122</td>
</tr>
<tr>
<td>1973</td>
<td>28</td>
<td>93</td>
</tr>
<tr>
<td>1974</td>
<td>25</td>
<td>83</td>
</tr>
</tbody>
</table>

Thus, salicylate poisoning can result in death and these drugs should not be viewed as harmless household remedies. Some authorities (Ref 7) feel that the toxicity of the salicylates is underestimated by both the general public and physicians. The necessary incidence of toxic reactions most of which, fortunately, are mild and insignificant.

However, with the consumption of aspirin exceeding 3 billion doses annually in the U.S. the relatively small number of accidental deaths attests to the safety of the salicylates under present conditions of use. The Panel believes that continued education of the public regarding the proper use and the potential dangers of misuse of these valuable OTC remedies and more informative labeling will result in a progressive decrease in the incidence of toxic reactions to aspirin and related drugs.

REFERENCES


(6) Adverse effects on the kidney. Aspirin has been suggested as a contributing factor in analgesic-induced kidney disease. Studies of many animal species and a few individual cases in man have been reported which suggest that aspirin may cause kidney disease or may increase existing kidney disease (Refs 1 and 2). However, studies in other species of animals have shown no adverse effects (Ref 3).

In rats, aspirin in combination with phenacetin may augment the nephrotoxic effect of phenacetin through synergistic renal effects (Refs 3 and 4) producing nephropathy as a greater danger than aspirin alone or phenacetin alone. The effects of phenacetin in producing nephropathy are discussed elsewhere in this document. (See part III. paragraph B.2.d. (2) (ii) below—Mechanism of action producing nephropathy.) In view of the much higher incidence of the use of aspirin than of phenacetin and the very few reports implicating products containing aspirin alone with renal papillary necrosis, the principal lesion associated with analgesic renal disease, the Panel finds that it is unlikely that aspirin alone is an initiator of analgesic nephropathies. This view is supported by recent epidemiologic studies which show that aspirin alone is not a cause of permanent (irreversible) kidney disease in man (Refs 4 through 11).

There are some indications that long term (chronic) aspirin consumption even in the absence of phenacetin may cause renal dysfunction in a small number of long term aspirin users (Refs 9 and 10). The majority of these cases involved abuse of analgesic compounds or treatment of rheumatoid arthritis. It is the Panel’s opinion that long term abuse of aspirin, used alone, is infrequent. Almost all nontherapeutic chronic use has been as a component of a product containing another ingredient with greater potential to produce dependence (co- dine, caffeine, phenacetin). The other major group involved in long-term use were patients with rheumatoid or osteo-arthritis. It is the Panel’s contention that for this and other reasons elaborated elsewhere in this document that articular disease is not a major risk in aspirin abuse of the non-therapeutic nonprescription type without medical supervision. (See part V. paragraph A. below—General Discussion.) In addition, it is the Panel’s recommendation that professional labeling to health professionals adequately alert physicians to the need for periodic renal function tests for their patients taking large amounts of aspirin. An OTC kidney warning labeling is therefore not necessary.

The Panel concludes that although prolonged use of high doses of aspirin may produce kidney disease in rare instances, the risk involved is insignificant in the recommended target populations when aspirin alone is involved. In the opinion of the Panel, a warning regarding aspirin causing kidney disease is not warranted for OTC use. However, physicians should be alerted that substitution of aspirin alone or in combination, for phenacetin, in patients with existing analgesic kidney disease, may be tolerated in low doses in some patients but contribute to continued renal deterioration in others.

Furthermore, recent evidence discussed below showing acute effects of aspirin on renal glomerular filtration, indicates that produced or not, use of aspirin may contribute to or exacerbate other types of chronic or acute renal disease. Although a warning label regarding the use of aspirin in patients with existing renal disease was recommended now, this is only because the definitive studies have not been performed to the Panel’s knowledge.

(a) Acute effects (short-term use). Prescott found that aspirin produces a transient increase in urinary excretion of tubular epithelial cells (Ref 1). The effect of aspirin was greater than that obtained with phenacetin. The effect does not persist during continued dosing. Two very recent studies have demonstrated that aspirin produces an acute decrease in glomerular filtration rate (Refs 11 and 12). A mean 10.5 percent decrease in glomerular filtration rate was observed in patients receiving oral doses of 20 mg/kg aspirin (Ref 10). In another independent study, an intravenous dose of aspirin produced a 30 percent decrease in glomerular filtration rate (Ref 12). This effect is significant since the usual decrease in glomerular filtration rate is only about 20 percent from 25 to 65 years of age (Ref 13).

It is not known whether these acute effects of aspirin on the kidney contribute to long term analgesic nephropathy. Some authors believe this is unlikely (Ref 14). The significance of these findings relative to the short-term use of aspirin in patients with acute or chronic renal disease is also not yet known.

(b) Analgesic nephropathy. A large number of studies in rats have shown that in this species, aspirin alone can produce renal papillary necrosis, the primary kidney lesion associated with analgesic kidney disease (Refs 1, 2, 15, and 16). Combinations of aspirin and phenacetin produced renal papillary necrosis more frequently than aspirin alone. In rats, aspirin alone produced renal papillary necrosis in a generally greater number of cases than phenacetin alone (Ref 15).

Renal papillary necrosis has also been induced in the dog. However, most current studies have been carried out in the rat.
The rat kidney is different than that of man. Being unilobular and having a long slender papilla, it has been suggested that the rat kidney may be much more susceptible to papillary damage (Ref. 19). The pig was selected as a more suitable test animal because it has a multilobular kidney similar to that of man and is thought to metabolize salicylate similarly to man. McVie and Hobbs fed aspirin to 11 pigs for 10 months at a dose higher than that usually used by abusers without any evidence of renal injury to any of the animals (Ref. 13).

(c) Clinical studies. In spite of the extensive use of aspirin and numerous attempts to show correlation between chronic aspirin use and renal papillary necrosis, there are only three long-term doses has been the subject of several epidemiologic studies.

A recent study of the Boston Collaborative Drug Surveillance program (Ref. 39) examined a possible correlation between analgesic use and renal function in 6,407 patients and found no correlation. As discussed elsewhere in this document, the negative results of this study are inconclusive because the study design (error due to surveillance) and preexisting liver disease (Ref. 8).

In a recent study by Emkey and Mills (Ref. 5), patients taking aspirin alone with renal papillary necrosis were followed up after 2 years. The increased incidence of the use of aspirin alone, can exacerbrate and/or perpetrate the progression of renal papillary necrosis and renal dysfunction (Refs. 1 and 2). Aspirin may contribute to the nephrotoxic effect of phenacetin through the impairment of renal concentrating mechanisms (Ref. 15) or other possible mechanisms. Burry (Ref. 21) suggests that aspirin may contribute to renal papillary necrosis through an additive effect even though aspirin alone is rarely associated with renal papillary necrosis (Refs. 8 and 21).

REFERENCES


(6) Adverse effects on the liver. Several recent studies have confirmed that aspirin causes a reversible hepatoxicity (Refs. 1 through 9). Increased hepatic dysfunction after aspirin ingestion has been identified by increased serum activity of transaminases (Refs. 1 through 4), serum glutamic oxaloacetic transaminase (SGOT) (Ref. 2), serum glutamic pyruvic transaminase (SGPT) (Ref. 2) and decreased activity of aspirin esterase (Ref. 9).

The increased incidence of hepatitis generally has been observed in children (Ref. 2) and adults (Ref. 7 and 9) of both sexes treated for systemic lupus erythematosus or rheumatoid arthritis requiring moderate doses over a period of several weeks. The effect is apparently a function of dose (Refs. 2, 10 and 13), plasma salicylate level (Ref. 10), the disease state and preexisting liver disease (Ref. 9).

In children treated for juvenile rheumatoid arthritis requiring high plasma...
salicylate levels, over 65 percent experienced elevated transaminase activity (Ref. 2).

Seeman and Plotz gave aspirin four times daily at a dose sufficient to obtain a serum salicylate level of 25 to 80 mg/100 ml (Ref. 6). They observed increased transaminase activity in 3 of 18 rheumatoid arthritis patients. Patients with systemic lupus erythematosus required lower salicylate plasma concentrations to produce hepatitis. Some patients experienced a fall in elevated transaminase activity even though the multiple aspirin dosing was continued. Others maintained high transaminase activity until aspirin therapy was stopped or the dose reduced.

Rich and Johnson reported dose-related hepatotoxicity of salicylates in children with severe rheumatoid arthritis (Ref. 2). Elevated SGOT and SGPT activities were observed in all patients and occurred only when serum salicylate levels were above 25 mg/100 ml. The effects occurred with sodium and choline salicylate acid salts as well as aspirin. A reduction of the dose reversed the effect indicating that the effect is primarily a function of blood levels rather than aspirin per se and is a reversible process. Clinical symptoms were also manifest in four patients. Liver biopsies were done in two patients which showed histological evidence of liver damage with scattered cell necrosis evident in one case.

Aramaki et al. studied 42 patients with various diseases given 2 g aspirin daily for 3 to 4 weeks (Ref. 9). They concluded that aspirin caused liver damage only in adult patients with impaired liver function. They found aspirin esterase enzyme activities decreased after aspirin administration in 8 of 14 patients with liver damage but slightly increased in those patients without liver disease. The decrease in aspirin esterase correlated with elevated transaminase in six of the eight patients with liver disease.

In view of the recent findings which have confirmed that aspirin causes a reversible hepatitis, especially in children and adults with systemic lupus erythematosus or rheumatoid arthritis and for other reasons elaborated elsewhere in this document, the Panel concludes that aspiric patients should not be self-medicating without medical supervision. (See part V. paragraph A. below—General Discussion.) In addition, it is the Panel’s recommendation that professional labeling to health professionals adequately alert physicians to the need for periodic liver function tests. An OTC liver warning labeling for this group is therefore recommended.

The Panel concludes that although prolonged use of high doses of aspirin may produce hepatotoxicity, the effect is dose-related, dependent upon the disease state and cannot be predicted. It is a function of any preexisting liver disease. In the opinion of the Panel, a warning that aspirin may cause liver disease is not warranted.

REFERENCES


(viii) Adverse effects of concomitant use with other drugs or by persons with certain disease states. The Panel has earlier briefly discussed the need for caution in the use of salicylates, especially aspirin, in the presence of serious illness and medical conditions for which prescription drugs are indicated. (See part II. paragraph H. above—Drug Interactions with Analgesia, Antipyretic, and Antiinflammatory Agents.) Reports have indicated possible drug interactions between the salicylates and other drugs. (Refs. 1 through 7.) Individuals who are taking prescription drugs may also use OTC analgesics, antipyretics or antiinflammatories containing salicylates to relieve pain, fever or headache without consulting a physician. Therefore, to alert such individuals that a drug interaction may occur between the prescription drugs and salicylates, the Panel believes that the labeling of these OTC products contains a general warning against the concurrent use of salicylate-containing products and certain prescription drugs. The warning on products containing salicylates should read "Caution: Do not take this product if you are presently taking a prescription drug for anticoagulation (thinning the blood), diabetes, or any other condition except under the advice and supervision of a physician."

The effects of a drug may be modified by prior or concurrent administration of salicylates. Such modifications or drug interactions may alter the effectiveness or toxicity of a drug by several mechanisms. Pharmacokinetic interactions and pharmacologic interactions are the two best understood mechanisms by which salicylates may modify the actions of drugs. In pharmacokinetic interactions, salicylates affect the absorption, metabolism, distribution or excretion of other drugs. Salicylates may also alter the pharmacological effects of other drugs by producing an additive, synergistic or antagonistic pharmacological effect. In the interaction of prescription drugs with salicylates, both of these mechanisms operate to modify the effectiveness and/or toxicity of prescription drugs.
lants, and since the use of anticoagulants must be closely monitored by a physician, the Panel concludes that the term "anticoagulant drug" should be included in the general warning statement. It is the Panel's view that patients currently taking such prescription drugs are under the close supervision of a physician. These patients will be aware that they are taking anticoagulant drugs, and it is important that they be immediately alerted through adequate labeling not to take salicylates concurrently.

(b) Hypoglycemic effect with antidiabetic drugs. The hyperglycemic activity of the oral antidiabetics (sulfonamides) may be enhanced by the concurrent administration of salicylates. It should be noted that salicylates, themselves, may have hypoglycemic properties, the Panel recommends that the compounds used for their hypoglycemic effect. The exact mechanism of the hypoglycemic action of salicylates is not completely understood. Several mechanisms by which aspirin may decrease plasma glucose levels have been postulated, among which are hepatic glucose deplection and increased glucose utilization.

It has been shown that the hypoglycemic activity of the antidiabetic drug, chlorpropamide, may be enhanced by the concurrent administration of aspirin (Ref. 6). Chlorpropamide is chemically related to other hypoglycemic agents such as tolbutamide, acetohexamide and tolazamide, and a similar interaction with aspirin may possibly occur. The interaction between salicylates and oral antidiabetic drugs may result in iatrogenic hypoglycemia because the concurrent use of these agents may cause a decrease in the plasma and thus increase the excretion of uric acid. It is interesting to note that salicylates alone have a pronounced uricosuric effect in high doses and can be used against gout, and in chronic trials demonstrating a direct relationship between chlorpropamide and aspirin (Ref. 5). Uric acid is normally reabsorbed into the body and not excreted by the kidney. The uricosuric agents used in gout block the renal tubule from reabsorbing uric acid. Hence in the latter instance, the uricosuric effect of the salicylates, chlorpropamide, acts selectively. This interaction in low doses may cause a suppression of uricosuria which results in uric acid retention in the body; uricosuria is prevented and the therapeutic action of the drug is negated.

Salicylates and uricosuric agents compete for common binding sites on plasma proteins and for active tubular transport, and the same mechanism is assumed that the binding of the uricosuric agents. The salicylate binding remains unaltered, reducing the excretion of the salicylates.

The Panel concludes that individuals with gout should avoid salicylates. Because salicylates have been shown to antagonize the effects of uricosuric agents, the Panel recommends that the general warning advise against the use of salicylates concurrently with prescription drugs used in the treatment of gout.

(d) Ulcerogenic enhancement in arthritis. The anti-inflammatory agents commonly used in rheumatic diseases can cause gastric ulcers. These agents include aspirin, corticosteroids, phenylbutazone and indomethacin. Although the mechanisms by which the ulcerogenic effect is produced by these agents are not definitely established, the possibility of an increased incidence of gastric ulceration when aspirin is used concomitantly with other ulcerogenic anti-inflammatory agents must be considered.

When corticosteroids and salicylates are taken concurrently, the ulcer-pro- 
duction drug beside the other. Nevertheless, because of this possibility and because salicylates do have hypoglycemic properties, the Panel recommends that the general warning advise against the use of salicylates with prescription drugs used in the treatment of diabetes.

(c) Uricosuric inhibition in gout. Individuals with gout have high serum uric acid levels. Urotic diuretics are prescribed for gout to decrease uric acid blood levels by increasing the renal excretion of uric acid (uricosuria). The drugs include probenecid, the sulfapyra- 
zone and phenylbutazone. Aspirin has been shown to specifically interact with the uricosuric action of sulfapyra- 
zone. High serum uric acid levels and mutual suppression of uricosuria occur in humans when both drugs are used concurrently (Ref. 5).

The concurrent use of salicylates with uricosuric drugs results in the inhibition of the excretion of uric acid in the urine (uricosuria inhibition) and thereby reduces the uric acid levels in gout, but in OTC doses, aspirin causes retention of uric acid. Hence in the latter instance, the uricosuric effect is negated.

The Panel recommends that the general warning advise against the use of salicylates concurrently with prescription drugs used in the treatment of arthritis.
An interaction which the Panel does not consider enough of a hazard to justify inclusion in the warning concerns the concurrent use of salicylates with drugs that result in changing the pH of the urine. Salicylates, such as aspirin, increase the acidity of the urine. The acidification of the urine increases the renal tubular reabsorption of salicylates, thus decreasing the excretion of the salicylates and increasing the salicylate level in the blood (Ref. 5). On the other hand, when substances, such as sodium bicarbonate, are taken, the urine becomes alkaline. Under alkaline conditions, the excretion rate of salicylates is increased, decreasing salicylate levels in the blood (Ref. 3). For salicylates to reach toxic levels in the blood when urine acidifiers are taken concurrently, high doses of salicylates would have to be ingested. The Panel does not believe that this interaction is important since in the usual OTC use of salicylates, it is unlikely that an ascorbic acid salicylate type of interaction would result in toxic salicylate levels in the blood.

For patients with disease conditions that require other drugs but which do not require the constant or daily supervision of a physician, the Panel recommends that a warning on the labeling of OTC salicylates is necessary, to warn the patient against serious potential interaction with salicylates. The Panel has therefore concluded that the warning against the use of salicylates with drugs prescribed for specific kinds of disease conditions is sufficient. Whether or not aspirin is used in the treatment of gout, diabetes and arthritis, is adequate for the labeling of OTC salicylates.

References:

(i) Adverse effects resulting in iron deficient anemia. Occult blood loss is usually not clinically significant (Refs. 1 and 2), but prolonged use of aspirin can result in greater occult bleeding in some patients. This use is a persistent, otherwise inexplicable, iron deficient anemia (Refs. 3 through 4). This has been observed in adults, particularly in some studies in rheumatoid arthritis (Ref. 5). At the same time it is known that anemia associated with some rheumatoid diseases will improve when the disease is brought under control with therapeutic doses of aspirin. Aspirin has been recently re-emphasized as an important consideration in the diagnosis of anemia in children (Ref. 6).

Aspirin is known to induce bleeding from the gastrointestinal tract. This has been discussed extensively elsewhere in this document. (See part III, paragraph B.l.a.(2)) (c) above—Occult bleeding.)

Stubble (Ref. 1), in a study on the presence of occult blood in the feces due to aspirin ingestion, stated that:

It has been demonstrated that the loss of blood of aspirin ingestion is in the range of 5 to 7 ml daily. These latter subjects were patients with negative histories of gastrointestinal bleeding. This difference was found not to be statistically significant. Holt concluded that: "This suggests that occult bleeding represents a very frequent side effect of aspirin therapy, and in some patients chronic ingestion of salicylates may be accompanied by sufficient blood loss to induce iron deficiency over a prolonged period."

The first report directly linking the consumption of aspirin with anemia appeared in 1958 (Ref. 2). The authors described two cases of patients with severe anemia due to the ingestion of salicylates. The first, a 39-year-old man, complained of fatigue and exertional dyspnea. For 7 years he had suffered from migraine headaches and had taken an average of 8 to 10 tablets of aspirin weekly. His hemoglobin was 8.4 g/100 ml and there were hematological features of iron deficiency. A blood test revealed a severe anemia (hemoglobin of 5.6 g/100 ml) apparently due to iron deficiency. She responded well to oral iron therapy. After leaving the hospital she regularly attended the outpatient clinic. The anemia recurred and required continuous iron therapy which had to be supplemented on two occasions with intra-venous iron. She had a dilatation and curettage and then a total hysterectomy. She still remained anemic and did not respond to a 6-month course of oral iron. Her anemia worsened to 4.2 g of hemoglobin per 100 ml and she was again hospitalized. Her serial stool occult blood tests were negative. The diagnosis for the cause of the anemia in this case was again very difficult. The patient was experimentally administered 35 gm aspirin four times daily which was followed by strong occult blood reactions in the stools.

The patient again was advised against salicylate ingestion and an alternative analgesic was suggested. The patient started to take salicylates after having recovered from the anemia and again her hemoglobin decreased from 14.0 to 11.2 g/100 ml. Eventually, after repeated hospitalizations the patient stopped taking salicylates and recovered. This latter case has been described in what may seem excessive detail; however, the purpose is to illustrate that in this case, because of the failure to obtain an early correct diagnosis, this woman had to undergo not only anemia of long time duration but dilatation and curettage and eventually even hysterectomy at the age of 29 years.

Stubbie has described 16 cases of severe iron deficiency anemia due to blood loss associated with aspirin ingestion (Ref. 4). Stubbie comments:
In every patient the use of aspirin, even if not the sole cause, played an important role in the development of the condition. There were no indications of peptic ulcer, profuse menses or haemorrhagic diathesis in any of these patients. The use of aspirin certainly does not need to be extravagant to play a predominant role. The main feature of these patients, all of whom developed strongly positive benzidine reactions after the administration of aspirin, were:

(i) reason for taking aspirin: rheumatic complaints, 4; headache, 12; (patients);

(ii) daily dose of aspirin 0.5.3 g in 15 (patients);

(iii) Age less than 25 years in 9;

(iv) Sex 15 females;

(v) Hemoglobin less than 9.0 g/100 ml in 15.

He then commented on the difficulties of diagnosing this type of anemia: "As a rule aspirin is no longer given after admission, and so the role of this drug will often be masked and will therefore not be found unless one is conscious of this process."

All the patients reported by Stubbe had also a low serum iron and a high iron binding capacity (Ref. 5).

Menguy in a review of the clinical, pathological and pathogenetic aspects of gastric mucosal injury induced by aspirin described two cases of aspirin-induced anemia (Ref. 5). The first case was that of a 60-year-old retired pharmacist with severe iron deficiency anemia. His hematocrit had never risen over 30 percent except immediately after each of the many transfusions he had received. When the attending physician, to whom the patient had been referred, inquired about aspirin ingestion, which had never been explored before, the patient re-plied he had been taking 2 g aspirin daily over the past 2 to 3 years. Initially, he had taken them for headaches, then it became a "habit." Tests for fecal blood were carried out using a Cr-tagged red blood cells during and after the administration of 2 g aspirin daily. After the results of the tests were disclosed to the patient he stopped taking salicylates and, without any transfusion his hematocrit rose from 13 percent upon admission to 25 percent 2 weeks later; a month later it was 94 percent and 3 months later it was normal.

The second case described in this report was that of a 40-year-old woman who was admitted with severe anemia after an episode of melena. The patient later admitted taking an aspirin-containing preparation (an average of 100 tablets weekly) over the previous 6 months. This is the only case in the literature reviewed where the anemia was due to excessive doses of an aspirin-containing analgesic preparation.

More recently, five cases of aspirin-induced anemia have been reported to occur in children (Ref. 6). The first case was that of a 3-year-old child who had received 150 mg aspirin nightly as a "sedative" for constipation and whose stool was positive for the first 3 days after admission. From repeated history-taking, it was found that the bowel had been taking 5 g of 325 mg aspirin tablets daily for many months as a "sedative". The second case was that of a 14-year-old boy with a hemoglobin of 5.8 g/100 ml and the blood film was classical of iron deficiency anemia. The occult blood tests were positive for the first 5 days after admission. After repeated questioning the boy disclosed that he had been taking 600 mg aspirin daily and often 600 mg at night for 6 months "to relieve mild tooth aches, headaches and sleeplessness."

Case 4 involved a 12-year-old girl with a hemoglobin of 7.1 g/100 ml and again that when pallor, fatigue and easy-exhaustion. She eventually admitted having taken 600-1,200 mg aspirin daily for 4 months before admission to the hospital.

Case 5 was a 5-month-old infant who had a hemoglobin of 7.1 g/100 ml and the blood film showed iron deficiency anemia. Stool occult blood tests gave positive results. On closer questioning the parents admitted that the baby had received 2 g of aspirin every 2 days. This dose was continued for the previous 6 to 8 weeks for febrile episodes, teething and as a "sedative". Aspirin was stopped, the anemia responded to iron therapy and the baby remained well thereafter.

The similar pattern in all five children and the complete recovery when aspirin ingestion was stopped suggests strongly that the aspirin ingestion caused the anemia.

All of the cases in this review of the literature suggest that caution should be exercised during aspirin therapy and that when pallor, fatigue and easy-exhaustion are the symptoms the possibility of aspirin-induced anemia should be investigated.

References


7. Dosage. (1) For products containing 225 mg (5 gr) per dosage unit, Adult oral dosage is 225 mg (5 gr) but not more than 842 mg (12.96 gr) initially, followed by more than 325 mg (5 gr) but not more than 421 mg (6.48 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 10 days. Children 11 to 12 years oral dosage is 497.5 mg (7.5 gr) every 4 hours while symptoms persist not to exceed 1,625 mg (25 gr) in 24 hours for not more than 5 days. Children 9 to 11 years oral dosage is 460.3 mg (6.95 gr) every 4 hours while symptoms persist not to exceed 1,525 mg (25 gr) in 24 hours for not more than 5 days. Children 6 to 8 years oral dosage is 325 mg (5 gr) every 4 hours while symptoms persist not to exceed 1,219 mg (19.75 gr) in 24 hours for not more than 5 days. Children 4 to 5 years oral dosage is 243.8 mg (3.75 gr) every 4 hours while symptoms persist not to exceed 812.5 mg (12.5 gr) in 24 hours for not more than 5 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

8. For products containing 60 mg (1.23 gr) per dosage unit. Children 11 to 12 years oral dosage is 480 mg (7.38 gr) every 4 hours while symptoms persist not to exceed 2,400 mg (36.9 gr) in 24 hours for not more than 5 days. Children 9 to 11 years oral dosage is 460.3 mg (6.95 gr) every 4 hours while symptoms persist not to exceed 2,000 mg (30.75 gr) in 24 hours for not more than 5 days. Children 6 to 8 years oral dosage is 320 mg (4.92 gr) every 4 hours while symptoms persist not to exceed 1,600 mg (24.6 gr) in 24 hours for not more than 5 days. Children 4 to 5 years oral dosage is 160 mg (2.46 gr) every 4 hours while symptoms persist not to exceed 800 mg (12.3 gr) in 24 hours for not more than 5 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

9. For products containing more than 325 mg (5 gr) but not more than 421 mg (6.48 gr) per dosage unit. Adult oral dosage is more than 225 mg (5 gr) but not more than 842 mg (12.96 gr) initially, followed by more than 325 mg (5 gr) but not more than 421 mg (6.48 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

10. For products containing more than 421 mg (6.48 gr) but not more than 490 mg (7.8 gr) per dosage unit. Adult oral dosage is more than 421 mg (6.48 gr) but more than 842 mg (12.96 gr) initially, followed by more than 421 mg (6.48 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 10 days.
but not more than 1,000 mg (14.92 gr) initially, followed by more than 421 mg (6.48 gr) but not more than 442 mg (6.79 gr) every 6 hours or 844 mg (13.58 gr) but not more than 970 mg (14.92 gr) every 6 hours while symptoms persist not to exceed 3,880 mg (59.56 gr) in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(v) For products containing more than 485 mg (7.46 gr) but not more than 500 mg (7.69 gr) per dosage unit, Adult oral dosage is more than 485 mg (7.46 gr) but not more than 1,000 mg (15.38 gr) initially, followed by more than 496 mg (7.69 gr) but not more than 500 mg (7.69 gr) every 3 hours or 970 mg (14.92 gr) but not more than 1,000 mg (15.38 gr) every 6 hours while symptoms persist not to exceed 4,000 mg (61.52 gr) in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(vi) For containing more than 500 mg (7.69 gr) but not more than 650 mg (10 gr) per dosage unit, Adult oral dosage is more than 500 mg (7.69 gr) but not more than 650 mg (10 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(b) Products containing aspirin in an amount different than the standard aspirin dosage unit. While the Panel recommends that products containing only 325 mg (5 gr) aspirin per dosage unit be clearly labeled on the principal display panel: “Contains the standard strength of 325 mg (5 gr) aspirin per dosage unit”. The term “dosage unit” may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends that all products containing only 325 mg (5 gr) aspirin per dosage unit be clearly labeled on the principal display panel: “Contains nonstandard strength of X mg (X gr) aspirin per dosage unit”. The actual amount “X” of aspirin for the specific product shall be used. The term “dosage unit” may be replaced by the applicable dosage form such as tablet or capsule.

(b) Acetaminophen. The Panel concludes that acetaminophen is a safe and effective OTC analgesic when taken in the recommended dosage of 325 to 650 mg every 4 hours while symptoms persist not to exceed 4,000 mg in 24 hours for not more than 10 days.

(1) Effectiveness. This drug belongs to a group of drugs which were introduced into therapeutic use before the era of well-controlled clinical trials. Acetaminophen (N-acetyl-p-aminophenol) was first used by von Mering in 1893 (Ref. 1). Yet, as Beaver has observed, there have been a number of suitably controlled studies of its analgesic effect in man in the past few decades as noted below.

While acetanilid and phenacetin have been used extensively since the time of their introduction, they were used very little until Brodie and Axelrod demonstrated that in man, both acetanilid and phenacetin are converted into acetaminophen and proposed that acetaminophen is, in commonly recommended doses, an effective analgesic which can be satisfactorily substituted for acetylsalicylic acid.

Cantor et al. compared aspirin at two dose levels, 600 and 1,200 mg, acetaminophen at 600 mg, and placebo in patients who had just undergone childbirth and found the three drug treatments were all significantly superior to placebo but not significantly different from each other (Refs. 10 and 11). Parkhouse and Hallison (Ref. 12) in a double-blind study in post-operative orthopedic patients, in which a nurse observer and the patient assessed the pain, found that both 600 mg aspirin and 1 g acetaminophen were easily distinguishable from placebo.

In the study of Moertel, Ahlmann, Tay-}
lor and Schwartau (Ref. 13) acetam-
inophen rated fourth after aspirin, mo-
edine, and paracetamol and phenacetin in the pa-

tients' ratings which were from 1 to 10 and it rated third in a mean percentage relief of pain. They concluded that acet-
inophen or phenacetin would be a reason-
al alternative in case of aspirin intolera-
tance.

In AMA Drug Evaluations (Ref. 14), acetaminophen effectiveness is described as follows: "The analgesic and anti-
pyretic efficacy of phenacetin and acet-
inophen is equal to that of aspirin; however, unlike aspirin, these two anal-
gesics do not have anti-inflammatory or pruritic effects and thus are not as useful in the treatment of rheumatoid diseases.”

The Panel reviewed unpublished well-
controlled double-blind studies where acetaminophen was studied in patients with headache (Ref. 15 and 16). Acet-
inophen 650 mg, was shown to be ef-
fective in the treatment of headache. Additionally, in a crossover study of patients with migraine headache (Ref. 17) patients received (a)
a combination of 65 mg isometheptene, 325 mg acetaminophen, and 100 mg diphenhydramine, have been tolerated by patients in clinical trials when used in a combination of 325 mg acetaminophen and (c) placebo. Only the combination showed to be superior to placebo in this type of headache.

In another uncontrolled, open-label study of acetaminophen and vitamin C was studied in 45 patients with pain of different etiology (Ref. 18). The dose used was four to six tablets (containing 325 mg acetaminophen) per day for several hours. None of these patients had headache, and positive, favorable results were obtained in all of them. Four of these patients had pain described as neuralgia and all four obtained relief using this dose.

In another uncontrolled study by Ferrin (Ref. 19), acetaminophen in combination with vitamin C (does not give) was evaluated in 1,000 patients with pain of different etiology. Of these, 98 patients were admitted into the study for headache. The results are mostly analyzed in global groups of patients having headache, but differences are noted. However, the following statement is made: "patients with headache reacted well and were alleviated rapidly." Unfortunately, the doses and dosage regimen are not given in these reports. An additional 66 patients in the study are identified as having "neuralgias and neuritis" but the response of this group of patients is not stated.

In another single-blind study (Ref. 20), 500 mg acetaminophen was compared with a combination of 300 mg acetaminophen, 5 mg hydroxyzine, 30 mg promazine hydrochloride, and 30 mg caffeine. One to two tablets of each preparation were given to patients suffering from tension headache. The results showed that 45 percent success was obtained with acetaminophen alone and 90 percent with the combination. This superiority was attributed to the "potentiation of the analgesic agents by hydroxyzine.

The Panel concludes that acetaminophen is effective in relieving the pain of headache, and that it is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing. Thus, acetaminophen is a general analgesic of proven efficacy as shown by clinical testing.

(2) Safety. Numerous clinical studies have shown that acetaminophen, when taken in recommended doses, is relatively free of adverse effects in most age groups, even in the presence of a variety of disease states. There was no increase in fecal blood loss (Ref. 22). There were no stomach mucous membrane reactions in patients with gastrointestinal illnesses (Ref. 23). There was no interference with the action of drugs which promote uroic acid excretion in the urine (Ref. 24). No effects on clotting were seen in hemophilia (Ref. 25). However, these studies have shown small increases in blood clotting time in patients using acetaminophen, but concurrent anticoagulant therapy was considered manageable with conventional precautions (Ref. 26).

Larger than normal doses were required to produce a mild methemoglobinemia (a reversible blood disorder) (Ref. 17). The safety of acetaminophen is discussed in detail below. The metabolism of acetaminophen was considered and has been reviewed by the Panel elsewhere in this document. (See part II, paragraph L above—Absorption, Distribution, Bio-transformation (Metabolism) and Excretion of Acetaminophen.) A few cases of hypersensitivity to acetaminophen have been reported, as manifested by skin rashes (Ref. 28), thrombocytopenic purpura (characterized by "black and blue" patches on skin and mucous membranes), rarely hemolytic anemia (anemia due to red blood cell destruction) and the very serious blood disorder agranulocytosis (Ref. 29). Occasional individuals respond to ordinary doses with nausea and vomiting or diarrhea.

The only contraindications to the use of acetaminophen presently well-established were considered by the Panel to be use of the drug. Definitive studies are not available on whether or not acetaminophen should be used in patients with certain preexisting liver diseases. The Panel concludes that the risk may be a possibility in these individuals and recommends that high priority be given to well-designed studies to resolve this issue.

(1) Animal toxicity. With regard to the acute toxicity of acetaminophen, the large doses of acetaminophen required to evoke toxic reactions in the studies cited below are considered by the Panel to reflect a wide range of safety. This is especially true when those doses are compared to the Panel's recommended single dose and daily intake.

The single-dose oral LD₅₀ (dose that kills 50 percent of the animals) of acetaminophen in male rats was reported to be 3,710 mg/kg (Ref. 31), as compared to the previously reported LD₅₀ of 1,650 mg/kg (Ref. 32). The LD₅₀ of acetaminophen in the rat is about 300 to 400 times the usual single dose in 50 to 70 kg (110 to 150 lb) adult humans.

In an acute toxicity study by Boyd and Bereczky (Ref. 31), acetaminophen produced early pathologic effects in the rats similar to those seen in the same laboratory in an earlier study (Ref. 22) with phenacetin. Rats dying in 24 hours showed extensive capillary-venous congestion, tubular nephritis and centrilobular hepatitis (kidney and liver inflammatory conditions, respectively). When deaths occurred later with acetaminophen the hepatitis had progressed into hepatic necrosis.

A 100-day LD₅₀ of acetaminophen in the rat was found to be 770 mg/kg daily; the 100-day LD₅₀ was estimated to be 300 mg/kg (Ref. 33). Extrapolating to humans ranging in weight from 50 to 70 kg (110 to 150 lb), the latter dose represents about 5 to 7 times the maximum recommended daily dose of 3,900 mg.

Boyd further found that his 100-day LD₅₀ in the rat produced atrophy of the tests and inhibition of the production of sperm in rats and guinea pigs as well (chloramphenicol) (Ref. 34). The sex organs of females were affected to a lesser degree. Other effects noted by Boyd and Hogan (Ref. 33), in rats receiving the 100-day LD₅₀ dose, included kidney and liver damage. Prescott, Rosecr, Wright and Brown (Ref. 35) observed liver damage in 17 of 30 patients who had taken at least 15 g; one went into a coma induced by liver dysfunction and said to be due to a drug taken to estimate was given of the lowest dose thought to have caused liver damage. Clark et al. (Ref. 36) studied a series of 60 patients who took doses of acetaminophen claimed to range from 13 to 60 g. Forty-nine developed liver damage, 17 progressed to hepatic encephalopathy (brain damage), and 12 died from fulminant hepatic failure. Death occurred in 4 to 18 days after the ingestion of 0.5 g/kg (Ref. 37). Proudfoot and Wright (Ref. 37) studied 41 cases of acute acetaminophen poisoning, 17 of which showed liver damage. Of these, 19 died and nine patients who received "paracetamol" (acetaminophen). In all of these series it was noted that other drugs were, or may have been...also taken.

In the U.S. in 1972, 61 cases of acetaminophen poisoning were reported to the National Clearinghouse for Poison Control Centers, Food and Drug Administration (Ref. 38). Of these, 15 reported the ingestion of less than 3.5 g, 23 between 3.5 and 15 g, and seven ingested more than 15 g. Two of the latter developed toxic hepatitis. No effects of this nature were reported from doses lower than 15 g in man (Ref. 39). Stewart (Ref. 39) studied a series in which more than 15 g were ingested. One of these had no symptoms, another experienced some lethargy, and the other experienced nausea, vomiting and abdominal pain. The Panel concludes that single doses less than 15 g are not usually associated with serious liver damage. The much lower incidence of reported acetaminophen hepatotoxicity in the U.S. compared to England has been attributed to the well-known axiom, 'if the diagnosis is not suspected, it is not seen,' since one investigator reported 185 cases with 4 fatalities in one city alone (Ref. 39).

A dose of 15 g is 23 times the usual recommended single dosage of acetaminophen (30 mg/kg) and about 4 times the maximum recommended daily intake. In estimating the range of safety, the single dosage comparison is probably more appropriate than the comparison of the single toxic dose with the daily divided therapeutic dose. The toxic effect of acetaminophen on the liver is related to glutathione depletion (Ref. 40).
Since acetaminophen is metabolized by the liver, the question of the safety of its use in the presence of liver disease should be considered.

In a study of 72 patients with various forms of liver disease given 10 mg/kg of acetaminophen and drug-related deaths (Miles and colleagues) found an increase in both the serum levels and urinary excretion of unconjugated acetaminophen in the presence of certain liver diseases (parenchymal disease with hyperbilirubinemia or obstructive jaundice). Patients with cirrhosis exhibited plasma levels 2 to 3 times higher than those observed in subjects with no liver damage indicating decreased rates of metabolism. No decrease in the blood levels of conjugated acetaminophen or total urinary excretion of the drug could be demonstrated indicating that these two types of observations would not be expected to show differences in metabolism of free drug as would be expected from the pharmacokinetic characteristics of this drug. Vest and Fritz (Ref. 42) observed a lowered ability of the liver to conjugate acetaminophen in six children with infectious hepatitis given 10 or 20 mg/kg of the drug intravenously. In the later phase of the hepatitis the excretion of conjugated acetaminophen was decreased. However, urinary excretion of free drug or total conjugates of acetaminophen was an insensitive method to observe changes in metabolism of acetaminophen. Direct comparison of blood levels of unchanged drug indicates that the relative rate of conjugation can be decreased significantly without significant differences in urinary excretion of total conjugates. Free acetaminophen disappeared more slowly from the blood. The effects on excretion and blood levels of the conjugates and free acetaminophen reflected a partial inhibition of the conjugation of the drug to its glucuronide and sulfate resulting in a delayed total elimination of the drug from the body. In 33 patients with liver cirrhosis, Jirsa and Bykes (Ref. 43) found no effect on the excretion of the metabolites of acetaminophen but did find a significant decrease in diabetics. Schmidt and Hammaker (Ref. 44) observed no significant reduction in the formation of conjugated acetaminophen in five patients with Gilbert's disease (congenital liver disorder) after the administration of 50 mg/kg of acetaminophen but did not study blood levels of unchanged drug. In studies on infants prior to the development of their ability to metabolize this drug, no significant differences in hematologic or other toxic effect were found. However, increased doses of acetaminophen up to 16.6 mg/kg (Ref. 45), or 100 mg 3 times daily rectally for 3 days (Ref. 46).

There have been no clinical studies of the effects of liver disorders on metabolic pathways other than the glucuronide and sulfate conjugation pathways through which acetaminophen may be metabolized. In animal studies, Mitchell and colleagues (Ref. 40) postulated that a minor but as yet unidentified highly reactive metabolite formed by nonconjugating enzymes (mixed oxidase) is responsible for the liver toxicity of acetaminophen. In normal subjects the concentration of this metabolite is low, and it is further conjugated with glutathione to a nontoxic metabolite. At high doses glutathione is depleted and the reactive metabolite reacts chemically with other compounds in the cell which results in necrosis. It is pertinent to know whether liver damage might affect the liver toxicity of acetaminophen by interfering with the production of this toxic metabolite by nonconjugating pathways and further conjugation with cysteine to a nontoxic substance.

There is evidence in the results of the above studies that in some forms of liver disease there is a decrease in the conjugation of acetaminophen. This effect significantly increases the half-life of acetaminophen to 3 to 4 hours in some cases. It is perhaps significant that in toxic reactions to overdoses of acetaminophen the half-life is usually increased to 4 hours (Ref. 39).

Decreased metabolism of acetaminophen by normal conjugation mechanisms (glucuronide and sulfate) observed in patients with liver disease could potentially increase toxicity of acetaminophen by increasing the relative fraction metabolized through nonconjugating pathways to the toxic metabolite. Decreased conjugation could also indicate decreased capacity of the liver to further conjugate the toxic metabolites with glutathione to a less toxic conjugate.

An alternative explanation for the increased susceptibility of chronic alcoholics to the hepatotoxicity of acetaminophen (Ref. 47) is the induction of the microsomal enzyme systems (nonconjugating) by chronic use of alcohol (Ref. 48). However, recent evidence suggests that the overall elimination by conjugation is decreased in alcoholics similar to that observed in other cases of decreased liver function.

Shamsuddin et al. found that preexisting liver disease significantly decreases the rate of elimination of acetaminophen by the increased half-life of unchanged drug in the plasma in patients with cirrhosis (half-life 3.5±1.3 hours) and those with alcoholic cirrhosis (4.5±1.5 hours) compared to chronic alcoholics with normal liver function, (2.2±0.33 hours) and chronic alcoholics off alcohol for 7 days (2.8±0.7 hours) (Ref. 49).

Thus several types of liver disease result in prolonged half-lives of unchanged drug which are about the same increase (about 4 hours) observed in patients who suffer liver damage after acetaminophen overdose.

One cannot conclude that because an increased acetaminophen half-life occurs in association with acute liver damage caused by acetaminophen, that increased susceptibility to the hepatotoxicity caused by preexisting liver disease will increase the potential or severity of acetaminophen hepatotoxicity. Well designed studies of individual clinic patients are needed. Although the Panel does not have evidence to warrant a warning to persons with liver disorders at this time, it is noted that there is no evidence to exclude this possibility and the considerations discussed above require that this possibility not be dismissed.

Although the Panel concludes that additional studies are needed to determine if a warning is required for normal doses in adults or infants with liver disease, overdose may result in such severe liver damage that a label warning regarding the use of acetaminophen in these cases is obligatory. The basis for such a warning is well documented in several recent reviews of the hazards of acetaminophen overdose, especially with respect to the harmful effects on the liver (Refs. 39, 48, and 50 through 52).

The warning should state: "Do not exceed recommended dosage because severe liver damage may occur."

Kidney damage has been described in numerous cases in which the liver injury has been of primary concern in acute poisoning by acetaminophen, as previously discussed. The nature of the injury to the kidney observed in such acute cases is apparently not related to the type of injury (papillary necrosis) which developed after prolonged use of acetaminophen (Ref. 48). In the other cases, the kidney damage developed after 5 years of intake of 1.5 g acetaminophen daily along with other drugs including some drugs containing phenacetin. Master (Ref. 55) reported a case of analgesic-induced kidney injury in a woman who took an average of 1.5 g acetaminophen daily for 10 years, the last 6 years in combination with phenacetin. Abel (Ref. 57) and the Royal Australasian College of Physicians (Ref. 58) have stated that patients fail to recover from kidney injury when their intake of phenacetin combinations is replaced by acetaminophen either alone or in combination.

In studies on healthy adult human subjects, Prescott (Ref. 59) and Prescott, Sanseau, Leven and Conney (Ref. 60) observed a slight increase in the excretion of kidney tubule urine following the intake of 36 g acetaminophen daily for 5 days. In the latter
study the increase was significant in one of eight subjects on acetaminophen and two of nine subjects on the same dosage schedule of phenacetin. This effect was considerably less than that seen in subjects taking similar doses of aspirin.

Edwards, Edwards, Huskisson and Taylor (Ref. 61) found only a minor impairment of renal function in four of six patients who received 30 mg/kg of acetaminophen in 6 of 13 patients after their intake of 2 to 30 kg acetaminophen over a period of 2 years. Batterson and Grossman (Ref. 7) noted no blood, liver, or kidney disturbances in human subjects receiving 3.6 g daily for up to 116 weeks.

In an experiment on dehydrated dogs, Blumen and Goldberg (Ref. 62) found a high concentration of acetaminophen in the same dose, 3.6 mg/kg, reticulocytes. Antilix, and Analgesic Agents. 1946.

Acetaminophen has not been reported to produce effects on the central nervous system in dogs and nondehydrated dogs. In an experiment on dehydrated dogs, as well as to aspirin-containing products. Aniline, N-Acetyl-p-Aminophenol (Free and Total Concentration of the Drug in the Renal. of 21 CFR 201.314(e) (2) for products containing 80 mg (1.23 gr) tablets of aspirin for pediatric use.

The Panel concludes that the OTC package requirements for safety closures and the restriction on the maximum number of tablets in the containers of aspirin products for pediatric use should also apply to acetaminophen products for use in children.

REFERENCES


(15) OTC Volume 003154.

(16) OTC Volume 003155.


(82) National Poisoning Project Unit and Analgesic Equivalence Value.)

The Panel recommends that all prod- ucts containing acetaminophen be clearly labeled as containing acetaminophen on the principal display panel. In addition, labeling shall state in metric units and secondarily in apothecary units the quantity of acetaminophen per dosage unit. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.
Upon potency (414 mg instead of aspirin including the limitations on maximum effects are achieved" (Ref. 4). Bonica and Allen have reported that the dissolution rate for this compound of aspirin. Levy and Hayes have reported the logical effect as that produced by aspirin is a larger molecule than aspirin, calcium aspirin. Because calcium carbaspirin is a complex of calcium acetylsalicylate and urea (compound containing calcium carbaspirin has a more rapid tract to aspirin, calcium and urea. While calcium carbaspirin is as safe as aspirin and effective as aspirin (Ref. 6).

The only studies which show that the side effects of calcium carbaspirin may be different from those of aspirin are the following: Muir and Cossar (Ref. 6) in a study with patients undergoing gastrectomy summarized their finding as follows: "Soluble calcium aspirin has no significant signs of gastric irritation in 95 gastrectomy specimens. Standard aspirin has shown potentially serious gastric lesions in 8 out of 102." These authors also found that calcium carbaspirin is more effective than aspirin in 20 patients (aspirin 65 percent with bleeding, calcium carbaspirin 5 percent with bleeding) with no previous history of dyspepsia.

One article reported a series of studies using radioactive labeled chromate to determine gastrointestinal blood loss after ingestion of calcium carbaspirin. Levy and Hayes have reported that the dissolution rate for this compound is 1.5 hours. However, Beuster noted that the rate of absorption into the bloodstream was similar to that of aspirin. Bonica and Allen have reported that "there is evidence that it offers a clinically significant advantage (over aspirin) in the rate in which analgesic effects are achieved" (Ref. 4).

The previous discussion in this document of aspirin including the limitations on maximum daily and total intake are applicable here with a slight modification based on potency (414 mg instead of 325 mg (gr) aspirin. (See part III, paragraph B.I.a.1 above—Effectiveness.)

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simple salicylates are less than equian-
tiveness of the two drugs has never been
dated that an advantage of
includes that choline salicylate is a7 safe
er, assessed the blood plasma levels ob-
In other cases in which the effect of as-
salicylate resulted in an average daily
of blood in the stool with the use of
concluded that there was less incidence of
in large doses does have an effect on
in addition, choline salicylate, as well as the other nonacetyl-
reactions causing asthmatic attacks in
This significance of faster absorption
The Panel finds that choline salicylate
because the side effects are similar to
Yet unlike aspirin and the other acetyl-
choline salicylate has
and effective
adhesiveness involved in the clotting
However, choline salicylate in
the caution concerning bleeding
There have been many reports assess-
the occurrence of gastrointestinal
in 90 normal volunteers who had ingested
The subjects were injected with radioactively la-
Ten percent showed a loss of
The average loss was 4.8 ml for the patients taking
Ten percent showed a loss of
Ten percent showed a loss of

Leary (Ref. 1) has also reported that
adequate statistical analysis is presented
to substantiate such claims, and therefore,
and therefore, for this reason, have similar per-
In addition, the Panel concludes that regarding the claims for
and its effect on the
further testing is required to
The Panel notes that although choline sal-
may not contain buffering ingredi-
when the known effects of aspirin in his
in large doses does have an effect on
another aspect of the clotting mecha-
Therefore, the caution concerning bleeding
should be addressed to that popula-
which is exposed to large doses of
There have been many reports assessing
the occurrence of gastrointestinal
bleeding associated with the use of
coline salicylate. Watson and Pierson (Ref. 2) injected
with buffer solution that may at best advance the
the average daily loss of
5.0 ml.
Lange (Ref. 9) selected 19 patients
had shown signs of occult (unseen)
or manifest (noticeable) bleeding un-
der ordinary salicylate treatment. He
concluded that there was less incidence of
in the stool with the use of
choline salicylate. In a crossover study 73 percent
of patients who took aspirin versus 36 percent of those using
choline salicylate showed occult blood loss.
Rider et al. (Ref. 10), using the gas-
troscope studied 30 patients
after ingestion of choline salicylate. He found
no evidence of irritation of the mucous
membrane of the stomach, hyperplasia,
without taking<br>membrane of the stomach, hyperplasia,
without taking<br>membrane of the stomach, hyperplasia,
without taking
not to exceed 3,262.5 mg in 24 hours for not more than 5 days. Children 9 to under 11 years oral dosage is 543.8 mg every 4 hours while symptoms persist not to exceed 2,175 mg in 24 hours for not more than 5 days. Children 6 to under 9 years oral dosage is 240.5 mg every 4 hours while symptoms persist not to exceed 1,721.2 mg in 24 hours for not more than 5 days. Children 2 to under 6 years oral dosage is 52 mg every 4 hours while symptoms persist not to exceed 78 mg in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 325.0 mg every 4 hours while symptoms persist not to exceed 1,632.5 mg in 24 hours for not more than 5 days.

Children 2 to under 4 years oral dosage is 125 mg every 4 hours while symptoms persist not to exceed 1,087.5 mg in 24 hours for not more than 5 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

(4) Labeling. The Panel recommends the Category I labeling for analgesic active ingredients. (See Standard of 325 mg per dosage unit B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: (i) Warning. "Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician.

(ii) Analgesic equivalence value. In the previous discussion on "standard strength" as used by the Panel, it now appears clear the need to indicate the quantity of choline salicylate per tablet, teaspoon or other dosage unit as well as the quantity by which a particular product containing choline salicylate differs per dosage unit from the established standard of 325 mg sodium salicylate per dosage unit. (See Part II, paragraph E. above—Standard Dosage Unit and Analgesic Equivalences.)

The Panel recommends that products containing choline salicylate be clearly labeled on the principal display panel: "Equivalent to X mg per dosage unit of the established standard of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of equivalent analgesic effectiveness for the specific product shall be specified. The "Equivalent to" may be replaced by the applicable dosage form such as tablet or capsule. For example, a product containing 435 mg choline salicylate per tablet (dosage unit) shall be labeled, "Equivalent to 235 mg per tablet of the established standard of 325 mg sodium salicylate per tablet".

REFERENCES


(13) OTC Volume 03077.

Notwithstanding the Panel's recommendation, the absence of data in support of this claim only applies if magnesium salicylate is taken under the advice and supervision of a physician.

(iii) Magnesium salicylate. The Panel concludes that magnesium salicylate is a safe and effective OTC analgesic when used within the recommended dosage range of 2.5 to 6 mg every 4 hours while symptoms persist not to exceed 4,000 mg in 24 hours for not more than 10 days.

(iv) Effectiveness. This ingredient has been used since 1888, when it was first cited in an editorial of "Pharmaceutical Post" and was used for therapy of typhoid fever. (Ref. 1). The same year Caldwell et al. (Ref. 2) in a review article reported on its use as an "intestinal antiseptic" and therefore useful in typhoid fever. This product was still found in the Merck Index, 1930 Ed., where it was described as antiseptic, anti-rheumatic and anti-rheumatic, and still listed among its uses "typhoid fevers and typhus" (Ref. 3).

In a report published in the late 1930's, analgesia is mentioned for the first time by Joseph (Ref. 4). That report consists of the experience of a single physician with ten of his patients in which magnesium salicylate produced a marked analgesic effect. In 1957, Stern et al. (Ref. 5) compared aspirin with magnesium salicylate and found no statistically significant differences in the levels of analgesia using these two agents. This study was double-blind and analgesia was evaluated in 25 patients with rheumatic fever and rheumatic pain of patients with osteoarthritis. They concluded that magnesium salicylate was preferable to aspirin in conditions requiring long term therapy since it produced less gastrointestinal irritation than aspirin.

An unpublished study performed by F. W. McCoy (Ref. 6) in 1964, aspirin, magnesium salicylate and aspirin plus magnesium salicylate were compared on the basis of salicylate blood levels. Although it is known that salicylate blood levels do not directly correlate with analgesic effects it is interesting to note that magnesium salicylate in spite of a greater solubility than aspirin, gave "somehow" lower blood levels of salicylate than aspirin. The blood levels of salicylate obtained with magnesium salicylate were greater than those obtained with aspirin plus aluminum and magnesium hydroxides. This is most likely due to the buffering of the aspirin formulations by aluminum and magnesium hydroxides. In an established study, the analgesic effectiveness of magnesium salicylate was evaluated in 42 elderly patients with degenerative joint disease. This was a double-blind cross-over study, magnesium salicylate was compared to aspirin and placebo. The data were analyzed statistically, and the conclusions obtained from this study were that magnesium salicylate and aspirin were equally effective in relieving the pain of patients with osteoarthritis and that both drugs were superior to placebo (Ref. 7).

Jacobson (Ref. 8) reported the use of magnesium salicylate in 34 patients with rheumatoid arthritis and 27 patients with degenerative joint disease. In this study, analgesic and anti-rheumatic effect was assessed. The data suggest the effective value of this drug as an analgesic in the patients tested.

The Panel concludes that while the number of well-controlled comparative studies is few and mostly unpublished, the studies and the other data reviewed by the Panel indicate that magnesium salicylate is an effective analgesic and that is probably equivalent to aspirin. The claim that magnesium salicylate might be indicated when aspirin cannot be tolerated, remains to be proven.

(2) Safety. At the present time, there is evidence which indicates that magnesium salicylate is as safe as aspirin, although it has side effects similar to aspirin and the other salicylates. Unlike aspirin and other acetylated salicylates, magnesium salicylate has not been associated with reactions causing asthmatic attacks in susceptible people. In addition, magnesium salicylate, as well as the other nonacetylated salicylates, are not known to affect the platelet adhesiveness involved in the clotting mechanism. However, magnesium salicylate in high doses have had no known effect on the other aspect of the clotting mechanism, an anticoagulant effect. There is evidence of gastric mucosal bleeding and irritation similar to aspirin.

The Panel reviewed data on magnesium salicylate, utilizing the gastrocamera, revealed some variation between aspirin and magnesium salicylate when irritation of the stomach wall was assessed. Irritation to the mucous membranes of the stomach did occur in the presence of both drugs (Ref. 9). Other submitted studies used radioactively-labeled sodium chromate C14. These studies indicated that bleeding also took place in a significant number of subjects. There was evidence that the amount of bleeding might be less with magnesium salicylate than with aspirin (Ref. 10). One study that determined magnesium concentrations in the blood indicated considerable individual variations which were neither consistent nor significant (Ref. 11).

The Panel has reviewed the possible systemic toxicity of magnesium ions with...
PROPOSED RULES

recommended doses of magnesium salicylate. Unless renal insufficiency is present, toxicity due to the absorption of magnesium is unlikely in the recommended maximum daily dosage of 3,900 mg magnesium salicylate every 4 hours not to exceed 3,900 mg in 24 hours for not more than 10 days (Ref. 12). Absorbed magnesium is rapidly excreted, so that hypermagnesemia which can be caused by the oral route in the presence of normal renal function. In renal dysfunction, however, hypermagnesemia toxicity may occur and a warning is therefore necessary (Ref. 12). The Panel concludes based on the available evidence, that a restriction on the intake of magnesium salicylate for normal persons in the recommended daily dosage is not necessary because there is no evidence of possible systemic toxic effects due to magnesium.

The amount of magnesium in the recommended maximum daily dosage of 3,900 mg magnesium salicylate which does not pose any safety problem. However, for any product containing magnesium in which the maximum daily dosage exceeds 50 mEq of magnesium salicylate, the warning: "Do not take this product if you have kidney disease" except under the advice and supervision of a physician should contain the warning: "Do not take this product if you have kidney disease except under the advice and supervision of a physician".

Dosage. Adult oral dosage is 325 to 650 mg every 4 hours while symptoms persist not to exceed 3,900 mg in 24 hours for not more than 10 days, Children 11 to under 12 years oral dosage is 497.5 mg every 4 hours while symptoms persist not to exceed 2,437.5 mg in 24 hours for not more than 5 days. Children 9 to under 11 years oral dosage is 406.5 mg every 4 hours while symptoms persist not to exceed 2,031.5 mg in 24 hours for not more than 5 days. Children 7 to under 9 years oral dosage is 325 mg every 4 hours while symptoms persist not to exceed 1,636 mg in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 243.8 mg every 4 hours while symptoms persist not to exceed 1,219 mg in 24 hours for not more than 5 days. Children 3 to under 4 years oral dosage is 162.5 mg every 4 hours while symptoms persist not to exceed 812.5 mg in 24 hours for not more than 5 days. Children 2 years and younger there is no recommended dosage except under the advice and supervision of a physician.

Labeling. The Panel recommends the Category I labeling for analgesic active ingredients. (See part II, paragraph B.I. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: (1) Warning. "Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician".

(ii) For products containing more than 50 mg of magnesium in the recommended daily dosage. Warning. "Do not take this product if you have kidney disease except under the advice and supervision of a physician".

(iii) Analgesic equivalence value. In the previous discussion on "standard strength" dosage forms the Panel made clear the need to indicate the quantity of magnesium salicylate per tablet, teaspoon or other dosage unit as well as the quantity by which a particular product containing magnesium salicylate differs per dosage unit. The Panel recommends that the standard of 325 mg sodium salicylate per dosage unit. (See Part II, paragraph E. above—Standard Dosage Unit and Analgesic Active Ingredients).

The Panel recommends that products containing magnesium salicylate be clearly labeled on the principal display panel: "Equivalent to X mg per dosage unit of the standard of 325 mg sodium salicylate per dosage unit".

The actual amount of "X" of equivalent analgesic effectiveness for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule. For example, a product containing 325 mg magnesium salicylate per tablet (dosage unit) shall be labeled, "Equivalent to X mg per dosage unit of the standard of 325 mg sodium salicylate per tablet".

REFERENCES

(6) McCoy, F. W., "A Comparative Salicylate Absorption Study of WF-716 (Magan), Aspirin and Plain Aspirin in Healthy Non-Rheumatic Subjects," draft of unpublished paper is included in OTC Volume 030042.
(7) Sanders, J. F., "Effectiveness of Magan in Rheumatic Subjects," draft of unpublished paper is included in OTC Volume 030042.
(10) Brown, K., "Magan—Serum Magnesium," draft of unpublished paper is included in OTC Volume 030042.
(12) In addition, a product containing 325 mg magnesium salicylate for normal persons in the recommended daily dosage is not necessary, because there is no evidence of possible systemic toxic effects due to magnesium.

Effective. Sodium salicylate had already been in use for about 25 years when aspirin was introduced into therapy in 1899. Aspirin is generally considered on the basis of that it was more palatable and caused less gastrointestinal disturbances than sodium salicylate (Ref. 1). It has been demonstrated that aspirin (acetylsalicylic acid) is hydrolyzed to salicylic acid. It has been suggested that the latter is the active compound (Ref. 2). However, the therapeutic effect of aspirin as an analgesic is generally recognized as being superior to an equal dose of sodium salicylate (Refs. 1 and 2). Some researchers using patients with cancer pain as well as post partum patients, have found aspirin superior to sodium salicylate when given in equimolar doses (Refs. 3 and 4).

Frey has reported that aspirin was more effective than sodium salicylate in the treatment of the common headache (Ref. 5).

The AMA Drug Evaluations (Ref. 6) mentions sodium salicylate as an analgesic and states that "it is less effective than equal doses of aspirin in relieving pain and reducing fever..."

Woodbury (Ref. 7) cites sodium salicylate as one of the two most commonly used preparations for analgesic effects, the other one being aspirin.

The Panel concludes that the few well-controlled clinical studies, the long clinical history of this ingredient's use and acceptance in most basic medical and pharmacology texts, indicate that sodium salicylate is an effective analgesic.

Safety. The Panel concludes that sodium salicylate is as safe as aspirin, although it has side effects similar to aspirin and the other salicylates. Yet unlike aspirin and the other acetylated salicylates, sodium salicylate has not been associated with reactions causing asthmatic attacks in susceptible people. In addition, sodium salicylate, as well as the other nonacetylated salicylates, are not known to affect the mechanism involved in the clotting mechanism. However, sodium salicylate in large doses does have an effect on another aspect of the clotting mechanism, an antihypertensive effect.

Comparison between aspirin preparations and sodium salicylate in various studies reveals some differences of opinion in the conclusions drawn by the authors. However, it would seem that some bleeding from the gastrointestinal tract does indeed take place.

Grossman et al. reported that sodium salicylate (aspirin) and aspirin all gave a significant increase of blood in the stools as compared to the controls. This was determined using the radioactive-labeled red blood cell technique (Ref. 8). Stubbe, Petersen and van Heunen after studying 130 patients found that there was much less blood found in the stools when using sodium salicylate, aspirin, and calcium aspirin (Ref. 9). Scott et al. in 1961 also reported decreased bleeding with sodium salicylate as compared to aspirin (Ref. 10).

Leonards and Levy (Ref. 11) have shown that 255 mg sodium salicylate
children to under 6 years old, oral dosage is 243.8 mg every 4 hours while symptoms persist not to exceed 1,219 mg in 24 hours for not more than 5 days. Children 2 to under 4 years old, oral dosage is 162.5 mg every 4 hours while symptoms persist not to exceed 812.5 mg in 24 hours for not more than 5 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

(ii) For products containing more than 325 mg but not more than 421 mg per dosage unit. Adult oral dosage is more than 421 mg but not more than 970 mg initially, followed by more than 842 mg every 4 hours while symptoms persist not to exceed 3,880 mg in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(iii) For products containing more than 421 mg but not more than 485 mg per dosage unit. Adult oral dosage is more than 485 mg but more than 1,000 mg initially, followed by more than 485 mg but not more than 500 mg every 3 hours or 970 mg every 6 hours while symptoms persist not to exceed 4,000 mg in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(iv) For products containing more than 485 mg but not more than 580 mg per dosage unit. Adult oral dosage is more than 580 mg but not more than 1,000 mg initially, followed by more than 580 mg but not more than 500 mg every 4 hours while symptoms persist not to exceed 5,000 mg in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(v) For products containing more than 580 mg but not more than 650 mg per dosage unit. Adult oral dosage is more than 650 mg but not more than 1,000 mg initially, followed by more than 650 mg but not more than 500 mg every 4 hours while symptoms persist not to exceed 6,000 mg in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(d) Labeling. The Panel recommends the Category I labeling for analgesics as shown on page 35421. In addition, the Panel recommends the following specific labeling:

(i) Warning. "Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician."

(ii) For products containing 0.2 mg or more of sodium per dosage unit. The labeling of the product contains the sodium content per dosage unit and is replaced as indicated if it is 0.2 mg or more.

(iii) For products containing more than 5 mg (125 mg) sodium in the maximum recommended daily dosage. Warning: Do not take this product if you are on a sodium restricted diet except under the advice and supervision of a physician.

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 25 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 25 mg sodium salicylate per dosage unit."

(b) Products containing sodium salicylate in a dosage form other than the standard sodium salicylate dosage unit. While the Panel recommends that products contain only 25 mg sodium salicylate per dosage unit, if the Food and Drug Administration is unable to implement this recommendation, the Panel recommends that products containing an amount of sodium salicylate other than 25 mg in any dosage form per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of X mg sodium salicylate per dosage unit compared to the established standard dosage of 25 mg sodium salicylate per dosage unit."

(c) The actual amount "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

REFERENCES


PROPOSED RULES


a. Categories of analgesics

1. CATEGORY I CONDITIONS UNLESS WHICH ANALGESIC AGENTS ARE NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE OR ARE MISBRANDED

2. CATEGORY II CONDITIONS UNLESS WHICH ANALGESIC AGENTS ARE NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE OR ARE MISBRANDED

b. Analgesics

1. Acetaminophen

2. Codeine

3. Caffeine as a single active ingredient

4. Other analgesics

1. Proposed categories

a. Category I labeling

b. Category II labeling

2. Warning statements

a. Adults

b. Children under 12 years

c. Children under 6 months

d. Children under 12 years with asthma

3. Safety studies

1. Acetaminophen

2. Codeine

3. Caffeine as a single active ingredient

4. Other analgesics

1. Toxicology

2. Metabolism

3. Pharmacology

4. Therapeutic use

5. Adverse effects

6. Drug interactions

7. Pregnancy

8. Nursing mothers

9. Children

10. Effectiveness

11. Safety

12. Misbranding

13. Claims for efficacy

14. Claims for safety

15. Claims for compliance

16. Claims for identity

17. Claims for therapeutic use

18. Claims for adverse effects

19. Claims for drug interactions

20. Claims for pregnancy

21. Claims for nursing mothers

22. Claims for children

23. Claims for effectiveness

24. Claims for safety

25. Claims for misbranding

26. Claims for therapeutic use

27. Claims for adverse effects

28. Claims for drug interactions

29. Claims for pregnancy

30. Claims for nursing mothers

31. Claims for children

32. Claims for effectiveness

33. Claims for safety

34. Claims for misbranding

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178. Claims for misbranding

179. Claims for therapeutic use

180. Claims for adverse effects

181. Claims for drug interactions

182. Claims for pregnancy

183. Claims for nursing mothers

184. Claims for children

185. Claims for effectiveness

186. Claims for safety

187. Claims for misbranding

188. Claims for therapeutic use

189. Claims for adverse effects
b. Codeine preparations (codeine, codeine phosphate, codeine sulfate). The Panel agrees with this limitation on OTC sale. The Panel notes that the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Anticholinergic Drug Products, in their report published in the FEDERAL REGISTER of September 9, 1976 (41 FR 38312), found codeine suitable for OTC use as an analgesic. The Panel notes that there were no submissions of data provided to the Panel, nor was the suggestion made through any other source, that codeine as an analgesic dose be considered for OTC use.

(1) Effectiveness. In a collaborative study, cited by Eddy et al. (Ref. 1), the oral effectiveness of codeine, aspirin and other analgesics was compared in the treatment of postoperative pain at several U.S. Veterans Administration hospitals (Ref. 1). The drugs were administered when postoperative pain began to subside so that parenteral medication was no longer needed. Oral doses of 30 and 60 mg codeine were compared with 500 and 800 mg aspirin. The studies showed the presence of codeine to be approximately 10 times that of aspirin. These results indicate that the effectiveness of 30-60 mg codeine as an analgesic would be approximately comparable to the recommended analgesic dosage range of 325 to 650 mg aspirin. At the doses permitted to be sold OTC, codeine is ineffective as an analgesic.

(2) Safety. The Panel concludes that codeine is not safe for use as an OTC analgesic.

Codeine is one of the opium alkaloids. It was isolated from opium in 1832 (Ref. 3). It is listed and described in virtually every monograph of drugs and details need not be reiterated here.

The AMA Drug Evaluations (Ref. 4) state, "adverse reactions to antitussive doses of narcotics occur infrequently when compared with those usually given for analgesia" and "dependence liability of codeine is less than with morphine or meperidine, and physical dependence occurs only rarely from its use, as an oral analgesic; however, the abuse of the drug, particularly in the form of cough syrup, is not uncommon."

Codeine as a single ingredient regardless of route of administration is codeine classified as a Schedule II prescription (high potential for abuse). When combined with other active medicinal ingredients or as an analgesic-antipyretic drug and OTC marketing is permitted. While the Panel does not believe that codeine has a high potential for the development of dependence, serious safety considerations of abuse have caused the severe marketing restrictions now placed upon it.

(3) Evaluation. The Panel finds that codeine is an effective analgesic drug at the doses restricted to prescription use and at the doses permitted to be sold OTC it is ineffective as an analgesic. However, because of the known abuse and potential for dependence of this ingredient leading to severe restrictions under the Federal Controlled Substances Act, the Panel concludes codeine is not safe for OTC use as an analgesic and should continue to be restricted to prescription use only. For these reasons, the Panel recommends that codeine's availability for analgesic use continue to be restricted to prescription use only.

References


(5) The Panel concludes that there were no studies of data provided to the Panel, nor was the suggestion made through any other source, that codeine as an analgesic dose be considered for OTC use.

(6) The Panel concludes that codeine is not safe for use as an OTC analgesic.

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The Panel concludes that there were no studies of data provided to the Panel, nor was the suggestion made through any other source, that codeine as an analgesic dose be considered for OTC use.


tion as an analgesic, and even the manufacturer who previously marketed the ingredient could find no data to demonstrate any effect, the Panel concludes that although it may be possible to determine that the effects of the ingredient are not safe for use as an OTC analgesic, and even the manufacturer could find no data to demonstrate any effect, the Panel concludes that although it may be possible to determine that the effects of the ingredient are not safe for use as an OTC analgesic because of the organic binding of iodine by the human thyroid and that the effects of the drug on the thyroid are wholly due to the iodide liberated shortly after ingestion.

(3) Evaluation. The Panel finds that iodopyrine is not safe for OTC use because of the significantly high availability of iodide following oral administration and increased likelihood of iodism. Accordingly, the Panel concludes that the risks from use of iodopyrine outweigh any possible benefit and classifies the ingredient not safe for use as an OTC analgesic.

REFERENCES

(2) OTC Volume 8023.
(3) OTC Volume 8031.

Iodopyrine as a Cause of Goitre,

The Panel concludes that phenacetin is an effective OTC analgesic but not safe for OTC use because of the high potential for abuse, the high potential for harm to the kidney and the possibility of hemolytic anemia and methemoglobinemia resulting from abuse and the lack of evidence of potential benefits of the drug. The benefit to risk ratio of phenacetin compounds compares unfavorably with other single agents and combination analgesic preparations available to target populations.

(1) Effectiveness. The nonnalcy late phenacetin was first synthesized in 1887 (Ref. 1). It was introduced as a therapeutic agent before controlled clinical trial was conducted. It was first used as an antipyretic and then as an analgesic. Its use has been widespread for over 80 years. In contrast to the salicylates, this drug has no anti-inflammatory activity and role as an analgesic and therefore is mostly used for the relief of "ordinary aches and pains." (Ref. 1). However, Mandel and Davison (Ref. 1) stated:

Psychologic effects of acetophenetidin (phenacetin) are more pronounced than from aspirin. Relaxation, drowsiness, and diminution in psychic activity has been observed. It is not causing depression in many cases, but rather is causing alertness. It is also leading to slight incoordination, attention, and retention are slightly impaired; restlessness is allayed, and anxiety is diminished. There is no euphoria. It is possible that these effects of acetophenetidin, coupled with the pain-threshold-raising action, are responsible for the popularity of the drug in many home remedies, especially when tension or anxiety is dominant.

Lauritzen and Pearson compared placebo, 600 mg aspirin, 600 mg phenacetin and 600 mg methamoglobinemia in patients with postpartum pain (Ref. 2). They found that acetaminophen and aspirin have a comparable and relative relief of this effect was superior to that of placebo. Phenacetin, although it had a greater analgesic effect than placebo, rated well behind the other two in analgesic activity.

Moertel et al. found that in patients suffering from pain due to cancer, 650 mg phenacetin relieved pain in 49 percent of the patients as compared to 36 percent of the patients receiving aspirin (Ref. 3). In their rating system (drugs rated 1 to 10 by each patient), phenacetin ranked below aspirin and mafenamic acid with all three drugs being superior to placebo.

Lasagna, Davis and Pearson, compared phenacetin, acetylsalicylic acid (a metabolite of phenacetin) and placebo in a group of patients with postpartum pain (Ref. 4). The authors concluded that their data showed no overall advantage of phenacetin over aspirin, and they showed that both drugs were superior to placebo for the same order as those of aspirin, but they are careful to mention the "unreliability" of pain threshold measurements (Ref. 1).

(2) Safety. (1) Short-term use. Short-term use of phenacetin at recommended doses for a period of 10 days seldom results in serious toxicity in adults. Even large doses are well-tolerated by adults and fatalities following acute overdose are rare. Complete recoveries have occurred following acute overdoses of as much as 50 to 60 g (about 200 to 300 tablets) (Refs. 5 and 6). However, severe blood disorders such as methemoglobinemia and hemolytic anemia can be induced in infants with only one or two usual doses and can be life-threatening (Refs. 7 and 8). This is because hemoglobin (the oxygen carrying component of the blood) of an infant at birth is twice as sensitive to the effects of phenacetin as that of an adult (Ref. 9). This highly sensitive fetal blood component is almost completely replaced with adult type hemoglobin within the first 4 months of life (Ref. 5). Consequently, ingestion of phenacetin during pregnancy can result in effects on the blood of an unborn child.

A 28-year-old pregnant woman, who for some months had ingested up to 2 tablets daily of an analgesic compound containing 250 mg phenacetin, found that the hospital with methemoglobinemia. The woman gave birth 4 hours later and the infant had methemoglobinemia. The woman died and marked eye-
thrombocytopenia. Iron deficiency anemia persisted for 7 months in the infant (Ref. 10).

(ii) Adverse effects of long-term use. Unlike short-term use of phenacetin, which is relatively safe, long-term use is unsafe and can result in hazardous effects to the urinary tract, blood, gastrointestinal and central nervous systems. Chronic use results in renal damage probably due to the well-documented central nervous system effects of phenacetin (Ref. 11).

Of particular significance and concern to the Panel is theollating at its conclusions on the safety of phenacetin is the evidence associating excessive chronic ingestion of phenacetin—containing analgesics with life-threatening urinary tract and other damage (renal papillary necrosis, nonobstructive interstitial nephritis, calcification), and cancer of the kidney and bladder.

The correlation between excessive intake of analgesic mixtures and kidney damage, first observed in Switzerland in 1963 (Ref. 12), has now been extensively studied. The fact that phenacetin-containing analgesics have been almost universally associated with cases of renal papillary necrosis, a form of kidney disease, throughout the world, has led several countries including Denmark, Sweden, England and Canada, to limit the availability of analgesic preparations containing phenacetin on the self-therapy market.

A thorough review of the literature on the relationship between phenacetin and severe renal disease has been made by the Panel and submitted to outside statistical evaluation. Numerous experts have appeared before the Panel to discuss these findings. In addition, the Panel has collected new information from a variety of sources including kidney dialysis centers and regulatory agencies of other countries (Refs. 13 and 14).

In the opinion of the Panel, the evidence relating phenacetin to severe renal disease now derives from a world body of published reports so numerous and varied in quality and scope that the possibility of coincidental association is negligible and requires that phenacetin be removed from the OTC drug market.

There is a view set forth in material submitted to the Panel that phenacetin should not be singled out as the causative agent in analgesic combination products because other agents in analgesic combinations, such as aspirin or acetaminophen, have been shown to produce kidney damage when used alone in man and animals, whereas phenacetin alone has rarely been shown to produce kidney damage (Ref. 15). The Panel does not agree with this argument because there are now thousands of reported cases of kidney disease associated with the use of phenacetin—containing mixtures, whereas phenacetin alone has been shown to produce more than ten well-documented cases of analgesic-induced kidney disease in the world literature that can be definitively associated with abuse of other single agent products or combination analgesic products not involving phenacetin, even though these products are extensively used throughout the world. The Panel has discussed the adverse effects of aspirin on the kidney elsewhere in this document. (See part III, paragraph B.1.a. (2) (vi) above—Adverse effects on the kidney.)

From the point of view of safety of chronic use of phenacetin, whether it causes kidney disease itself, augments effects of other active ingredients or increases the use of other nephrotoxic agents, it is the Panel's opinion that prolonged excessive ingestion of a drug containing phenacetin will significantly increase the probability of serious kidney disease and premature death. These levels and duration of ingestion, far exceeding those reported in the available data also indicate that phenacetin as a single entity is rare, it could not be expected that renal disease resulting from its use alone would occur or be reported. It should be noted though that at least one case allegedly involving only phenacetin has been reported (Ref. 15). Although only common analgesic products containing phenacetin will significantly increase the probability of serious kidney disease, other nephrotoxic agents, it is the Panel's evidence for a relationship between the use of analgesic-containing products and kidney disease. (See part III, paragraph B.2.d. (2) (ii) below—Evidence for a relationship between phenacetin abuse and kidney disease.)

This conclusion not only supports the assumption of causality but also the conclusion that removal of OTC drug status would be beneficial. Data collected from kidney dialysis units in the U.S. and previous autopsy studies suggest the incidence of analgesic-induced kidney disease to be significantly high to warrant the Panel's action to recommend restriction of this drug from the OTC drug market (Ref. 13).

The Panel further believes that these data provide the same early warning indications seen in other countries just before analgesic-induced kidney disease was diagnosed as a major public health problem. The "lag time" between several initial diagnoses of analgesic-induced kidney disease and the recognition that the problem was widespread is what most concerns the Panel. While there are not large numbers of cases of analgesic-induced kidney disease being presently reported in the U.S., the Panel believes that if the medical community were aware of this problem and looked for this type of kidney disease, the incidence of analgesic-induced kidney disease would in fact be found to be a major public health problem in the U.S.

The following sections provide more detailed examination and documentation of the available data supporting these conclusions.

(a) Central nervous system effects. The central nervous system effects of phenacetin appear to be a major factor in the chronic abuse of analgesic combinations containing this drug. The habituation potential has been noted by several authors (Refs. 17 through 20).

Most chronic phenacetin takers have used the drug for nonanalgesic purposes. This is probably due to its euphoric and stimulant effects. For example, analgesic kidney disease has occurred most often in middle-aged women with migraine syndrome (Refs. 5, 6, 11, 15, and 17 through 20) or in male factory workers who have taken the drug as a stimulant to increase work output. The latter group includes Swiss watch workers (Ref. 11), Huskvarna factory workers (Ref. 12) and workers in the southern part of the U.S. (Ref. 11).

Krumholz, Sheppard and Merlis found fearfulness and depression were more effectively reduced by a phenacetin—containing product than by aspirin, placebo or a mild tranquilizer (Ref. 21).
Eade and Lasagna (Ref. 22) compared the subjective effects of phenacetin and acetaminophen in 20 normal male volunteers. Phenacetin depressed mood, energy and mental activity. It was assessed as a drug with no initial effect on the subjective effects of phenacetin rather than the effect of its metabolite, acetaminophen. This was demonstrated by Prescott et al. (Ref. 24) who studied phenacetin and acetaminophen blood levels and CNS effects resulting from administration of different formulations containing phenacetin. In this study the peak blood levels of phenacetin correlated very well with the appearance of CNS effects while maximum blood levels of acetaminophen were usually achieved at a stage when the CNS effects were diminishing. There are several factors involved in the central nervous system effects of phenacetin. Initially the drug may be taken for pain or for the CNS effect of phenacetin as a “pick-me-up” or stimulant. After prolonged use, however, chronic headache, fatigue and apathy begin to appear (Refs. 5, 19, and 25). Individuals with these symptoms experience temporary relief shortly after taking phenacetin but these symptoms then reappear. Abnormal (epileptiform) activity brain EEG patterns (Ref. 29), and psychic symptoms including instability, disordered volition and acute disturbances may occur (Ref. 23). However, all these effects generally decrease or disappear when phenacetin is discontinued.

Schweingruber found neuropsychiatric symptoms in 28 percent of all phenacetin abusers (Ref. 26).

Murray and coworkers (Ref. 27) found a high incidence of abuse of phenacetin-containing preparations in psychiatric patients. 82 patients (14.40 percent) had taken for psychological rather than physical reasons. 16 of these patients had taken for psychological reasons. This has been shown in studies (Refs. 31, 33, 35, 37, 38, and 41) and large populations (Refs. 12 and 39) when phenacetin is withdrawn; a history of drug intake (the independent variable) should precede the onset of renal symptoms (dependent variable), and a similar lag time should be observed between changes in intake and changes in the degree of renal function in an individual or changes in the incidence of renal disease in a population. Studies that provide data which meet these criteria and provide convincing evidence of a causal relationship between phenacetin ingestion and kidney disease are discussed below.

The town of Huskvarna had a population of 13,000 in 1963. Three thousand of these worked at the Huskvarna Factory which manufactures appliances, guns, small machinery,等. To study the effect of phenacetin-containing products on the incidence of renal disease in a Swedish population, the Swedish government appointed a committee of experts to study the problem. The committee was asked to look into the use of phenacetin-containing products in the town and to make a report on its findings.

The committee found that the use of phenacetin-containing products was widespread in the town. The products were available in a variety of forms, including tablets, capsules, and liquids.

The committee also found that the use of phenacetin-containing products was correlated with the incidence of renal disease. In areas where the use of these products was high, the incidence of renal disease was also high. In areas where the use of these products was low, the incidence of renal disease was also low.

The committee concluded that the use of phenacetin-containing products was a significant factor in the incidence of renal disease. They recommended that the Swedish government take steps to reduce the use of these products and to promote the use of alternative analgesic agents.
The ratio of men to women in the population of patients who received Huskvarna residents was 96 to 190. Diffusive diagnosis of uremia was made on autopsy of 186 patients, 66 (47 percent) of whom were abusers of analgesic drugs. The ratio of men to women was consistent with earlier years (64 men, 22 women) and 45 of the men were Huskvarna workers.

The number of deaths of abusers did not diminish until 1968 which is consistent with the lag time of 6 to 8 years observed by Bergman. In this series 3 deaths due to uremia were reported.

This study showed that while removal of phencetin from the OTC analgesic market did not affect the degree of analgesic abuse, the incidence of kidney damage dropped significantly.

Studies in Huskvarna also provide data which strongly suggest that the high female to male ratio of renal injury in Sweden is due to increased age alone and also because in other detailed studies there has been no correlation between the age of patients, duration of use, or incidence of renal disease and is more likely to have consumed more analgesics which could give a false correlation unless a control group was used which was matched relative to age. This criticism is given by one of the consultant review groups as a major factor in evaluating the dose-response data in Grimmel's study (Ref. 12). While the age factor conceivably could have biased the relationships shown by Grimmel, it is highly unlikely that the correlations were spurious due to the age effect because the magnitude of the changes in drug intake or renal function is much greater than would be expected due to increased age alone and also because in other studies there has been no correlation between the age of patients, duration of use, or incidence of use.

An analysis of the data of Bell and coworkers (Ref. 34) shows no correlation between age (average 57 years, range 33 to 79), duration of use (average 12 years, range 6 to 23 years) and phencetin total dose (average 5.6 kg, range 2.2 to 12.0 kg). The average age of patients in Grimmel's study was 63 years.

Several other researchers have found a correlation between the degree of phencetin intake and probability of serious kidney damage (Refs. 16, 34 and 35). The prospective autopsy study of Burry, de Jersey and Weeden (Ref. 16) provides significant evidence for phencetin involvement in renal papillary necrosis. Pathological diagnosis and degree of analgesic consumption, as determined by questioning the next of kin, were determined independently. In 507 autopsies when other possible reasons for renal papillary necrosis (obstruction, diabetes, and papillary amyloidosis) were excluded, severe papillary necrosis (42

PROPOSED RULES

Incidence of renal dysfunction with ingestion of phencetin

In [percent]

Phencetin—amount ingested—

<table>
<thead>
<tr>
<th>In total population</th>
<th>In group</th>
<th>In group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>14</td>
<td>2.4</td>
</tr>
<tr>
<td>1 to 4 kg</td>
<td>21</td>
<td>2.4</td>
</tr>
<tr>
<td>5 to 9 kg</td>
<td>21</td>
<td>2.4</td>
</tr>
<tr>
<td>10 to 19 kg</td>
<td>14</td>
<td>2.4</td>
</tr>
<tr>
<td>20 to 59 kg</td>
<td>14</td>
<td>2.4</td>
</tr>
</tbody>
</table>

(h) The degree of elevated serum creatinine correlated with the progosis of recovery or death in the patients is summarized in the following table:

Correlation of serum creatinine to patient prognosis

Serum creatinine (milligram percent)

<table>
<thead>
<tr>
<th>Total</th>
<th>Recovery</th>
<th>Unchanged</th>
<th>Deterioration</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 to 2.5</td>
<td>21</td>
<td>21</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>2.6 to 3.5</td>
<td>14</td>
<td>14</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>3.6 to 4.5</td>
<td>14</td>
<td>14</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>4.6 to 5.5</td>
<td>14</td>
<td>14</td>
<td>14</td>
<td>14</td>
</tr>
</tbody>
</table>

In addition to an evaluation by the Panel, several of these studies were also submitted to two consultant review groups (Refs. 51 through 53) for an independent evaluation of the validity of the data and procedures and factors in the experimental design which would support or invalidate the conclusions of the studies. Evaluations of the studies by the two groups were carried out independently.

Based on the studies reviewed, one group concluded that there is an association between the use of phencetin-containing analgesic compounds and kidney disease and that statistically there is an increased incidence of kidney disease in abusers of phencetin compounds compared to nonabusers and decreased renal function in abusers compared to abusers who cease use. This group felt that Grimmel's study of the Huskvarna workers (Ref. 12) provided the strongest evidence for association between phenacetin compounds and nephropathy (Ref. 52).

The second consultant review group concluded that the paper by Waters (Ref. 45) represents the only paper out of the 14 reviewed which does not support a relationship between analgesic consumption and renal damage. The remaining papers all tend to support a relationship between phencetin-containing compounds and renal damage (Ref. 53).

Based on experimental design, the strongest evidence, in their opinion, were the studies by Bell and coworkers, (Ref. 34). Pearson and Wilson (Ref. 41) which rely on the patient as his own control and where improvement in the patient's renal condition occurred once the analgesic abuse was stopped.

A common variable which might bias correlations between the amount of drug used and nephropathy incidence would be the age of the patient. As age increases, a person is more likely to have renal disease and is more likely to have consumed more analgesics which could give a false correlation unless a control group was used which was matched relative to age. This criticism is given by one of the consultant review groups as a major factor in evaluating the dose-response data in Grimmel's study (Ref. 12).

While the age factor conceivably could have biased the relationships shown by Grimmel, it is highly unlikely that the correlations were spurious due to the age effect because the magnitude of the changes in drug intake or renal function is much greater than would be expected due to increased age alone and also because in other studies there has been no correlation between the age of patients, duration of use, or incidence of use.

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cases) correlated with heavy phenacetin abuse (2 to 4 kg total).

This retrospective case-control study indicated that total doses of 4.0 kg would result in a 73 percent probability of renal papillary necrosis (kidney damage). The probability of death in patients with papillary necrosis was 37 percent. This is similar to the findings of Bell, Kerr, Swinney and Yeates, who reported that 23 percent of patients with renal papillary necrosis associated with phenacetin abuse died of renal (knee) failure (Ref. 34). Murray, Lawson and Lenton (Ref. 38) found that total analgesic intake greater than 1 kg resulted in the finding of renal papillary necrosis (kidney damage) in 85 percent of autopsies; 26 percent of these patients died of uremia (uremic blood poisoning) due to kidney failure. Olafsson, Gudmundsson and Brekkjol (Ref. 50) have also shown a correlation between increased intake of phenacetin compounds and decreased renal function.

A change in renal function in individuals following a change in drug intake has been shown in several studies. The effect of substituting acetaminophen for phenacetin in products used by analgesic abusers was studied by Murray, Lawson and Lenton (Ref. 38). The study took advantage of a change in formulation of two popular products among the most commonly abused compounds in Scotland and in which phenacetin was removed and aspirin substituted. Other preparations which retained phenacetin provided a basis for comparing aspirin-phenacetin compounds with preparations containing aspirin only. As seen in other studies, the lag time after removal of phenacetin until changes in the incidence of renal disease (nephropathy) were observed was found to be from 4 to 6 years. Renal function of those who continued to abuse analgesics containing aspirin-only or aspirin with phenacetin as measured by creatinine clearance continued to deteriorate. The study showed that renal function continued to deteriorate even after the completely free phenacetin compounds were abused but the rate of progression was significantly less rapid (4.9 ml/minute/year compared to 12.9 ml/minute/year) for phenacetin compounds.

Furthermore, the incidence of deaths due to uremia was less (3 out of 12 patients) in patients taking nonphenacetin-containing products than the number of deaths in patients taking products containing phenacetin (9 out of 14 patients), and the total number of new cases was reduced.

Bell and coworkers substituted acetaminophen for phenacetin in 5 patients with renal disease (0.5 to 6.0 g acetaminophen daily) and aspirin for phenacetin in 2 patients (0.1 to 1.3 g aspirin daily) with no apparent difference in renal function from that seen in patients with total withdrawal of analgesics (Ref. 34). Evidence of the beneficial effects of removal of phenacetin from the OTC drug market is provided in two other studies which have removed phenacetin from nonprescription use. The total withdrawal of phenacetin compounds from the OTC drug market has resulted in significant decreases of renal disease in Sweden and Denmark.

As a basis of comparison, in Australia and Sweden, studies of patients who attempted public education on the hazards of analgesic abuse but have not restricted nonprescription use of phenacetin compounds, the incidence of analgesic-induced renal disease has not changed appreciably in spite of the widespread awareness of the problem (Ref. 14).

In Sweden, Bengtsson (Ref. 28) reported that following restriction of OTC drug sales in 1961, consumption decreased 10-fold and the incidence of renal disease decreased from 58 percent in 1961 to 25 percent in 1965 and according to Nordenfelt continued in a favorable direction after 1965 (Ref. 39).

In Denmark, it has been reported that the incidence of renal papillary necrosis in all deaths due to renal disease decreased when phenacetin compounds were removed from nonprescription use (Ref. 43).

In Sweden, where nonprescription phenacetin compounds are still available, the deaths due to uremia have not changed during the period from 1966 to 1971. The total number of uremic deaths each year for the period was 73, 71, 69, 70, and 68, respectively (Ref. 14).

Australia has been cited as an example of a country where the removal of phenacetin compounds from the OTC drug market has not modified the incidence of analgesic nephropathy. The Panel finds that statements of this nature are a misrepresentation of the actual facts since phenacetin compounds have never been actually withdrawn from the OTC drug market in Australia. In 1966, phenacetin compounds were withdrawn from the public health list which simply prevents free payment on the National Welfare funds. Phenacetin-containing products are at least as readily available for unlimited self-treatment as they are in the U.S. (Ref. 34). The Panel was unable to find any evidence that the act of excluding phenacetin compounds from free payment on the National Health list or the public education campaign resulted in any change in the ingestion habits of the analgesic abusers or the increasing incidence of analgesic renal disease in Australia.

As briefly mentioned above, the lag time between renal damage and the appearance of kidney effects is relatively long and provides further evidence of a causal relationship between chronic phenacetin intake and analgesic-induced kidney disease. Bell and coworkers noted that in 52 cases of analgesic nephropathy involving patients consuming greater than 2 kg phenacetin total, only 1 of 19 deaths occurred in less than 10 years. Severe renal damage was rarely seen in less than 5 years (Ref. 16).

Wilson (Ref. 41) observed that analgesic kidney disease required a development period in patients consuming 84 percent of patients and more than 10 years in 62 percent of patients. Thus after 10 years of use, one would see only 39 percent of the total number of individuals who ultimately will develop symptoms. This provides an explanation for the continued appearance of analgesic nephropathy for several years after drug intake is stopped.

In 35 patients from Huskvarna who died of uremia the time between initial use and onset of symptoms was several years. Phenacetin was the initial analgesic, and death, however, was quite rapid, usually 1 year or less in 75 percent of patients. Only 2 of 35 patients survived for 4 to 5 years. Abuse of the product containing phenacetin was probably continued in most of these cases.

A few authors have suggested the possibility that high analgesic use is a result of renal disease rather than the cause. It has been suggested that renal pain may be subthreshold and not be recognized except for a better feeling after analgesic use. Because of the long lag time (3 to 10 years) between initial analgesic use and the first indication of renal dysfunction, which has been observed in many different studies, there is little possibility that the statement of this nature is a reasonable explanation in most reported cases. Other authors have provided other valid reasons or data to clearly refute any serious considerations of analgesic-induced renal dysfunction. Burry and others (Ref. 18) refuted the idea that patients take analgesics to allay the pain of kidney infection (pyelonephritis). To his study there was no association between analgesic consumption and pyelonephritis in the absence of papillary necrosis. Furthermore, many cases of papillary necrosis were associated with analgesic abuse in the absence of pyelonephritis.

(2) Mechanism of action producing nephropathy. The difficulty of showing the mechanism by which phenacetin causes nephropathy in animals, even when large amounts of phenacetin are administered over long periods of time, has been a primary factor in the belief of many authorities that no primary agent responsible for analgesic-induced nephropathy. However, this difficulty in showing kidney-disease in animals has also been shown to be a factor of experimental variables such as difference in metabolism between different species, type of diet, water intake, and others.

Clausen (Ref. 46) found rabbits given either 355 mg aspirin or phenacetin orally developed interstitial nephritis (kidney inflammation) with both drugs and an increased susceptibility to kidney infection. Abrahams et al. (Ref. 51) found papillary necrosis (kidney disease) in two rats who received an aspirin-phenacetin-cafleine combination. Renal papillary hemorrhage (kidney bleeding) was noted in rats consuming phenacetin alone and in the aspirin-phenacetin-cafleine-containing product.

Fordham et al. (Ref. 55) administered phenacetin to Sprague-Dawley rats (300 mg for 30 days or 600 mg for 20 days) resulting in physiologic and histologic evidence of renal damage.
dysfunction including papillary necrosis in 3 of 59 rats. Boyd et al. (Refs. 55 and 57) found that hepatic (liver and kidney disease) that occurred in acute toxicity to phenacetin was influenced by diet and mode of administration (intestinal against intragastric). Elsalso and Talantti (Ref. 58) observed interstitial nephritis (kidney inflammation) in 7 of 18 rats given 100 mg/day of phenacetin in food and in 5 of 18 rats given 100 mg/kg by the intravenous route. However, no papillary necrosis (permanent kidney injury) was observed.

Animal studies are useful to study mechanisms of toxicity. However, care must be taken in extrapolating data from animal to man. Furthermore, it must be realized that strain difference is important. Recently Mazze, Cousins and Kosek showed that dose-related methylene blue necrotoxicity in rats varied markedly with strain (Ref. 59). Thus, when studying a toxic effect in animals extreme care must be taken in interpreting whether results are positive or negative.

The primary sites of kidney injury are the papillae and medulla. Papillary necrosis is thought to be vascular in origin, resulting from ischemia. In lay language, this means that the type of kidney disease which occurs is thought to be due to constriction or obstruction of blood vessels in the kidneys.

Kincade-Speer has described early lesions in the efferent vasa recta of rats treated with phenacetin and aspirin/phenacetin/caffeine (Ref. 60). Abraham and Levin have observed platelet deposition in the vasa recta in animals with analgesic abuse can be distinguished from renal papillary necrosis, is the primary lesion observed most often with analgesic abuse (Ref. 63). Koch states that renal papillary necrosis associated with analgesics often consist of multipleler, which are largely from Scandinavia and the United States. In 1953, these reports were largely from Scandinavia and Australia. Prior to 1959, there were only 11 cases reported in Great Britain. The next year Prescott reported 30 cases in northeast Scotland alone (Ref. 68). Four years later in 1970, only 117 total cases had been reported, 89 of which were from Scotland, 28 from England and Wales. There was only one from the London area (Ref. 69). This led to the false conclusion that the problem was confined primarily to Scotland. Between June 1964 and January 1970 Koutsaimanis and de Wardener (Ref. 65) detected 16 cases at a small 200 bed hospital in London. Seven of these patients had been treated in other departments of the hospital before the diagnosis was made. Based on these cases they estimated that the overall incidence of analgesic-induced kidney disease in England and Wales was 500 cases per year. The actual rate of detection, however, was only 5 percent of this number.

The same lag time in recognition of the problem has occurred in Canada. In 1967,
14 years after the first Swiss report, there were only seven cases reported in Canada. In 1968, Koch reported 26 cases of kidney injury in 196,054 cases (0.013 percent) admitted to a general hospital between 1961 to 1966. Fifteen of these cases (58 percent) were analgesic abusers who had taken more than 1 kg phenacetin-containing products. Furthermore, as many as 20 percent of patients with end-stage renal disease in Ontario had been treated at the University of Pennsylvania Hospital, during the period 1969 to 1972, had abused analgesics which was considered the primary cause of renal disease in Canada (Ref. 61) and Europe (Refs. 73 and 74). The signs and symptoms of this group (headache, anemia, hypertension, urinary tract infection and papillary necrosis) also were comparable to previous reports. The authors state that this high rate of detection was not due to a selective population but was simply due to the fact that they were aware of and specifically looked for analgesic kidney disease in these patients. It is significant that the referring physicians did not make the correct diagnosis in any of the 20 cases not in the incidence study. 


tives. Two of the cases had other family members with analgesic kidney disease. The authors conclude that their experience is typical of what would be expected elsewhere and suggest that the prevalence of analgesic kidney disease in the U.S. may be about 7 percent of all end-stage renal patients.

The incidence of renal papillary necrosis in the U.S. and other countries has been estimated by Heptenstall (Ref. 75). These figures summarized in the table below probably represent the minimum incidence and are compared to estimates of the per capita consumption of phenacetin in different countries (Refs. 49 and 50):

<table>
<thead>
<tr>
<th>Incidence of renal papillary necrosis compared to phenacetin consumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries surveyed</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>Australia</td>
</tr>
<tr>
<td>Canada</td>
</tr>
<tr>
<td>Japan</td>
</tr>
<tr>
<td>Northern England</td>
</tr>
<tr>
<td>Netherlands</td>
</tr>
<tr>
<td>Switzerland</td>
</tr>
<tr>
<td>United States (U.S.)</td>
</tr>
</tbody>
</table>

This Panel has requested information on the cases of analgesic kidney diseases that had been detected in several renal dialysis centers. A total of 103 cases of suspected analgesic nephropathy were reported which represented about 1.1 percent of all renal dialysis patients. Only two of these cases were stated to have involved aspirin preparations not containing phenacetin. Five cases were not specified. The remaining 95 cases were stated to have involved phenacetin-containing compounds (Ref. 13).

In a recent report (Ref. 15), analgesic abuse was identified as the primary cause of renal disease in 30 (12.5 percent) of 2,395 chronic hemodialysis patients treated in 91 dialysis centers in California between January 1, 1974 and September 1, 1974. Of 332 deaths in 1974, 17 (5.1 percent) was attributed to abuse of analgesic compounds. A detailed analysis of cases of suspected analgesic kidney disease was supplied by the Minneapolis Regional Kidney Disease Program (Ref. 76). The amounts used (1 to 3 g/day), duration of use (6 to 12 years) and reasons for use (headache, nervous tension) are essentially the same as reports in the literature. The Panel can only conclude that the same lag time in detecting and reporting analgesic-induced kidney disease is now occurring in the U.S. as previously occurred in the United Kingdom and Canada.

(c) Cancer of the urinary tract. During the past few years, several reports have implicated long-term use of phenacetin-containing products with cancer of the renal pelvis (kidney) and urinary bladder. The first report, in 1965, was a retrospective study by Flithunger et al. of 15 of the patients with cancer of the renal pelvis in the Huskvarna Hospital (Ref. 76). All but two had renal papillary necrosis associated with long term analgesic use. Bengston and colleagues (Ref. 77) reported a study of 193 patients with documented nephropathy in which patients were followed for a period of 1 to 11 years (average 5.3 years). During this time, none of the patients developed renal pelvis carcinoma (cancer of the kidney) and another two patients developed cancer of the urinary bladder. No tumors were found in 86 individuals with chronic pyelonephritis (kidney inflammation) who served as a control population of nonanalgesic abusers observed during the same period of time. In a followup study by Angervall et al. (Ref. 18), the average total ingestion of phenacetin (cancer of the kidney) is an infrequent disease in Sweden, the average yearly incidence being only 11 cases per 156,090 inhabitants which is about 10,000 times less than the incidence reported for analgesic abusers. A more recent study by Johansson and coworkers (Ref. 79) was based upon known abusers of phenacetin-containing compounds (37 of 43 women) who had uroepithelial tumors of the renal pelvis (carcinomas) treated at the hospitals throughout Sweden. All tumors were diagnosed during the years 1953 through 1973. Among the patients who took compounds of the same composition but containing varying amounts of the same ingredients, 38 patients, detailed data of drug intake were available. The average total ingestion of phenacetin was estimated to be 0.1 kg, with a mean exposure time of 17 years. Chronic kidney disease had been established in 23 patients for a period of 3 to 18 years before a diagnosis of kidney cancer was made. Forty patients had a history of urinary tract infection. A diagnosis of analgesic-induced papillary necrosis was made in 66 (12.7 percent) of the patients, and another two patients developed cancer of the urinary bladder. No tumors were found in 46 individuals with chronic pyelonephritis (kidney inflammation) who served as a control population of nonanalgesic abusers observed during the same period of time. In two patients, examination was not possible. In the remaining three patients, there were no signs of papillary necrosis, even though these patients were known analgesic abusers. The authors concluded that renal papillary necrosis was a prominent feature, but not essential, for the development of renal pelvic tumors in abusers of phenacetin-containing drugs. The sudden appearance of this relatively rare condition in patients, almost universally associated with analgesic abuse, leaves little doubt that a strong association exists. There are now many case reports available from Sweden, Denmark, Germany, Canada and the U.S. which associate phenacetin abuse with cancer of the kidney (Refs. 80 through 88).

A large number of cases of tumors of the renal epithelium (cancer of the kidney) associated with analgesic abuse have been reported in Germany by Rathart and workers (Ref. 83) and Schabert, Nagel and Leistenschneider.
The studies of Lorenzen and Schwartz (Ref. 89) have summarized a number of cases of transitional cell tumors of the renal pelvis (kidney cancer) in Denmark over a 5-year period.

Their retrospective review of patients with chronic pyelonephritis (kidney inflammation) and abuse of phenacetin, revealed two cases of transitional tumors among 101 patients who abused phenacetin. They conclude that cancer of the kidney should be suspected in patients with renal papillary necrosis (kidney injury) associated with abuse of phenacetin, particularly when hematuria occurs without accompanying pain. Liu, Smith and Rankin have reported one case in Canada (Ref. 81). There is a report of bladder cancer associated with aspirin (Ref. 15) and another report of bladder cancer associated with abuse of phenacetin in one patient in the U.S. (Ref. 81). The patient had never smoked. He worked intermittently for the past 20 years. The tumor was removed from his bladder.

The studies of Lorenzen and Schwartz indicate that abusers of phenacetin have increased incidence of renal carcinomas, while cases of transitional cell tumors have not been reported among aspirin abusers. This difference may be related to the chemical structure of phenacetin and aspirin, or to different pharmacological effects. The studies also suggest that phenacetin may be more nephrotoxic than aspirin, and that the combination of aspirin and phenacetin may be more nephrotoxic than either drug alone.

(c) Additional considerations of benefit to risk consequences of removal of phenacetin from OTC analgesic preparations. The Panel has discussed the evidence showing that OTC analgesic preparations containing phenacetin were subject to abuse and that the chronic misuse of such preparations resulted in a high incidence of life-threatening kidney disease. In addition to its toxic effect on the kidney, phenacetin has also been reported to cause serious blood dyscrasias.

It is thought that the central nervous system effects, such as euphoria and stimulation, are the major factors contributing to phenacetin's abuse potential. The habituation potential of OTC combinations containing phenacetin. The Panel, therefore, concludes that the risks from use of OTC analgesic preparations containing phenacetin were subject to abuse and that the chronic misuse of such preparations resulted in a high incidence of life-threatening kidney disease. In addition to its toxic effect on the kidney, phenacetin has also been reported to cause serious blood dyscrasias.

Additional considerations of bone-marrow effects, thrombocytopenia, occlusive phenomena and the possible occurrence of renal papillary necrosis are involved.

(d) Adverse effects on blood. Phenacetin has been implicated as a cause of hemolytic anemia, decreased red blood cell survival time, enlarged spleen, hemoglobinemia and anemia in patients who were given large amounts of phenacetin. Phenacetin has been shown to decrease red blood cell survival time in rats.

Additional considerations of bone-marrow effects, thrombocytopenia, occlusive phenomena and the possible occurrence of renal papillary necrosis are involved.

The Panel has discussed the evidence showing that OTC analgesic preparations containing phenacetin were subject to abuse and that the chronic misuse of such preparations resulted in a high incidence of life-threatening kidney disease. In addition to its toxic effect on the kidney, phenacetin has also been reported to cause serious blood dyscrasias.

The Panel recommends that OTC analgesic preparations containing phenacetin be removed from the market. The Panel also recommends that alternative preparations be developed and marketed. The Panel further recommends that the FDA consider removing other analgesics from the market that are associated with serious adverse effects.

In cases where phenacetin compounds have been substituted by nonphenacetin containing compounds, the renal consequences of abuse are less severe. Substitution has resulted in decreased proportion of existing nephropathy or decreased incidence of new cases.

Some authors have opposed the recommendation to remove phenacetin from OTC analgesic preparations. They argue that phenacetin is less nephrotoxic than aspirin and that the combination of aspirin and phenacetin is less nephrotoxic than either drug alone. However, the studies of Lorenzen and Schwartz indicate that abusers of phenacetin have increased incidence of renal carcinomas, while cases of transitional cell tumors have not been reported among aspirin abusers. This difference may be related to the chemical structure of phenacetin and aspirin, or to different pharmacological effects. The studies also suggest that phenacetin may be more nephrotoxic than aspirin, and that the combination of aspirin and phenacetin may be more nephrotoxic than either drug alone.

The direct effects of phenacetin, including production of methemoglobinemia and hemolytic anemia may interact with direct hemolytic effects of aspirin and aspirin-phenacetin combinations. These combined effects related to gastrointestinal bleeding.

Unlike other analgesics, such as aspirin and acetaminophen, phenacetin is mainly available in OTC combinations, whereas aspirin and acetaminophen are available in single ingredient products as well as in combinations. These phenacetin combinations are less effective than other analgesics as a separate combination. The general public would not be deprived of a useful agent for which alternative drugs are not available.

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ulcer symptoms and renal papillary necrosis. Large amounts of phenacetin-containing 
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aspirin in eastern Australia has been attributed to the 
tory of peptic ulcer.

Rapaport, White and Ran- 
gesic nephropathy had gastric or duo-
ral ulcers. Rapaport, White and Ran-

of symptoms in gastric damage in- 
cluding gastrointestinal hemorrhage, a 
history of gastrectomy and peptic ulcer. 

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reported that 42 of 23 patients with anal-
gesic nephropathy had gastric or duo-

eras, Rapaport, White and Ran-

Ingestion of large amounts of the compound, which had been taken for 
ience in renal function and they all died shortly 

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e. Quinine. The Panel concludes that quinine is an effective analgesic but that it is not safe for OTC use.

(1) Effectiveness. The analgesic and antipyretic properties of quinine have been recognized but considered inferior to febrile illnesses, but was relatively ineffective in fevers due to diseases other than malaria. However, when used as an antipyretic in febrile illnesses it was noted that pain and discomfort were relieved and thus the analgesic action was discovered. Modern use of quinine for analgesia and antipyresis is based on long experience of controlled studies. In the first edition of the Pharmacological Basis of Therapeutics, published in 1941 (Ref. 1), Goodman and Gilman stated:

"Quinine in oral doses of 0.3 to 6 gr is employed for the relief of headache, myalgia, arthralgia, neuralgia, etc., and for reducing fever. It has, therefore, the same general field of usefulness as aspirin, but with what is less effective. Repeated medication may cause unpleasant symptoms of cinchonism." ...

An almost identical statement is made in the fourth edition of Goodman and Gilman’s text published in 1970, indicating no change in the status of quinine for treatment of pain and fever during the last 30 years.

Apparently, there has never been complete agreement as to the dose. For instance in the eighth and last edition of his text, Sollmann states that the clinical antipyretic dose of quinine is 0.05 to 0.2 gr, 1.0 to 3.0 gr may be used for pain in colds, headaches and neuralgias (Ref. 2). Further evidence that the antipyretic analgesic action of quinine is still recognized but considered inferior to other drugs is found in the following quotation from the AMA Drug Evaluations (Ref. 3): “Quinine has been used as an antipyretic analgesic, however, more effective drugs are currently available for these purposes.” No controlled or uncontrolled effectiveness studies on either antipyretic or analgesic activity of quinine were found in an industry submission which included quinine in combination with other ingredients as a cold preparation. It may be noted that the doses recommended by Sollmann for pain are lower than those recommended by Goodman and Gilman and therefore, modern controlled clinical trials would be necessary to establish the effective analgesic and antipyretic doses for quinine.

The use of quinine relief of nocturnal leg cramps was introduced in the 1940’s when Moss and Herman (Ref. 4) and Gootnick (Ref. 5) reported on the basis of uncontrolled studies that quinine in the doses of 3 to 6 gr (200 to 335 mg) abolished the spasms. Nicholson and Falk (Ref. 6) reported relief following quinine treatment in about 2/3 of 35 young men and women who had acupuncture points for pain. Rawls (Ref. 7) found a combination of quinine and aminophylline superior to quinine alone. The Medical Letter (Ref. 8), while stating that controlled clinical trials evaluating quinine’s effectiveness for nocturnal or recumbency cramps were needed, did recommend using quinine for nocturnal leg cramps pending the outcome of trials to establish efficacy and dosage. These uncontrolled studies suggest that quinine may be useful for leg cramps but the lack of controlled studies and comments by authors that patients may remain free of cramps for indefinite periods following quinine therapy suggest that trials of quinine against placebo are in order. In addition, the recommended dosage varies widely, from 200 mg at bedtime to 5 gr (335 mg) 4 times daily as recommended by Perchuk (Ref. 9) who also suggests that the drug should be used only when everything else has failed. Until controlled studies show that a dose of not more than 335 mg daily is safe and useful for relief of nocturnal leg cramps the drug should not be available for OTC use for treatment of nocturnal leg cramps.

(2) Safety. The Panel concludes that quinine is not a safe analgesic for OTC use when taken in the recommended dosage.

Although quinine has demonstrated analgesic, antipyretic and muscle relaxant actions, its numerous toxic effects give it an unfavorable benefit to risk ratio for these purposes. The high dosage recommended by some for relief of nocturnal leg cramps should be dispensed with. The toxicity of quinine has been the subject of innumerable reports and is well summarized in many modern text books of pharmacology and toxicology. The toxicity of quinidine and its stereoisomer quinine is well summarized by Gleason et al. (Ref. 10), and in the fourth edition of Goodman and Gilman, Rolfe (Ref. 11) states that the fatal oral dose of quinine for adults is approximately 8.0 g. When quinine is repeatedly given at full doses, e.g. 0.3 to 0.8 g with a total daily dose of not more than 2.0 g, a group of symptoms known as cinchonism may appear. These include tinnitus, headache, nausea and visual disturbances. The body systems which may be involved include gastrointestinal, nervous and cardiovascular systems, and the skin. Actions on the gastrointestinal tract are evidenced by nausea, vomiting, abdominal pain and diarrhea. Damage to the nervous system is manifested by hypotension, weakness, shock, coma and death. Renal damage has been reported, as has acute hemolytic anemia and hypoprothrombinemia. Thrombocytopenia purpura (Refs. 12 and 13) has been reported in young people taking quinine for nocturnal leg cramps. Some cases of agranulocytosis have been reported following quinine ingestion. Idiosyncrasy to quinine is a frequent subject of medical reports.

(3) Evaluation. The Panel concludes that because the toxic effects described above may occur following repeated administration that the risks from use outweigh any benefit and therefore classifies quinine not safe for use as an OTC analgesic.

REFERENCES


(5) Gootnick, A., “Night Cramps and Quinine,” Archives of Internal Medicine, 71:555-559, 1943.


CATEGORY II LABELING

The Panel has examined the submitted labeling claims for analogues alone and for combination products with nonanalgesic ingredients and has placed certain claims into Category II. These Category II claims have been further divided by the Panel into those labeling claims that are unsupported by scientific data or by sound theoretical reasoning, claims containing modifying adjectives associating pain with illnesses, and unacceptable claims related to product performance as follows:

a. Certain labeling claims that are unsupported by scientific data and in some instances by sound theoretical reasoning.

...
claims are "jumpy nerves", "tirefulness", "under the weather", etc.

(2) Claims requiring diagnosis and care of a physician. These claims are not amenable to self-diagnosis and self-treatment and require medical diagnosis and supervision for safe use. Examples of such claims are "bursitis", "arthritis", "rheumatism", "gout", "swollen tissues", "functional menstrual pain", etc. In addition, there are claims for conditions which are appropriately treated by mild analgesics but presuppose that the patient is under the care of a physician or dentist. Such claims include "pain following dental work", "inoculation" or "vaccination". "Pain of teeth" is also included here because the use of OTC drugs in children under 2 years of age requires the advice and supervision of a physician.

b. Modifying adjectives associating pain with illnesses. In its discussion of the inclusion or disease rather than use information on the labeling of OTC drug products, the Panel concluded that the indications for use should be simply and clearly stated, should include the statement that the establishment is for temporary relief of symptoms applicable to the ingredient(s) in the product, and that the implication that these drugs are to be used for the treatment of diseases should be avoided. Further information under the headings of "Claims," "Claims that the preparation is for the temporary relief of symptoms associated with the physical condition and/or disease". In addition, the Panel feels that the use of only a partial list of some claims such as "low back pain", "rheumatism", etc. may effectively ameliorate the pain associated with the physical condition and/or disease.

In addition, the Panel feels that the use of only a partial list of some claims such as "low back pain", "rheumatism", etc. may effectively ameliorate the pain associated with the physical condition and/or disease.


(3) Calcium carbamazepine: "pains due to sinusitis", "mild pains of arthritis", "minor aches and pains of rheumatism"

(4) Choline salicylate: "menstruation", "menstrual cramps", "neuritis", "pains of arthritis", "pains of rheumatism"

(5) Magnesium salicylate: "pain of menstrual period", "pains of sciatica", "dental pain", "overexertion", "fatigue", "minor aches and pains of arthritis", "minor aches and pains of arthritis", "minor aches and pains of arthritis", "minor muscle aches", "aches and pains due to fatigue"

(6) Sodium salicylate: "minor muscle pains and aches", "arthritis", "rheumatism"

(7) Salsalate (salicylsalicylic acid): "minor pains, swelling, stiffness of arthritis", "minor pain, swelling, stiffness of osteoarthritis", "minor pain, swelling, stiffness of osteoarthritis", "aspirin for relief of arthritis"

(2) Unacceptable claims related to product performance. Terms such as "faster", "starts working", "special pain relieving formula", "so strong and so gentle", "so gentle can be taken on an empty stomach", "acts 5 times faster than aspirin", "reaches peak action 12 times faster than aspirin", "long-lasting pain reliever", "enhanced relief of pain", etc., are in the opinion of the Panel confusing and misleading to the consumer unless they can be substantiated and clearly supported by scientific data.

Terms were submitted for buffered and highly buffered aspirin products that allow to the beneficial performance of these products as a result of the antacids or buffering agents they contain. The Panel has examined these terms which in essence assert that these products are more rapidly absorbed into the blood and that they consequently prevent the adverse reactions to the stomach that may be caused by plain (unbuffered) aspirin products.

The Panel concludes that until adequate data are available, labeling terms pertaining to product performance for buffered and highly buffered aspirin should be restricted to the following: 'Faster to the bloodstream than plain aspirin' and "providing relief that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label". These terms were discussed labeling elsewhere in this document. (See part VI, paragraph B.I.D., below—Labeling claims for marketed products containing analgesics combined with an antacid or buffering ingredient.) The Panel further concludes that any other statement(s) are classified as Category II.

3. CATEGORY III CONDITIONS FOR WHICH THE AVAILABLE DATA ARE INSUFFICIENT TO PERMIT FINAL CLASSIFICATION AT THIS TIME.

CATEGORY III ACTIVE INGREDIENTS

The Panel has concluded that the available data are insufficient to determine effectiveness as an OTC analgesic in the recommended dosage of 365 to 730 mg every 4 hours while symptoms persist not to exceed 4,380 mg in 24 hours for not more than 10 days.

(1) In general. Aluminum aspirin (aluminum acetylsalicylate) is chemically very similar to aspirin. The aluminum salt has been used because of greater palatability with less astringency to the taste. It is claimed to have no acetic odor. It has been reported that because of its greater stability, it is compatible with more drugs than is aspirin (Ref. 1). However, the presence of the aluminum makes the salt practically insoluble in water and probably accounts for the greatly decreased dissolution, and subsequent slower absorption when compared to aspirin, possibly rendering this ingredient ineffective. Several studies relating to absorption, point out that aluminum aspirin is poorly absorbed from the gastrointestinal tract (Refs. 1, 2, and 3). It is claimed that this drug is absorbed somewhat more slowly than aspirin. It apparently produces a satisfactory degree of analgesia similar to that produced by aspirin (Ref. 4).

Lewy and Sahli (Ref. 2) compared the absorption of aluminum aspirin and aspirin in man. They concluded that "acetylsalicylic acid (aspirin) - absorp-
tion from orally administered aluminum acetylsalicylate (aluminum aspirin) was found to be less rapid than that from aspirin probably due to the very slow dissolution of the aluminum salt in gastrointestinal fluids. This may be due to its water insolubility. They suggested that this drug be carefully evaluated in humans. They compared six sugar coated analgesic tablets. The ingredients were: sulfapyridine, aminopyrine, phenacetin, bucetin, N-acetyl-p-aminophenol, salicylamide. The ingredients were: sulfasalicylate and aluminum aspirin. They concluded that aluminum aspirin release rate was slower than that of any of the others and that aluminum aspirin should be required for aluminum aspirin.

However, one submission cites two bioavailability studies which are pertinent; the first, an oral study in rabbits and the second, a study of absorption by man of aluminum aspirin from suppositories. They concluded that aluminum aspirin release rate was slower than that of any of the others and that aluminum aspirin should be required for aluminum aspirin.

3 Proposed dosage. Adult oral dosage is 365 to 730 mg every 4 hours while symptoms persist, not to exceed 4,300 mg in 24 hours for more than 10 days. Children 11 to under 12 years oral dosage is 365 mg every 4 hours while symptoms persist not to exceed 1,525 mg in 24 hours for more than 5 days. Children 9 to under 12 years oral dosage is 305 mg every 4 hours while symptoms persist not to exceed 1,075 mg in 24 hours for more than 5 days. Children 7 to under 10 years oral dosage is 215 mg every 4 hours while symptoms persist not to exceed 1,075 mg in 24 hours for more than 5 days. Children 4 to under 6 years oral dosage is 180 mg every 4 hours while symptoms persist not to exceed 900 mg in 24 hours for more than 5 days. Children 2 to under 4 years oral dosage is 120 mg every 4 hours while symptoms persist not to exceed 600 mg in 24 hours for more than 5 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

4 Labeling. The Panel recommends the Category I labeling for analgesic active ingredients. (See part III, paragraph B.1.b., below—Category I Labeling.) The Panel recommends the following specific labeling:

(a) Warnings. (a) This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician.

(b) Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician.

(c) For oral product formulations to be chewed before swallowing: "Do not take this product for at least 7 days after tonsillectomy or oral surgery except under the advice and supervision of a physician."

(d) Analytic equivalence value. In the previous discussion on "standard analgesic strength" dosage forms the Panel made clear the need to indicate the quantity of aluminum aspirin per tablet, teaspoon or other dosage units as well as the quantity by which a particular product contains or differs per dosage unit from the established standard of 325 mg (5 gr) aspirin. (See part II, paragraph E, above—Standard Dosage Unit ad Analytic Equivalence Value.)

The Panel recommends that products containing aluminum aspirin be clearly labeled on the principal display panel; "Equivalent to X mg (X gr) per dosage unit of the established standard of 325 mg (5 gr) aspirin per dosage unit". The actual amount of "X" of equivalent analgesic effectiveness for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule. For example, a product containing 365 mg aluminum aspirin per tablet (dosage unit) shall be labeled, "Equivalent to 325 mg (5 gr) per tablet of the established standard of 325 mg (5 gr) aspirin per tablet".

5 Evaluation. Data to demonstrate effectiveness will be required in accordance with the standard of evaluation which is set forth below for analgesic drugs. Bioavailability studies of aluminum aspirin in man must show comparable blood levels of salicylates to these following administration of a standard aspirin as detailed below and/or clinical evaluation of efficacy. (See Part III, paragraph C, below—Data Required for Evaluation.)

REFERENCES


(4) OTC Volume 030037.

(5) Watrous, R. M., "Clinical Trial of 21/2 Grain Aluminum Aspirin Dulcet Tablets," draft of unpublished paper is included in OTC Volume 030037.

(6) Harris, S., draft of unpublished paper is included in OTC Volume 030037.

b. Antipyrine. The Panel concludes that there are insufficent data to determine the safety and effectiveness of antipyrine as an OTC analgesic when, as recommended, the dosage is limited to a single 975 mg dose in 24 hours while symptoms persist for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(1) Effectiveness. Antipyrine was synthesized in 1895 by Knorr (Ref. 1) after a 40-year search to find a safer and more effective antipretolic than quinine. When its use as an antipyretic was declining, antipyrine continued to be used for its analgesic effectiveness which was first discovered in 1886. In the last 50 years, however, for reasons not entirely clear, antipyrine has declined in use as an analgesic. This is thought to be due to the increased use of the salicylates and not because of a demonstrated lesser effectiveness or safety of antipyrine (Ref. 1). In Europe, where it is much more commonly used than in the U.S., it is found mainly in combination with other products. Therefore, there are insufficient data on the safety and effectiveness of...
antipyrine as a single ingredient. The world consumption is estimated at 900 tons annually (Ref. 2).

Though antipyrine has been generally recognized since 1888 as an effective analgesic, no well-controlled studies of its analgesic effectiveness in the clinical situation have been reported. As reviewed by Brodie and Axelrod (Ref. 3), there are numerous reports of experimental tests of the pain threshold in man, using mechanical, thermal, or electrical stimulation, described only moderate or, in many cases, inconsistently ineffective adverse effects of antipyrine in elevating the pain threshold. Similar tests designed for use in animals yielded significantly positive results only when excessive doses of antipyrine were used. These questionable results are undoubtedly attributable to the inadequacy of such methods in measuring parameters related to the true clinical effectiveness of analgesic action.

The manufacturer of the only product submitted containing antipyrine cites in his labeling and in his submission a study by Brodie and Axelrod (Ref. 3) who state that "the only adverse reaction of antipyrine is slow, so that plasma levels after a single therapeutic dose decline only 1 to 12 percent per hour, resulting in plasma levels of 15 hours or more. This is considerably slower than the elimination of phenacetin or N-acetyl-p-aminophenol." Thus, from this study it appears that the metabolism of antipyrine is slow and that one would expect it to provide longer antipyretic and analgesic action.

The panel finds that antipyrine may be an effective analgesic, but because of a lack of clinical studies, its effectiveness compared to aspirin cannot be established at this time.

The panel believes that in view of these uncertainties, appropriate comparative clinical studies should be completed before antipyrine can be considered generally recognized as effective. (See part III, paragraph C. below—Data Required for Evaluation.)

(2) Safety. The panel concludes that there is sufficient data to determine the safety of antipyrine when taken in the recommended dose and dosage schedule for the relief of occasional minor aches and pains, and headache. Because of safety considerations discussed below, the panel has made no recommendations for the use of antipyrine in children under 12 years of age.

Antipyrine has been said to have fewer side effects than aspirin. It is said to not interfere with the blood clotting mechanism as does aspirin. There is no evidence that antipyrine is hepatotoxic as is acetaminophen in large doses. However, it should be pointed out that the side effect liability of this compound is not as well understood as that of aspirin because of its limited use in the US.

Unlike antipyrine, acetaminophen has not been established as a significant cause of agranulocytosis. According to Greenberg's extensively documented review (Ref. 1), only two cases of agranulocytosis had been reported to be due to antipyrine prior to 1950, and there was doubt that antipyrine was the specific etiologic agent even in these two cases. Since that time no further cases have come to light.

Though antipyrine is closely related chemically to amino-pyrene it is metabolized differently (Refs. 3 and 4), which undoubtedly accounts for the different propensities of the two drugs to produce agranulocytosis. Of 394 cases of antipyrine poisoning, reported prior to 1950 and reviewed by Greenberg (Ref. 1), 77 percent were of an allergic nature and 18 percent nonallergic (5 percent undetermined). Of these 394 cases, 23 were reported as terminating in death, all of which were in the groups showing reactions of the nonallergic or undetermined nature. In none of the fatal cases could the contributory role of antipyrine be fully assessed because the patients were suffering from serious diseases, such as typhoid, typhus, pneumonia, purpura, fever and brain tumors, and therefore were taking or had taken other drugs, or had taken obvious overdoses of antipyrine. It is noteworthy that all of the "fatal cases" described (Ref. 13) were reported between 1855 and 1913. There is serious doubt of a definite causal relation between these fatalities and antipyrine, except in one case of a murder by the use of 4 drachms (16 g) of the drug. Subsequently, in Greenberg's 1950 review (Ref. 1), no fatalities definitely attributable to antipyrine have been reported.

The panel reviewed numerous case reports of adverse reactions in which antipyrine was suspected of playing a causative role. These case reports are summarized in the following table:

### Antipyrine Case Reports

#### Case Report I (Ref. 2):
- **Author:** Brocq (1949).
- **Medication:** Antipyrine.
- **Patient description:** Three white females.
- **Signs and symptoms:** Fixed pigmented erythema.
- **Antipyrine test dose:** +
- **Outcome:** +

#### Case Report II (Ref. 6):
- **Author:** Applan (1949).
- **Medication:** Antipyrine ointment.
- **Patient description:**
- **Signs and symptoms:** Erythema reap- pears after local application of antipyrine ointment.
- **Antipyrine test dose:** +
- **Other drug test dose:** +
- **Outcome:** +

#### Case Report III (Ref. 7):
- **Authors:** Hitchie & Spiller (1949).
- **Medication:** Antipyrine-containing cold medicine (2 tablets).
- **Patient description:** One white male.
- **Signs and symptoms:** Large, dusky erythemas and scaly plaques scattered over shoulders, arms and thighs.
- **Antipyrine test dose:** +
- **Outcome:** +

#### Case Report IV (Ref. 8):
- **Authors:** McGrolloch & Zellman (1951).
- **Medication:** Antipyrine-containing cold preparation.
- **Patient description:** One black male.
- **Signs and symptoms:** Numerous erythematous and hyperpigmented welldemarcated plaques, some of which contained central bullae. They were located in the face, neck, chest, back, buttocks, abdomen, upper and lower extremities, scrotum, and plane penis.
- **Antipyrine test dose:** +
- **Other drug test dose:** +
- **Outcome:** Hospitalization for more than 7 days.

#### Case Report V (Ref. 9):
- **Authors:** Goldman & Rockwell (1951).
- **Medication:** Antipyrine-containing cold preparation.
- **Patient description:** One black male.
- **Signs and symptoms:** 7 days history of sore lips and penis, fever and chills, loss of appetite and headache. The lips and penis were edematous and denuded with crusting and bleeding.
- **Antipyrine test dose:** +
- **Other drug test dose:** +
- **Outcome:** Hospitalization for more than 19 days.

#### Case Report VI (Ref. 10):
- **Authors:** Kennedy et al. (1957).
- **Medication:** Antipyrine-containing cold preparation.
- **Patient description:** 21 black males and 7 black females.
- **Signs and symptoms:** Pruritus, burning of the mouth and throat, sometimes choking sensation and sometimes pain referred to the genito-urinary system. The mucosa of the mouth and genitalia was involved and large, pigmented bullous lesions, of the type seen in erythema multiforme, appeared over the body, particularly on the neck, thighs and genitalia. Patients were acutely ill and had fever over 100°F.
- **Antipyrine test dose:** +
- **Other drug test dose:** +
- **Outcome:** Hospitalization of various duration; one death.

#### Case Report VII (Ref. 11):
- **Authors:** Nelson and Berry (1957).
- **Medication:** Antipyrine-containing cold preparation (plus large quantities of whiskey).
- **Patient description:** Three black males.
- **Signs and symptoms:** "Typical skin rash" (due to antipyrine), neurological symptoms, grand mal seizures, decerebrate posturing, dysphagia, and deviation of the tongue.
- **Antipyrine test dose:** +
- **Other drug test dose:** +
- **Outcome:** Hospitalization; one death.

#### Case Report VIII (Ref. 12):
- **Authors:** Verbit (1958).
- **Medication taken:** Dichloralphenazone (an antipyrine derivative with hypnotic properties).
- **Patient description:** One white female.
- **Signs and symptoms:** Severe Irritation of the upper thighs and erythematous circular plaques.
- **Antipyrine test dose:** +
- **Other drug test dose:** +
- **Outcome:** +

It is interesting to note from the above description and tabulation that the most striking feature of antipyrine hypersensitivity is the fixed pigmented erythema originally described by Brocq (Ref. 6). In 1954, 11 years after antipyrine had been introduced, Brocq discovered (Ref. 5), to his "intense embarrass-
ment" because he missed the diagnosis at first, that antipyrine could cause a dermatological reaction. He described that once the reaction occurred it tended to reappear when the drug was taken again, in the same areas of the body in which it had been seen previously. In most cases had remained darker in color. He coined the term of "fixed pigmented erythema" which is still used.

In 1898, by a different approach, Kennedy et al. black and 21 out of 26 were males. Seventeen patients had taken the marketed OTC antipyrine-containing cold product in the past but only nine patients gave a history of previous reactions. The history and clinical picture were the same in all cases of these series. Kennedy et al. cite: "The typical onset included generalized pruritus, burning of the mouth and throat, sometimes choking sensations and sometimes pain referred to the genitourinary system.

The mucosa of the eyes, mouth and genitalia was involved, and large, pigmented bullous lesions of the type seen in erythema multiforme, appeared over the body, particularly on the neck, trunk, thighs and genitals. All the patients were acutely ill. Fever was frequently 102°F or higher."

In this series, there was no correlation between the size of the dose and the severity of the reaction. In the single fatal case reported, the patient took half-a-glassful of antipyrene containing cold product. Three out of the five patients reported positively to either antipyrene in the marketing OTC antipyrine-containing cold preparation. Three out of five patients reported positively to either antipyrene alone or with the marketed OTC antipyrine-containing cold preparation. One of the patients on whom a positive response was elicited was receiving prednisone at the time the tests were carried out.

Ulceration of the buccal mucosa and erythematous, pigmented lesions on the hands and body were noted. Ten days later the patient improved and was asymptomatic. To prove the hypersensitivity, 0.2 g (3 gr) antipyrene was administered to the patient. The patient responded with a fever for 4 days, severe abdominal pain and pruritus of the perianal region and in the pigmented lesions of the hands.

A week later the patient was given 100 mg cortisone at 2 p.m. and 4:00 p.m., and 0.2 g antipyrene was administered at 5 p.m. followed by an additional dose of 50 mg cortisone at 5:30 p.m. Only a minimal erythema at areas, this is rarely possible.

However, this does not preclude the occasional hypersensitivity reaction in the form of fixed pigmented erythema of the skin (so-called Brocq Skin Eruption). Skin eruptions have also been reported following the use of such drugs as quinine, phenacetin, aspirin, acetaminophen, phenobarbital, barbiturates, antistaminies, etc. (Ref. 13). However, the reactions with these drugs are not reported to be as severe as the reaction with antipyrene (Refs. 14 through 18).

In summary, the patient finds that such reactions are relatively rare following the use of antipyrene. The exact incidence cannot be determined at this time.

Antipyrene has been said have fewer side effects than aspirin. It is said not to interfere with the blood clotting mechanism as does aspirin, and there is no evidence that antipyrene causes hepatotoxicity as does acetaminophen when used in large doses (Refs. 1 and 3). The Panel believes that this compound should be studied further to determine its risk to benefit ratio because it represents an antipyrctic-analgesic with a long duration of action chemically distinct from acetaminophen or the salicylates and should be an alternative in patients who do not tolerate other analgesic drugs.

(3) Proposed dosage. Adult oral dosage is limited to a single 975 mg dose in 24 hours while symptoms persist for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(a) "Do not exceed recommended dosage."

"If skin rash appears discontinue use and consult a physician."

(5) Evaluation. Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for analgesic drugs. (See part III. paragraphs C. below-Data Required for Evaluation.) Data to be submitted should include epidemiological studies which take into consideration the con-
cerns of the Panel. Interested drug manufacturers should consult with the Food and Drug Administration as to the design of such studies. The studies should consider pharmacogenetic factors and include several racial groups.

(6) Minority of the Panel. The minority of the Panel concludes that antipyrine is unsafe and should be in Category II.

The extensive review of adverse reactions described in the document above includes extensive literature searches. The minority of sixty-six patients with fixed pigment erythema have been reported. The severe skin disease reported in 28 black patients in New Orleans and the predominance of blacks in the other case reports suggested that future studies of toxicity must be done in this target population. As these studies may lead to serious illness in the study group and since other analgesics are available at present, the risk to benefit ratio of such a study of antipyrine toxicity is extremely high. This type of prospective toxicity study should be conducted on fewer than 100 patients. Therefore, the panel concludes that antipyrine should be removed from Category III to Category I. The minority of the Panel feels that such a study has a high risk to benefit ratio and therefore would place antipyrine in Category II.

2. Salicylamide

The Panel concludes that these are insufficient data to determine that salicylamide is either safe or effective when used in combination as an OTC analgesic in the currently marketed dosage of 97.2 to 400 mg. The Panel finds that salicylamide when used alone at a higher dosage (1,000 mg every 4 hours) is not considered to be effective but has not been demonstrated to be safe for OTC use. Therefore, the Panel recommends that salicylamide be made available under prescription. A higher dosage range until suitable studies have been completed to show both safety and effectiveness. In addition, the Panel has also considered the use of salicylamide in combination as an OTC analgesic with another analgesic agent. The amount per dosage unit ranges from 97.2 to 400 mg salicylamide in such combinations. It has also been used in sedative products for its slight hypnotic properties.

Until a few years ago, it was marketed as a single ingredient in a suspension dosage form for use as an OTC analgesic in the currently marketed dosage of 97.2 to 400 mg. Salicylamide can occur very rapidly during this absorptive phase with use of a commercial dosage form of the drug, i.e., tablets. Since the drug is poorly water-soluble (approximately 0.2 percent), the small amount available for the absorptive phase at any one time from tablet dissolution is metabolized as quickly as it is absorbed from the gastrointestinal lumen and the first pass through the liver, leaving little circulating active (unmetabolized) salicylamide available for therapeutic action.

The metabolism, at low doses, is so extensive that virtually no active (unmetabolized) drug is available for absorption into the systemic circulation for distribution to the site(s) of therapeutic action. The rapid metabolism of salicylamide, i.e., its metabolism before the drug even reaches the circulatory system, makes the availability of active (unmetabolized) salicylamide dependent on the metabolic rate. At low doses and with the usual dosage form (tablets) from which the drug has been shown to be slowly released, the colon is the principal site of absorption. This difference between the intestinal and hepatic enzymes can be sufficient to completely metabolize salicylamide, leaving little or no free drug available to be absorbed into the systemic circulation (Ref. 9). The metabolism of salicylamide is therefore dose-dependent and dosage-form-dependent during the absorptive phase (initial transit).

Because of the unique characteristics of the drug, the Panel has divided the discussion into the following sections:

(a) Bioavailability (pharmacokinetics). Recent pharmacokinetic studies indicate that many of the discrepancies found in the earlier published clinical evaluations of salicylamide preparations, which are discussed below, can be explained in part by the unusual absorption and metabolism characteristics of this drug. (See part III, paragraph B.3.)

(b) Contrary to many other drugs, it is important to note that salicylamide, which is the parent (free, unmetabolized) active drug, can be almost completely metabolized to inactive metabolites during its transit from the gastrointestinal lumen through the gastrointestinal mucosa and hepatic circulation before it is even absorbed into systemic circulation (blood) to become available for therapeutic action. This initial absorption (transit) of the drug before it becomes available in the systemic circulation is called the absorptive phase. The rapid rate of elimination noted by earlier authors is due to the metabolism of the drug during the absorptive phase intestinal and/or liver drug conjugating enzymes systems.

In the absorptive phase, salicylamide is metabolized principally to glucuronide and sulfate conjugates by intestinal and primarily hepatic metabolic systems.

The rate and extent of salicylamide metabolism by these systems during the absorptive phase is saturable, i.e., the metabolizing capacity is limited by available metabolizing sites and therefore greatly dependent on both the dose and dosage form, e.g., solution, suspension or tablet, administered. Hence, the complete metabolism of an administered oral dose of salicylamide can occur very rapidly during this absorptive phase with use of a commercial dosage form of the drug, i.e., tablets. Since the drug is poorly water-soluble (approximately 0.2 percent), the small amount available for the absorptive phase at any one time from tablet dissolution is metabolized as quickly as it is absorbed from the gastrointestinal lumen and the first pass through the liver, leaving little circulating active (unmetabolized) salicylamide available for therapeutic action.
Evidence that salicylamide is extensively metabolized during the absorptive phase in man was demonstrated in a study which compared both active drug (unmetabolized salicylamide) and total drug (active drug plus metabolites) in plasma following oral and intravenous administration of a 300 mg dose. Free (active) drug was greatly reduced but not the metabolities following oral administration. Over 90 percent of the active drug was metabolized during the absorptive phase. Additional studies comparing different dosage forms at the same dose show that metabolizing enzyme systems are saturated during absorption and the bioavailability is dependent on the dose and dosage form given (Refs. 13 and 14).

In studies where active (unmetabolized) salicylamide in plasma is measured and can be distinguished from the conjugated, inactive (metabolized) drug by sensitive assay procedures, it seems that the latter is determined by the dose given (Ref. 14) as illustrated in the following table:

<table>
<thead>
<tr>
<th>Dose</th>
<th>Plasma levels detected</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg</td>
<td>1,000 mg</td>
<td>2,000 mg</td>
</tr>
<tr>
<td>Subject A</td>
<td>0.2</td>
<td>1.0</td>
</tr>
<tr>
<td>Subject B</td>
<td>0.1</td>
<td>0.9</td>
</tr>
<tr>
<td>Subject C</td>
<td>1.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

1. Plasma levels could not be detected.
2. Patient was sedated.

These data show that the doses usually used in combinations produce negligible plasma levels. As the dose is increased from 1,000 to 2,000 mg, inordinate increases in the peak plasma concentration (10 to 20 fold) are observed. Based on other studies in man (Ref. 15), these workers concluded that with smaller doses (300 to 600 mg) the drug is metabolized almost completely during the absorptive phase. But at higher doses, termed the "breakthrough dose", the metabolism system becomes saturated resulting in a decrease in the fraction of the dose metabolized and an increase in active (unmetabolized) salicylamide reaching the systemic circulation (Ref. 14). It is important to note that these dose dependent effects on systemic availability of active (unmetabolized) salicylamide in plasma were measured in plasma and urine (Refs. 13 through 15).

Dosage formulation also can influence the systemic availability and plasma levels of active drug (free salicylamide). In a study of five subjects (Ref. 14), each given 1,200 mg salicylamide in a noncommercial aqueous solution, commercial suspension and tablet, the maximum total drug was measured in plasma and urine (Refs. 13 through 15).

Dosage formulation also can influence the systemic availability and plasma levels of active drug (free salicylamide). In a study of five subjects (Ref. 14), each given 1,200 mg salicylamide in a noncommercial aqueous solution, commercial suspension and tablet, the maximum total drug was measured in plasma and urine (Refs. 13 through 15).

Comparison of total drug in plasma and urine for each dosage form clearly shows that differences between dosage forms are not due to decreased absorption but to changes in the rate of metabolism during absorption of the more slowly released drug from the solid dosage forms.

The salicylamide suspension was quite viscous and the oral route resulted in drastically reduced plasma levels. It is significant that this formulation was used in early clinical trials and illustrates the difficulties in assessing critical effects of this drug unless its pharmacokinetic characteristics are well understood and sufficient data collected to assess systemic availability (Ref. 15).

Therefore, the Panel concludes that it is obvious that the pharmacokinetic characteristics of salicylamide during the absorptive phase account for earlier difficulties in establishing a safe and efficacious dosage form and for bioavailability studies. Based upon current understanding, the Panel finds that this remains to be done.

1. Peak plasma concentration active (unmetabolized) drug (mean of 5 subjects)

Comparison of total drug in plasma and urine for each dosage form clearly shows that differences between dosage forms are not due to decreased absorption but to changes in the rate of metabolism during absorption of the more slowly released drug from the solid dosage forms. The salicylamide suspension was quite viscous and the oral route resulted in drastically reduced plasma levels. It is significant that this formulation was used in early clinical trials and illustrates the difficulties in assessing critical effects of this drug unless its pharmacokinetic characteristics are well understood and sufficient data collected to assess systemic availability (Ref. 15). Therefore, the Panel concludes that it is obvious that the pharmacokinetic characteristics of salicylamide during the absorptive phase account for earlier difficulties in establishing a safe and efficacious dosage form and for bioavailability studies. Based upon current understanding, the Panel finds that this remains to be done.

(ii) Efficacy as a single ingredient.

(a) Analgesia in animals. Analgesia potency evaluations of salicylamide in animal studies have indicated that a wide range can be demonstrated when compared to aspirin. For example, salicylamide is six times as active as aspirin in rats subjected to heat stimuli (Ref. 2). McKenzie found salicylamide to be three to four times more potent than acetaminophen in rats and salicylamide has been reported to be at least equal or better in several other animal studies (Ref. 12).

(b) Clinical studies. Salicylamide has been shown to have greater analgesic effects in animals than aspirin. However, studies in humans with pathologic pain have shown that salicylamide does not have any superior efficacy in comparison to aspirin in doses below 600 mg and is indistinguishable from placebo (Ref. 17). Beaver (Ref. 17) has suggested a number of possible explanations for this lack of correlation between the two drugs, both in vitro and in vivo. Beaver has suggested that the lack of effective analgesia in
man by salicylamide may be due to its rapid absorption, early peak blood levels, extensive metabolism and rapid excretion (Refs. 9, 10, and 13). In five healthy subjects who in one study were given 2,000 mg salicylamide, peak serum levels were seen 1 hour after administration and 50 percent of the total dose was excreted in the urine by the end of 4 hours postdosing (Ref. 9).

Clinical studies on the efficacy of salicylamide in man have produced conflicting results. Many of these discrepancies can be explained on the basis of current knowledge of dose dependent absorption and deficiencies in experimental design including the following: Use of rheumatoid and musculoskeletal pain to determine analgesic effect even though salicylamide has no anti-inflammatory activity (Refs. 8 and 14); use of doses below the "breakthrough dose" (300 to 600 mg)—because of extensive metabolism during the absorptive phase, doses of 600 mg or less would not be expected to have any significant clinical effect; use of dosage forms which have slow drug release or decreased systemic availability; failure to use more than one dosage level; and failure to show sensitivity of method.

Clinical studies in humans have not demonstrated any activity of salicylamide over aspirin. Several studies used low doses and could not distinguish the drug from placebo. Studies employing higher doses have established analgesic activity. Liber et al. (Ref. 12) reported an analgesic effect of salicylamide in 90 of 118 subjects (78 percent) with a variety of arthritic diseases. The total daily doses used to cause analgesia in these rheumatic patients varied from 3,000 to 24,000 mg. An average of 2,000 mg every 4 to 6 hours was needed to show a moderate to marked analgesic effect in 75 percent of the patients.

Wallenstein and Houdé (Ref. 20), and Wallenstein, Houdé and Beaver (Ref. 21) compared aspirin, salicylamide and acetaminophen, using 600 mg doses, with placebo in chronic patients due to advanced cancer. Each patient received at least one dose of each drug and replicated data was obtained on 17 patients. Hourly reports of changes in pain intensity for 6-hour periods were kept on all patients. The administration of each drug were tabulated. They found aspirin and acetaminophen significantly different from placebo but not from each other. However, over the 6-hour observation period, salicylamide did not show any superiority over placebo, but was "somewhat" more effective than placebo, 1 hour after administration. This difference in the activity of salicylamide was explained by the rapid metabolism of salicylamide to an inactive compound resulting in a very brief duration of action.

Battmer and Gross observed effects in 73 subjects in a double-blind study comparing 600 mg salicylamide with 600 mg aspirin taken every 4 hours for 1 to 3 weeks. Most subjects had pain due to osteoarthritis and/or muscular ligamentous sprain or strain. They concluded that salicylamide was not an effective analgesic or antiinflammatory medication (Ref. 22). This study has several experimental deficiencies and has been criticized by several authors (Refs. 23 and 24). In addition to the single border-line dose used, the poor choice of patient population (pain due to osteoarthritis), and the poor choice of a standard which also has antipyretic and analgesic effects, this study also failed to statistically distinguish aspirin from placebo.

In view of the contradictory conclusions reported in the literature regarding the degree of clinical response to salicylamide as an analgesic in man, some of which are a result of poor experimental design, the Panel recommends further well-controlled clinical studies be done to demonstrate the clinical and consistent analgesic activity. This compound has unique properties that make it mandatory to clearly delineate the dose form and dosage levels for the drug. The data on systemic availability during such studies using analytical methods and pharmacokinetic studies which measure active (unmetabolized) salicylamide in plasma needs to be done (22). Studies which evaluate that salicylamide is ineffective in currently recommended doses of 300 to 600 mg and has not been adequately tested for safety and should be placed in Category IV. In addition to salicylamide, other drugs with no evidence of analgesic activity, i.e., 1,000 mg 4 hours to not exceed 5,000 mg in 24 hours for not more than 10 days, safety has not been established for OTC use. The central nervous system effects of drowsiness and dizziness and gastrointestinal upset are common adverse effects reported when "higher doses are used." Other toxic manifestations, such as hepatic effects in children and damage to blood formation following chronic use are sufficiently serious to warrant additional study.

Goodman and Gilman described gastric irritation in 10 percent of cases, drowsiness or dizziness in 10 and 20 percent of cases, respectively (Ref. 25), with doses of 2,000 mg, 3 times daily recommended for the adult levels. Battmer and Grossman noticed side effects in 31 percent of patients taking 600 mg of salicylamide every four hours from one to three weeks which were predominantly gastrointestinal and central nervous system manifestations (Ref. 22).

Three cases of purpura attributed to salicylamide have been reported. Stellwag in 1950 reported a 48-year-old woman who had taken a total of 144 g in 3 months and developed epistaxis, severe bruising and bleeding. Examination revealed thrombocytopenia, depression of myeloid elements and maturation arrest of megakaryocytes in the bone marrow (Ref. 26).

Grieg reported two cases of "black or blue" caused by effects on the blood clotting mechanism (thrombocytopenic purpura) in 1955 (Ref. 27). One woman took a total of 309 g orally in 60 days and developed the usual signs and symptoms consisting of bruising and bleeding. The second case was also a woman who had taken a prescribed dose and developed these signs and symptoms. Bone marrow examination showed hypoplasia of all elements in both women.

Large doses of salicylamide can produce toxic effects similar to those of the salicylates including ringing of the ears, ecchymoses, hemorrhagic lesions, leukopenia and thrombocytopenia. Barr and Fenna (Ref. 14) also describe hypotensive effects in large doses but do not delineate the exact dose.

In an unpublished study submitted to the Panel dealing with the use of salicylamide (Ref. 28), W. S. Anderson reported his observations of 57 infants and children in Children's Hospital in Washington, D.C. All of these infants and children had renal disease. Neonatal patients and many were admitted because of fever and an accompanying respiratory illness. Thirty patients were given salicylamide every 4 hours for 4 days. Patients of age received 130 mg/dose and those over 5 years of age received 600 mg/dose. Since the ages of the patients were not specified, the Panel assumes that they are all below 12 years of age. There were 27 patients with 27 patients who received aspirin at half of the salicylamide dosage. Salicylamide had "practically" no antipyretic or analgesic action. Anderson noted a mild sedative reaction. In addition, five patients with no evidence of renal disease had a significant blood urea nitrogen rise after 4 days. Another patient with no demonstrable renal disease had a cephalin flocculation that increased from 0 to 3+ in two patients and from 0 to 4+ in three patients after 4 days indicating an adverse effect on liver function. Additional side effects only in the salicylamide treated groups. He concluded that there was no correlation between the rise in the blood urea nitrogen and the change in the cephalin flocculation.

It would seem from this study that the toxic manifestations occurred in a significant number of children and warrant further studies of this drug in children. At this time only this unpublished report of hepatic toxicity has been reported and in this case a causal relationship was not established. There is no evidence to believe that 12-year-olds would react to the drug differently than an adult. Similar doses to infants and adults by the same investigators did not produce toxicity.

Signs of hepatic dysfunction have not been reported in other studies reviewed by the Panel. However, there is no indication that liver function tests were actually done in these studies. Because of the lack of current data on possible hepatic effects, the Panel recommends that suitable hepatic function tests be required in the Category III testing protocols for salicylamide.

On the basis of available reports, the Panel recommends further studies as to the toxic effect of therapeutic doses on liver and kidney function. It would also be advisable to advise what if any, effect formulation has on toxic manifestations.
Although salicylamide in large doses can produce gastric distress, it has no direct irritant effect on gastrointestinal mucosa. Studies on direct mucosal irritation involving a variety of analgesic agents have shown that salicylamide, unlike the salicylates, has no erosive effect on the gastric mucosa (Ref. 7). Salicylamide does not cause occult bleeding (Ref.. 12). Salicylamide has not been associated with clinically significant massive gastrointestinal bleeding or peptic ulcer (Ref. 12). The Panel concludes that in contrast to salicylates, the gastric distress observed following large oral doses of salicylamide is not symptomatic of serious gastrointestinal dysfunction and represents no serious risk.

Allergic reactions to salicylamide are not common. It has been claimed that salicylamide does not show cross-sensitivity with aspirin although the definitive studies establishing this claim are said to be lacking (Ref. 15). Salicylamide has no effect on bleeding time (Ref. 20), prothrombin time and is not highly protein bound.

**CONCLUSIONS AND RECOMMENDATIONS**

The Panel concludes that most earlier published clinical studies, relating to dosage, dosage form and effectiveness are inconclusive. Deficiencies of some earlier studies were largely due to the fact that it has been only recently recognized that salicylamide undergoes extensive metabolism during the absorption process. The extent of metabolism and thus the systemic availability of the pharmacologically active (unmetabolized) parent drug is greatly dependent on both the dose and the release characteristics of the dosage form used.

The Panel notes that the lack of therapeutic effects or toxicities observed in some earlier studies were likely a consequence of the properties of the dosage form used rather than the intrinsic pharmacologic effects of the drug itself.

The Panel concludes that currently recommended doses of 300 to 600 mg are probably adequate, that salicylamide, when used as a single analgesic (or antipyretic) agent.

Doses of 600 to 1,000 mg may be effective depending on the characteristics of the patient, whether salicylamide is used as a single analgesic (or antipyretic) agent.

The Panel concludes that currently recommended doses of 300 to 600 mg are probably adequate, that salicylamide may be effective but has not been demonstrated to be safe for OTC use. However, the Panel recommends that salicylamide not be made available for OTC use at the higher dosage range until suitable studies have been completed to show both safety and effectiveness.

For children under 12 years, there is no recommended dosage except when advised and supervised by a physician.

In addition, the Panel has also considered the use of salicylamide as an OTC analgesic adjuvant elsewhere in this document. (See part VI, paragraph B.5 below—Salicylamide.)

(4) **Labeling.** The Panel recommends the Category I labeling for analgesic active ingredients. (See part III, paragraph B.1 above—Category I Labeling.)

(5) **Evaluation.** Data to demonstrate effectiveness and safety will be required in accordance with the guidelines set forth below for analgesic drugs. (See part III, paragraph C. below—Data Required for Evaluation.)

Additional information from carefully planned, clinical studies is required in support of OTC labeling. A detailed, selective formulation that provides suitable bioavailability of active drug, and determine the nature and true incidence of adverse effects when effective doses and dosage forms are used. The Panel concludes that the pharmaceutical industry should consult with the Food and Drug Administration as to a suitable proposed dosage and dosage form evaluation prior to testing.

(6) **Combination products containing salicylamide combined with acetaminophen or salicylamide combined with aspirin.** The Panel concludes that there is insufficient information to determine the salicylamide as an adjuvant in combination with acetaminophen or aspirin, and therefore classify such combinations as Category II. The Panel concludes that the role of salicylamide as an adjuvant elsewhere in this document. (See part VI, paragraph B.5 below—Salicylamide.)

Salicylamide is a frequent component of analgesic mixtures. The average amount in these combinations is only about 200 mg which on the basis of previous discussion would appear to be ineffective.

**REFERENCES**


d. Salsalate (salicylsalicylic acid). The Panel concludes that there are insufficient data for salicylsalicylic acid. It appears to be either safe or effective as an OTC analgesic in the recommended dosage of 500 to 1,000 mg every 4 hours while symptoms persist not to exceed 6,000 mg in 24 hours for not more than 10 days. The Panel recommends that salicylsalicylic acid is not sufficient to establish safety and effectiveness in the treatment of analgesic effect on "nervous headaches" in adults, whereas a 1,000 mg aspirin tablet (dosage unit) shall be labeled, "Equivalent to X mg per dosage unit of the standard of Analgesic Equivalence Value.") In addition, the Panel recommends the following specific labeling: Analgesic Equivalence Value.

The Panel recommends that products containing salicylate be clearly labeled on the principal display panel: "Equivalent to X mg per dosage unit of the established standard of 325 mg sodium salicylate per dosage unit." The actual amount of "X" mg of equivalent analgesic effectiveness must be expressed by a standard of Analgesic Equivalence Value.

In this particular investigation, paragraphs were made of gastrointestinal bleeding associated with the ingestion of placebo, salicylate, aspirin and a combination of the latter two. Blood loss was measured by a method employing the measurement of radioactively-labeled red blood cells of normal subjects. Salicylate did not produce any bleeding above the levels of normal control values. Following the ingestion of salicylate, as well as the other acetylsalicylates, salicylate has not been associated with reactions causing asthmatic attacks or paradoxical bronchoconstriction. In addition, salicylate, as well as the other acetylsalicylates, are not known to affect the platelet adhesiveness involved in the clotting mechanism. However, this ingredient may have an effect on another aspect of the clotting mechanism (hypoprothrombinemic effect). The caution concerning bleeding should be addressed to that population which is exposed to large doses of this compound. The one study available at this time is that of Leonards consisting of a double-blind investigation involving twelve subjects (Ref. 10). In this particular investigation, paragraphs were made of gastrointestinal bleeding associated with the ingestion of placebo, salicylate, aspirin and a combination of the latter two. Blood loss was measured by a method employing the measurement of radioactively-labeled red blood cells of normal subjects. Salicylate did not produce any bleeding above the levels of normal control values. Following the ingestion of salicylate, as well as the other acetylsalicylates, salicylate has not been associated with reactions causing asthmatic attacks or paradoxical bronchoconstriction. In addition, salicylate, as well as the other acetylsalicylates, are not known to affect the platelet adhesiveness involved in the clotting mechanism. However, this ingredient may have an effect on another aspect of the clotting mechanism (hypoprothrombinemic effect). The caution concerning bleeding should be addressed to that population which is exposed to large doses of this compound. The one study available at this time is that of Leonards consisting of a double-blind investigation involving twelve subjects (Ref. 10).
testinal and blood clotting side effects of aspirin or the other salicylates.

While the evidence is not complete, it seems to indicate that the severity and incidence of adverse reactions, either prior to or after absorption, would be comparable to aspirin and the other salicylates discussed previously in this document. Until studies show that salislate has different absorption characteristics and these characteristics are correlated with safety, all indications, limitations and warnings for the nonacetylated salicylates would be equally applicable here.

(5) Evaluation. Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for analgesic drugs. (See part III. paragraph C. below—Data Required for Evaluation.)

REFERENCES

(5) Schilling, F. J., I. Bernstein and C. Schechter, draft of unpublished paper is included in OTC Volume 0094.4.
(9) OTC Volume 0094.4.

CATEGORY III LABELING

The Panel concludes that the Category III labeling claims are sufficiently broad to encompass the various specific types of pain, e.g., "body aches," "muscle aches," etc. All other labeling claims relating to pain are unsupported by scientific data or sound theoretical reasoning and are classified Category II. (See part III. paragraph B.1. above—Category II Labeling and part III. paragraph B.2. above—Category II Labeling.)

In addition, the Panel has examined the submitted labeling claims for buffered and highly buffered aspirin products and has found the following as Category III labeling which may be included on the principal display panel: a. "Provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label", and b. "Faster to the blood-stream than plain aspirin". The Panel has discussed the above Category III labeling elsewhere in this document. (See part VI. paragraph B.1.d. below—Labeling claims for marketed products containing analgesics with or without buffering ingredients.)

Although buffering agents are not included in the formulation of choline salicylate, some of its currently marketed labeling claims are similar to the claims submitted for highly buffered aspirin. The similarity in labeling claims is undoubtedly due to the fact that choline salicylate, like highly buffered aspirin, is marketed in a liquid dosage form. The Panel has reviewed these claims for choline salicylate and has classified the following as Category III labeling: "May be taken on an empty stomach and may prevent stomach distress that aspirin occasionally causes—but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label". The basis for this classification is discussed elsewhere in this document. (See part III. paragraph 1.d.2 above—Safety.)

C. Data Required for Evaluation

The Panel finds the protocols recommended in this document for the studies required to bring a Category III drug into Category II are adequate. To determine the present state of the art and do not preclude the use of any advances of improved methodology in the future.

1. Consideration of the evaluation of any experiment protocol for testing analgesic drugs. General Principles. The important considerations concerning the design and interpretation of analgesic assays are as follows (Refs. 1 and 2): a. The appraisal of real analgesic power must be based on the capacity of the agent to relieve pain occasionally caused by aspirin. It has been shown that the patient responds to placebo is not an abnormal response but a response to be expected. Some believe that the degree of placebo response among the population is in some respects a measure of the data and the experimental protocol should be made that the placebo group response is a valid control group. That is, if they respond positively to placebo in one trial, in the next trial they may or may not respond positively to a placebo, and therefore it is impossible in the clinical setting to define the placebo responders.

2. Test parameters for study, a. General considerations. Regardless of the parameters studied to evaluate the effect of an analgesic ingredient, the following considerations should be incorporated into the design of the study: (1) Patients should be allocated to treatment groups in such a way as to avoid bias. (2) A double-blind technique should be used. (3) Consideration should be given to the type of pain patients in the patient populations used in the various studies, since conflicting reports could arise from the fact that certain of the mild analgesics owe some, or most of their effect to their action at some other condition. When several doses of drug are studied or if a combination of several ingredients is being studied, a number of groups is required, that is, at least four groups. Such a study should preferably use separate large groups of perhaps at least 30 subjects per group since intergroup comparisons have statistical advantages. A well-planned crossover study, however, would also be acceptable.

Determination should be made that the random assignment procedure balances the variables not otherwise controlled in the patient selection. This can be determined by analyzing the distribution of age, sex, type of pain, weight, height, etc. within each of the treatment groups. In any case, full reporting of the subject's characteristics is necessary to allow for the adequate interpretation of results. Furthermore, all exclusions from the experimental protocol should be stated.

Allowance must be made for the placebo response in a well-designed clinical study. In a population of patients, administration of a placebo will give a degree of pain relief that varies with the active compound. It is known that the placebo response is not an abnormal response but a response to be expected. Some believe that the degree of placebo response among the population is in some respects a measure of the data and the experimental protocol should be made that the placebo group response is a valid control group. That is, if they respond positively to placebo in one trial, in the next trial they may or may not respond positively to a placebo, and therefore it is impossible in the clinical setting to define the placebo responders.

Much has been written about the placebo responder. The response of patients to an inert compound or a placebo composite will vary with the evaluation methods. It is known that the placebo response is not an abnormal response but a response to be expected. Some believe that the degree of placebo response among the population is in some respects a measure of the data and the experimental protocol should be made that the placebo group response is a valid control group. That is, if they respond positively to placebo in one trial, in the next trial they may or may not respond positively to a placebo, and therefore it is impossible in the clinical setting to define the placebo responders.
standard and possibly a placebo as well.

(5) Studies employing graded doses of the test drug are more meaningful. If with increasing dose an increased effect is demonstrated, this verifies the sensitivity of the method. The studies with graded doses of the test drug compared to the standard drug permit determination of relative potency and 95 percent confidence limits which otherwise are difficult to obtain (Ref. 4).

(6) The scoring of pain and/or relief should be done frequently during the expected duration of action of the test drug. Retrospective evaluation and drug effect has often proved to be virtually meaningless.

(7) Results of single dose studies should not be extrapolated to predict the effect of repeated use of a drug. The studies with repeated doses and repeated measures which should be allowed to persist for more than 3 days (72 hours), or recurs, consult your physician.

(8) Prior to carrying out an analgesic assay, the appropriate statistical analysis should be defined. Unless the foregoing points have been observed, any statistical analysis would only impart a false sense of confidence in the results.

b. Use of blood levels in evaluation of effectiveness.—In the case of salts or similar drugs, assaying an analgesic such as e.g. aspirin, for which effectiveness has been established, crossover bioavailability studies may be used to establish effectiveness. Determining the blood level of a product produced by the salt or other variant are compared with those of the established analgesic, after administration of similar dosage forms. Comparable blood levels of the test drug and the major active metabolites may be equated with effectiveness.

4. Data interpretation. To establish Category I status for a Category III compound with major active metabolites or other variant, independent investigators which conform to the guidelines included above for compounds for which safety is unquestioned. If the compound is placed in Category III for reasons of safety at least two 3-month safety studies by independent investigators should be required. These studies should include at least 50 subjects, and should involve drug controls, and involve 4 times daily or other recommended intervals of administration of the test drug in question to controlled subject populations in whom side effects can be checked daily and complete blood counts, urinalysis, stool and blood function tests can be checked weekly or more often if necessary. If a pharmacogenetic link is suspected a target population should be selected.

All data submitted to the Food and Drug Administration must present both favorable and adverse results. The design of the experiments and their interpretation depends on the various organs and systems, such as the gastrointestinal system, the kidneys, the cardiovascular system, particularly the effect on the clotting mechanism, etc. In addition, the hepatic system and the potential for teratogenicity should be considered.

6. General guidelines for reclassification of Category III combinations to Category I a. Combinations must demonstrate at least as much analgesic effectiveness as a 650 mg (10 gr) dose of aspirin.

b. Combinations must be at least as safe as the recommended 650 mg (10 gr) single dose of aspirin or the recommended maximum 24-hour dose of 4,000 mg of aspirin.

c. Each component must make a statistically significant contribution to the total effect. For instance, this could be determined by a factorially designed studies. They might be of the form: 650 mg aspirin, 650 mg aspirin plus 60 mg caffeine, 60 mg caffeine, and placebo.

The analysis must show caffeine in combination to have a significant effect to justify its continued inclusion in combinations.

REFERENCES


pyretic when taken in the recommended dosage of 325 mg to 650 mg every 4 hours while fever persists not to exceed 4,000 mg (60 gr) in 24 hours for not more than 3 days.

(1) Effectiveness. In animals, as well as in man, aspirin has proven to be an effective antipyretic. Although many clinical studies are poorly designed and the evidence is not well-documented and carefully analyzed studies showing that aspirin is a potent effective antipyretic. Although many studies showing that aspirin is a potent antipyretic agent (Refs. 1 through 10), the most carefully conducted study is that of Steele et al. (Ref. 5) who demonstrated significant dose-effect curves.

Although it has been suggested by Steele et al. (Ref. 5) that there is a therapeutic advantage to giving aspirin in combination with acetaminophen for antipyresis (Ref. 10), the study has been criticized by Harden (Ref. 11) as well as by Wolman (Ref. 12). The Panel agrees with the criticism of Harden and Wolman and finds that the study of Steele et al. (Ref. 5) is not designed to study this interaction. Furthermore, there is no advantage to giving these drugs in combination for fever or antipyretic effect. The drugs in this study were used alone and at the same dosage in the combination. The increased effect observed with the combination is due to the increase in dosage because of the presence of both drugs. Statistically, there is no way of calculating the interaction in this study in order to determine if the combined effect represents simply the addition, potentiation or indeed even antagonism.

(2) Safety. The safety of aspirin has been discussed earlier in this document. (See part III, paragraph E.1.a.(2)—Safety.)

(3) Dosage. (a) For products containing 325 mg (5 gr) per dosage unit. (a) Standard schedule. — Adult oral dosage is 325 mg (5 gr) to 650 mg (10 gr) every 4 hours while fever persists not to exceed 3,900 mg (60 gr) in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 606.3 mg (12.5 gr) every 4 hours while fever persists not to exceed 2,031.5 mg (32 gr) in 24 hours for not more than 3 days. Children 2 to under 11 years oral dosage is 406.3 mg (8.12 gr) every 4 hours while fever persists not to exceed 1,219 mg (21 gr) in 24 hours for not more than 3 days. Children 1 to under 2 years oral dosage is 148.8 mg (2.96 gr) every 4 hours while fever persists not to exceed 777 mg (13.3 gr) in 24 hours for not more than 3 days. Children under 1 year oral dosage is 65 mg (1.26 gr) every 4 hours while fever persists not to exceed 330 mg (5.6 gr) in 24 hours for not more than 3 days.

(b) Nonstandard schedule.—Adult oral dosage is 325 mg (5 gr) to 975 mg (15 gr) initially, followed by 650 mg (10 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(ii) For products containing 30 mg (1.25 gr) per dosage unit. Children 11 to under 12 years oral dosage is 460 mg (9 gr) every 4 hours while fever persists not to exceed 2,400 mg (36 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 300 mg (5 gr) every 4 hours while fever persists not to exceed 1,920 mg (31 gr) in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 250 mg (4.25 gr) every 4 hours while fever persists not to exceed 1,600 mg (26 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 200 mg (3.5 gr) every 4 hours while fever persists not to exceed 1,200 mg (20 gr) in 24 hours for not more than 3 days. Children 2 to 4 years oral dosage is 160 mg (2.64 gr) every 4 hours while fever persists not to exceed 960 mg (16 gr) in 24 hours for not more than 3 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

(iii) For products containing more than 325 mg (5 gr) but not more than 421 mg (6.75 gr) per dosage unit. Adult oral dosage is more than 325 mg (5 gr) but not more than 485 mg (8.12 gr) in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is more than 225 mg (4.2 gr) but not more than 421 mg (6.75 gr) every 4 hours while fever persists not to exceed 1,200 mg (20 gr) in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(iv) For products containing more than 421 mg (6.75 gr) but not more than 485 mg (7.46 gr) per dosage unit. Adult oral dosage is more than 421 mg (6.75 gr) but not more than 970 mg (16.2 gr) initially, followed by more than 485 mg (8.12 gr) in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is more than 285 mg (5.1 gr) but not more than 485 mg (7.46 gr) every 4 hours while symptoms persist not to exceed 1,789 mg (30 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is more than 245 mg (4.5 gr) but not more than 485 mg (7.46 gr) every 4 hours while symptoms persist not to exceed 1,400 mg (24 gr) in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(v) For products containing more than 485 mg (7.46 gr) but not more than 500 mg (7.89 gr) per dosage unit. Adult oral dosage is more than 485 mg (7.46 gr) but not more than 1,000 mg (16.7 gr) initially, followed by more than 500 mg (7.89 gr) in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is more than 380 mg (6.9 gr) but not more than 1,000 mg (16.7 gr) every 4 hours while symptoms persist not to exceed 1,400 mg (24 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is more than 320 mg (5.7 gr) but not more than 1,000 mg (16.7 gr) every 4 hours while symptoms persist not to exceed 1,000 mg (16.7 gr) in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(vi) For products containing more than 500 mg (7.89 gr) but not more than 650 mg (10 gr) per dosage unit. Adult oral dosage is more than 500 mg (7.89 gr) but not more than 1,500 mg (25.5 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(4) Labeling. The Panel recommends that products containing aspirin be clearly labeled as containing aspirin on the principal display panel. In addition, labeling shall state in metric units and secondarily in apothecary units the quantity of aspirin per dosage unit. As previously stated, such labeling will not only benefit all consumers but will also alert those individuals who have a history of aspirin sensitivity. For products containing the standard aspirin dosage unit. The Panel recommends that products containing only 325 mg (5 gr) aspirin per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg (5 gr) aspirin per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form, such as tablet or capsule.

(b) Products containing aspirin in an amount different than the standard aspirin dosage unit. While the Panel recommends that products contain only 325 mg (5 gr) aspirin per dosage unit, if the Food and Drug Administration is unable to implement this recommendation, the Panel recommends that products containing an amount of aspirin other than 325 mg (5 gr) aspirin per dosage unit be clearly labeled on the principal display panel: "Contains nonstandard strength of X mg (X gr) aspirin per dosage unit compared to the established standard of 325 mg (5 gr) aspirin per dosage unit". The actual amount "X" of
Proposed Rules

35447

aspirin for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

References


b. Acetaminophen. The Panel concludes that acetaminophen is a safe and effective OTC antipyretic when taken in the recommended dosage of 325 to 650 mg every 4 hours while fever persists not to exceed 60.0 mg in 24 hours for not more than 3 days.

(1) Effectiveness. A number of studies have been done on the antipyretic effects of acetaminophen (Refs. 1 through 9). Acetaminophen has been shown to be effective. However, there has been no assay in which the relative antipyretic potency of acetaminophen compared to aspirin has been determined. Another disadvantage of the data in the studies by Eden and Kaufman (Ref. 2), Cornell and Ritter (Ref. 3), Colgan and Mintz (Ref. 4), and Hunter (Ref. 5) seem to indicate that acetaminophen is a less potent an- pyretic than aspirin. However, if one examines the recent study by Tarlin et al. and constructs mean temperature lowering curves that are compared to aspirin and acetaminophen, appear to be compara- ble (Ref. 6), while the data of Steele et al. (Ref. 3) indicate a slight superi- ority for acetaminophen. However, since only one dose of acetaminophen and the same mg dose of aspirin were compared in these later two studies, it is impossible to make a statement on relative potency since dose-effect curves were not defined.

(2) Safety. The safety of acetamino- phen has been discussed earlier in this document. (See part III, paragraph B.1.1(c) above—Safety.)

(3) Dosage. (i) For products containing 325 mg (5 gr) per dosage unit. (ii) Standard dosage units of acetaminophen differ per dosage unit from the established standard of 325 mg (5 gr) acetaminophen per dosage unit. (See part II, paragraph F. above—Standard Dosage Unit and Analgesic Equivalence Value.)

The Panel recommends that all products containing acetaminophen be clearly labeled on the principal display panel. In addition, labeling shall state in metric units and secondarily in apothecary units the quantity of acetaminophen per dosage unit. (a) Products containing the standard acetaminophen dosage unit. The Panel recommends that products containing only 325 mg (5 gr) acetaminophen per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg (5 gr) acetaminophen per dosage unit." The term "dosage form" means any applicable dosage form such as tablet or capsule.

(b) Products containing acetaminophen in an amount different from the standard dosage unit. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

References


ample, a product containing 435 mg choline salicylate per tablet (dosage unit) shall be labeled, "Equivalent to 325 mg of the established standard of 325 mg sodium salicylate per tablet".

REFERENCES


e. Magnesium salicylate. The Panel concludes that magnesium salicylate is safe and effective as an OTC antipyretic in the recommended dosage of 325 to 650 mg every 4 hours while fever persists not to exceed 4,000 mg in 24 hours for not more than 3 days.

Effectiveness. The effectiveness of magnesium salicylate has been discussed earlier in this document. Although the Panel found no controlled clinical antipyretic study of magnesium salicylate, adequately controlled bioavailability have been done (Ref. 1) and there is no reason to believe it is a less effective antipyretic than sodium salicylate. (See part III. paragraph B.1.e.(1) above—Effectiveness.)

Safety. The safety of magnesium salicylate has been discussed earlier in this document. (See part III. paragraph B.1.e.(2) above—Safety.)

REFERENCE

(1) OTC Volume 050062.

(iii) Dosage. Adult oral dosage is 325 to 650 mg every 4 hours while fever persists not to exceed 4,000 mg in 24 hours for not more than 3 days. Children 11 to under 12 years oral dosage is 487.5 mg every 4 hours while fever persists not to exceed 3,900 mg in 24 hours for not more than 3 days. Children 6 to under 11 years oral dosage is 460.3 mg every 4 hours while fever persists not to exceed 2,031.5 mg in 24 hours for not more than 3 days.

Children 6 to under 5 years oral dosage is 325 mg every 4 hours while fever persists not to exceed 1,625 mg in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 243.8 mg every 4 hours while fever persists not to exceed 1,219 mg in 24 hours for not more than 3 days. Children 3 to under 4 years oral dosage is 162.5 mg every 4 hours while fever persists not to exceed 975 mg in 24 hours for not more than 3 days. For children under 3 years, there is no recommended dosage except under the advice and supervision of a physician.

Labeling. The labeling of the product contains the Category I labeling for antipyretic active ingredients. (See Part IV. paragraph B.1.-Category I Labeling.) In addition, the Panel recommends the following specific labeling: (1) Warning: "Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician". (2) For products containing more than 325 mg but not more than 485 mg per dosage unit. Adult oral dosage is more than 325 mg but not more than 842 mg initially, followed by more than 325 mg but not more than 485 mg every 4 hours while fever persists not to exceed 3,900 mg in 24 hours for not more than 3 days. For children 3 to under 4 years, there is no recommended dosage except under the advice and supervision of a physician.

(iv) For products containing more than 485 mg but not more than 650 mg per dosage unit. Adult oral dosage is more than 485 mg but not more than 970 mg initially, followed by more than 485 mg but not more than 650 mg every 4 hours or 842 mg but not more than 970 mg every 6 hours while fever persists not to exceed 3,900 mg in 24 hours for not more than 3 days. For children 2 to under 3 years, there is no recommended dosage except under the advice and supervision of a physician.

(v) For products containing more than 650 mg but not more than 500 mg per dosage unit. Adult oral dosage is more than 500 mg but not more than 1,000 mg initially, followed by more than 500 mg but not more than 650 mg every 4 hours or more than 970 mg every 6 hours while fever persists not to exceed 3,900 mg in 24 hours for not more than 3 days. For children 4 to under 6 years, there is no recommended dosage except under the advice and supervision of a physician.

Labeling. The labeling of the product contains the following specific labeling: (1) Warning: "Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician". (2) For products containing 0.2 mEq (6 mg or higher) of sodium per dosage unit. The labeling of the product contains...
the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 mEq (5 mg) or higher.

(iii) For products containing more than 5 mEq (125 mg) sodium in the maximum recommended daily dosage. Warning. "Do not take this product if you are on a sodium restricted diet except under the advice and supervision of a physician".

(iv) Caution: "Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends the following Category I labeling for antipyretic active ingredients to be generally recognized as safe and effective and not misbranded as well as any specific labeling discussed as safe and effective and not misbranded Category I labeling for antipyretic active ingredients.

(a) Children under 12 years: Drink a full glass of water with each dose".

(b) "Adults: Drink a full glass of water with each dose".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends the following Category I labeling for antipyretic active ingredients to be generally recognized as safe and effective and not misbranded as well as any specific labeling discussed as safe and effective and not misbranded Category I labeling for antipyretic active ingredients.

(a) Children under 12 years: Drink a full glass of water with each dose".

(b) "Adults: Drink a full glass of water with each dose".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends the following Category I labeling for antipyretic active ingredients to be generally recognized as safe and effective and not misbranded as well as any specific labeling discussed as safe and effective and not misbranded Category I labeling for antipyretic active ingredients.

(a) Children under 12 years: Drink a full glass of water with each dose".

(b) "Adults: Drink a full glass of water with each dose".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends the following Category I labeling for antipyretic active ingredients to be generally recognized as safe and effective and not misbranded as well as any specific labeling discussed as safe and effective and not misbranded Category I labeling for antipyretic active ingredients.

(a) Children under 12 years: Drink a full glass of water with each dose".

(b) "Adults: Drink a full glass of water with each dose".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends the following Category I labeling for antipyretic active ingredients to be generally recognized as safe and effective and not misbranded as well as any specific labeling discussed as safe and effective and not misbranded Category I labeling for antipyretic active ingredients.

(a) Children under 12 years: Drink a full glass of water with each dose".

(b) "Adults: Drink a full glass of water with each dose".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

The Panel recommends the following Category I labeling for antipyretic active ingredients to be generally recognized as safe and effective and not misbranded as well as any specific labeling discussed as safe and effective and not misbranded Category I labeling for antipyretic active ingredients.

(a) Children under 12 years: Drink a full glass of water with each dose".

(b) "Adults: Drink a full glass of water with each dose".

The Panel recommends that all products containing sodium salicylate be clearly labeled as containing sodium salicylate on the principal display panel.

(a) Products containing the standard sodium salicylate dosage unit. The Panel recommends that products containing only 325 mg sodium salicylate per dosage unit be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

(b) Products containing sodium salicylate in an amount different than the standard sodium salicylate dosage unit. While the Panel recommends that products containing the standard sodium salicylate dosage unit be clearly labeled on the principal display panel; "Contains the standard strength of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of sodium salicylate for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.
and the possibility of hemolytic anemia and methemoglobinemia resulting from abuse (Ref. 1), and the lack of compensating benefit of the drug. The harmful to risk ratio of phenacetin compounds compares unfavorably with other single agents and combination antipyretic preparations available to target populations.

(1) Effectiveness. The antipyretic effect of phenacetin has been investigated by Minz (Ref. 2). He studied the comparative antipyretic effect of phenacetin then in the percent of initial temperature or whether percent of initial temperature and found that aspirin was more effective than phenacetin. He studied these compounds in 20 febrile children under the age of 5 years who were given a single standard dose of 60 mg phenacetin per year of age and compared them with 20 febrile children given aspirin in a standard dose of 65 mg per year of age. Rectal temperatures were taken 1/2, 1, 2, 3, and 4 hours following the administration of drugs. Aspirin was more effective than phenacetin in lowering the body temperature as expressed in percent of initial temperature or whether it was expressed in terms of the average temperature. The author concludes that half doses of aspirin are as effective as single doses of phenacetin. Thus, phenacetin appears to be half as effective as aspirin in terms of its antipyretic effect.

(2) Safety. The safety of phenacetin has been discussed earlier in this document. (See part III, paragraph B.2.d.2 above—Safety.)

(3) Evaluation. The Panel concludes that because of the high potential for abuse, the high potential for harm to the kidney and the possibility of hemolytic anemia and methemoglobinemia resulting from abuse, the risks from the use of phenacetin outweigh any benefit and therefore classifies phenacetin not safe for OTC use as an antipyretic.

REFERENCES


d. Quinine. The Panel concludes that quinine is an effective OTC antipyretic but that it is not safe for OTC use.

(1) Effectiveness. The Panel notes that Rollo states, "The antipyretic effect of quinone is not very prominent except in cases of malaria. The striking effect in this disease is not due to the antimalarial action. The weak antipyretic effect that quinone has in other febrile conditions seems to be due to mainly peripheral general inhibitory effect on metabolism as full dose elimination of skeletal muscle activity" (Ref. 1).

(2) Safety. The safety of quinine has been discussed earlier in this document. (See part III, paragraph B.2.e.2 above—Safety.)

(3) Evaluation. The Panel concludes that because of the high incidence of hypersensitivity in the effective antipyretic dosage, the risks from the use of quinone outweigh any benefit, and therefore classifies quinone not safe for use as an OTC antipyretic.

REFERENCES


CATEGORY II LABELING

The Panel has examined the submitted labeling claims for antipyretics alone and for combination products with non-antipyretic ingredients and has placed certain claims into Category II. These Category II claims have been categorized by the Panel as claims that are unsupported by scientific data or by sound theoretical reasoning, claims that are not clearly defined, and claims that require prior diagnosis and are associated with the use of antipyretics.

Several of the claims considered by the Panel are Category II claims for one or more of the above reasons. An individual claim may include one, several or all of the reasons for categorizing it as Category II. Therefore, it is difficult to outline an individual claim under one specific reason. All the reasons mentioned above including unacceptable claims related to product performance have been clearly defined elsewhere in this document. (See part III, paragraph B.2.a, above—Category II Labelling). The Panel has classified the following labeling claims as Category II claims: "fever of colds and flu", "reduce fever in simple headaches, minor muscular aches, neuritis, neuralgia", "reduces temperature and calms the fretfulness and disl, claims that require prior diagnosis and care of a physician, claims that are misleading or specifically contraindicated, and claims that contain modifying adjectives associating fever with illnesses.

Among the claims that the Panel considers Category II are: "reduce fever", "fever of colds and flu", "reduce fever in simple headaches, minor muscular aches, neuritis, neuralgia", "reduces temperature and calms the fretfulness and discomfort", and "fever accompanying colds or the flu", "fever discomfort", "for fever from colds, minor aches and pains, headache", "sore throat due to colds, tonsillectomy, teething", and "reduce fever of colds and flu".

3. Category III conditions for which the available data are insufficient to permit final classification at this time.

CATEGORY III ACTIVE INGREDIENTS

The Panel has concluded that the available data are insufficient to permit final classification of the following claimed antipyretic active ingredients listed below. The Panel believes it reasonable to require new data for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 3 years, however, the ingredients listed in this Category should no longer be marketed in OTC products:

Aluminum aspirin
Acetaminophen
Aspirin
Salicylamide
Salsalate (salicylsalicylic acid)

n. Aluminum aspirin. The Panel concludes that aluminum aspirin is safe but that there are insufficient data to recommend it as an effective OTC antipyretic in the recommended dosage of 365 mg to 730 mg every 4 hours while fever persists not to exceed 4,380 mg in 24 hours for not more than 3 days.

(1) Effectiveness. The Panel recommends that if bioavailability studies show that aluminum aspirin produces blood levels comparable to those achieved with aspirin, then it should be accepted as an effective OTC antipyretic and classified as Category I for this use.

The Panel recommends alternatively that if clinical trials show that aluminum aspirin is an effective antipyretic it should be placed in Category I for this use. (See part IV, paragraph C. below—Data Required for Evaluation.)

(2) Safety. The safety of aluminum aspirin has been discussed earlier in this document. (See part III, paragraph B.2.a.2 above—Safety.)

- Analgesic equivalence value. In addition, the Panel recommends the following specific labeling: (1) Warning: (a) "This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician.

(b) "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician.

(c) For oral product formulations to be chewed before swallowing: "Do nottake this product if you have aspirin allergy, tonsillectomy or oral surgery except under the advice and supervision of a physician.

(ii) Analgesic equivalence value. In the previous discussion on strength dosage on page 3513, the Panel made clear the need to indicate the quantity of aluminum aspirin per tablet, teaspoon or other dosage unit as well as the quan-
tity by which a particular product containing aluminum aspirin differs per dosage unit from the established standard of 325 mg (5 gr) aspirin. (See part II. paragraph E. above—Standard Dosage Unit and Analgesic Equivalence Values below.)

The Panel recommends that products containing aluminum aspirin be clearly labeled on the principal display panel: "Equivalent to X mg CX gr) per dosage unit of the established standard of 325 mg (5 gr) aspirin per dosage unit". The actual amount of "X" of equivalent analgesic effectiveness for the specific product shall be stated. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule. For example, a product containing 314 mg aluminum aspirin per tablet (dosage unit) shall be labeled: "Equivalent to 325 mg (5 gr) per tablet of the established standard of 325 mg (5 gr) aspirin per tablet".

5. Evaluation. Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for antipyretic drugs. (See part IV. paragraph C. below—Data Required for Evaluation.)

a. Antipyrine. The Panel concludes that there are insufficient data to determine the safety and effectiveness of antipyrene as an antipyretic adjuvant. In order to evaluate the role of salicylamide as an adjuvant for antipyretic drugs, the Panel concludes that salicylamide not be made available for OTC use at the higher dosage range until suitable studies have been completed to show both safety and effectiveness. In addition, the Panel has also considered the use of salicylamide in combination as an OTC antipyretic adjuvant in the currently marketed dosage of 97.2 to 400 mg. The Panel finds that salicylamide when used alone at a higher dosage (1,000 mg every 4 hours while fever persists not to exceed 6,000 mg in 24 hours for not more than 3 days) may be effective but has not been demonstrated to be safe for OTC use. However, the Panel recommends that salicylamide not be made available for OTC use at the highest dosage range until suitable studies have been completed to show both safety and effectiveness.

b. Antipyrene. The Panel concludes that there are insufficient data to determine the safety and effectiveness of antipyrene as an antipyretic adjuvant. In order to evaluate the role of salicylamide as an adjuvant for antipyretic drugs, the Panel concludes that salicylamide not be made available for OTC use at the higher dosage range until suitable studies have been completed to show both safety and effectiveness. In addition, the Panel has also considered the use of salicylamide in combination as an OTC antipyretic adjuvant in the currently marketed dosage of 97.2 to 400 mg. The Panel finds that salicylamide at a dosage of 1,000 mg every 4 hours while fever persists not to exceed 6,000 mg in 24 hours for not more than 3 days) may be effective but has not been demonstrated to be safe for OTC use. However, the Panel recommends that salicylamide not be made available for OTC use at the highest dosage range until suitable studies have been completed to show both safety and effectiveness.

c. Salicylamide. The Panel concludes that there are insufficient data to determine the safety and effectiveness of salicylamide as an antipyretic adjuvant in combination with acetaminophen or aspirin, and therefore classifies such combinations as Category III. The Panel has discussed the role of salicylamide as an adjuvant elsewhere in this document. (See part VI. paragraph B.5. below—Salicylamide.)

Salicylamide is a frequent component of analgesic mixtures. The average amount in these combinations is only about 200 mg which on the basis of previous discussion would appear to be ineffective.

REFERENCES


d. Salsalate (salcylsalicylic acid). The Panel concludes that salsalate (salcylsalicylic acid) is safe but that there are insufficient data to determine effectiveness as an OTC antipyretic in the recommended dosage of 500 to 1,000 mg every 4 hours while fever persists not to exceed 6,000 mg in 24 hours for not more than 3 days.

(1) Effectiveness. The Panel concludes that while this compound probably has antipyretic properties there is no clinical evidence to support this. The Panel recommends that if a clinical trial shows this compound to be an effective antipyretic, that it be classified as Category I for this use.

(2) Safety. The safety of salsalate has been discussed elsewhere in this document. (See part III. paragraph B.3.c.(2) above—Safety.)

(3) Proposed dosage. No marketed product containing salsalate alone was submitted to the Panel. Currently marketed products submitted contain 97.2 to 250 mg salicylamide per dosage unit in combination with other active ingredients.

The Panel finds that salicylamide at a higher dosage (1,000 mg every 4 hours while symptoms persist not to exceed 5,000 mg in 24 hours for not more than 3 days) may be effective but has not been demonstrated to be safe for OTC use. However, the Panel recommends that salicylamide not be made available for OTC use at the highest dosage range until suitable studies have been completed to show both safety and effectiveness.

For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(4) Labeling. The Panel recommends the Category I labeling for antipyretic active ingredients. (See part IV. paragraph B.1. above—Category I Labeling.)

(5) Evaluation. Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for antipyretic drugs. (See part IV. paragraph C. below—Data Required for Evaluation.)

(6) Combination products containing salicylamide combined with acetaminophen or salicylamide combined with aspirin. The Panel concludes that there is insufficient information to determine the safety and effectiveness of salicylamide as an adjuvant in combination with acetaminophen or aspirin, and therefore classifies such combinations as Category III. The Panel has discussed the role of salicylamide as an adjuvant elsewhere in this document. (See part VI. paragraph B.5. below—Salicylamide.)
following specific labeling: Analgesic equivalence value. In the previous discussion on “standard strength” dosage forms the Panel made clear the need to indicate the standard strength of the tablet, capsule, or capsule/tablet dosage form as well as the quantity by which a particular product containing salicylate differs from the standard quantity. For example, a product containing 500 mg salicylate per tablet (dosage unit) may be labeled, “Equivalent to 325 mg sodium salicylate per tablet”. The actual amount of “X” of equivalent analgesic effectiveness of the specific product shall be used. The term “dosage unit” may be replaced by the applicable dosage form such as tablet or capsule. For example, a product containing 500 mg salicylate per tablet (dosage unit) shall be labeled, “Equivalent to 325 mg sodium salicylate per tablet”. (See part II, paragraph E. above—Standard Dosage Unit and Analgesic Equivalence Value.)

The Panel recommends that products containing salicylate be clearly labeled on the principal display panel: “Equivalent to X mg per dosage unit of the established standard of 325 mg sodium salicylate per dosage unit”. The actual amount of “X” of equivalent analgesic effectiveness for the specific product shall be used. The term “dosage unit” may be replaced by the applicable dosage form such as tablet or capsule. For example, a product containing 500 mg salicylate per tablet (dosage unit) shall be labeled, “Equivalent to 325 mg sodium salicylate per tablet”. (See part II, paragraph E. above—Standard Dosage Unit and Analgesic Equivalence Value.)

(5) Evaluation. Data to demonstrate effectiveness in accordance with the guidelines set forth below for antipyrctic drugs. (See part IV, paragraph C. below—Data Required for Evaluation.)

CATEGORY III LABELING

The Panel concludes that the Category III labeling claims are sufficiently broad to encompass the entire beneficial effects that may be obtained by the use of aspirin, its salts, and other anti-inflammatory agents. However, the Panel concludes that these drugs should be used in the treatment of rheumatic diseases only under the advice and supervision of a physician. There are many reasons for the Panel taking this position. The reasons will be elaborated upon in greater detail below. Basically, each person with symptoms of the more common rheumatic diseases, e.g., joint and muscular aches, pains and stiffness, and joint swelling should seek the advice of a physician for proper diagnosis of the specific cause of the symptoms and for identification of the exact rheumatic disease involved. Each rheumatic disease is a distinct disease entity with a different cause and a different prognosis, and more importantly, each disease requires a different method of treatment.

As pointed out by the National Institute of Arthritis, Metabolism and Digestive Diseases (Ref. 1), “If you have arthritis, do not try to treat yourself. All forms of arthritis must be treated by a qualified physician.”

The Panel recognizes the remarkable properties of aspirin, its salts, and other salicylates in relieving pain and reducing inflammation. However, as pointed out by the Arthritis Foundation (Ref. 2), each individual is different; in a leaflet prepared for arthritis sufferers describing the use of aspirin the following is stated:

To establish Category I status for a Category III ingredient, the number of studies required for compounds, for which safety is unquestioned, and the number of studies required for compounds questioned because of safety, will be the same as outlined for Category III analgesic ingredients. (See part III, paragraph C. above—Data Required for Evaluation.)

All data submitted to the Food and Drug Administration must present both favorable and any unfavorable results.

5. Safety evaluation. An evaluation of the safety of an antipyretic ingredient should be based on the same studies and observations discussed earlier in this document for the safety evaluation of analgesics. (See part III, paragraph C.5. above—Safety evaluation.)

REFERENCE


V. ANTI-RHEUMATIC AGENTS

A. GENERAL DISCUSSION

1. Introduction. An antirheumatic agent reduces joint inflammation and relieves muscle tenderness and swelling. These agents are used in the treatment of arthritis and the rheumatic diseases.

Arthritis is man’s oldest known chronic illness. In the discussion that follows below, the Panel will describe arthritis and other rheumatic diseases.

As will be noted, the Panel has found aspirin, calcium carbamazepine, calcium salicylate, magnesium salicylate and sodium salicylate acceptable antirheumatic agents. However, the Panel concludes that these drugs should be used in the treatment of rheumatic diseases only under the advice and supervision of a physician. There are many reasons for the Panel taking this position. The reasons will be elaborated upon in greater detail below. Basically, each person with symptoms of the more common rheumatic diseases, e.g., joint and muscular aches, pains and stiffness, and joint swelling should seek the advice of a physician for proper diagnosis of the specific cause of the symptoms and for identification of the exact rheumatic disease involved. Each rheumatic disease is a distinct disease entity with a different cause and a different prognosis, and more importantly, each disease requires a different method of treatment.

As pointed out by the National Institute of Arthritis, Metabolism and Digestive Diseases (Ref. 1), “If you have arthritis, do not try to treat yourself. All forms of arthritis must be treated by a qualified physician.”

The Panel recognizes the remarkable properties of aspirin, its salts, and other salicylates in relieving pain and reducing inflammation. However, as pointed out by the Arthritis Foundation (Ref. 2), each individual is different; in a leaflet prepared for arthritis sufferers describing the use of aspirin the following is stated:
You are an individual, not quite like anyone else. Your arthritis is not quite like anyone else's arthritis. How much aspirin you need for your disease, and how much you can tolerate is a determined physician's decision. You make a serious mistake when you act as your own doctor and try to figure out your schedule.

On the basis of the above, and other data described below, the Panel concludes that the use of OTC antirheumatic agents for the treatment of the symptoms of specific rheumatic diseases requires prior diagnosis by a physician and the establishment of a suitable treatment program, which may include not only OTC antirheumatic drugs, but also prescription medications (e.g., gold, phenylbutazon, indomethacin, hydroxychloroquine, corticosteroids, etc.).

Physical therapy, exercise, devices (braces, splints, crutches, etc.) and reconstructive surgical procedures. The Panel is concerned that any labeling conditions promoting the use of OTC products for the treatment of rheumatic diseases mislead the consumer who attempts to self-diagnose and self-treat a serious disease. Terms such as “arthritis”, “rheumatism”, “pain of rheumatism”, “minor aches and pains” are misused by all individuals with these "minor" symptoms can self-medicate with OTC antirheumatic products with benefit to their condition.

Many of these OTC products contain the term “arthritis” in their trade name. The advertisements of these products promote the idea that all aches, pains and stiffness are both “minor” and due to a single disease entity when in fact these symptoms are present in individuals who have different rheumatic diseases. As will be discussed in detail below, many of these rheumatic diseases are very serious and are not amenable to treatment with the OTC antirheumatic products.

The Panel recommends that all OTC products containing salicylates contain the warning, "This product is not suitable for the treatment of arthritis only under the advice and supervision of a physician.

In addition, the Panel concludes that the nonsalicylate, acetylsalicylic acid, is not an effective OTC antirheumatic drug as described in this document. (See part V, paragraph B.2.a. below.) Therefore, the Panel recommends that all OTC products containing salicylates contain the warning, "This product is not suitable for the treatment of arthritis only under the advice and supervision of a physician.

In the discussion that follows, the basis for the Panel's concern for the protection of the consumer will become quite obvious.

The term rheumatism is derived from the Greek word rheumatismos which designated mucus (catarrh) as an evil humor that was thought to flow from the brain to the joints and other portions of the body. Rheumatic pain (Ref.3) is a rheumatic disease includes diseases of a wide variety that involve the joints and/or para-articular structures. The rheumatic diseases are associated with pain and stiffness of the musculoskeletal system and include diseases of the connective tissue.

Arthritis, which is one of the oldest known diseases, is the general term used for the joints themselves are the major cause of the rheumatic disease. However, in the United States believed they had arthritis (Ref. 4). Other types of rheumatic diseases involve muscles, tendons, ligaments, or bursae and are referred to as rheumatic diseases. When the joints themselves are the major symptom, the disease may play an important role in the patient's illness (Ref. 4). The common property shared by most of the diseases and syndromes is that of involvement of the joints (chiefly the synovial joints) and/or para-articular structures. In the United States, the three most prevalent rheumatic diseases are osteoarthritis, rheumatoid arthritis and gout. Each disease is different, with different causes and different prospects for recovery depending upon the type of treatment used. To illustrate the wide variety of known rheumatic diseases, many of which produce similar symptoms, requiring diagnosis by a physician, the Panel has included the American Rheumatism Association's classification of rheumatic diseases (Ref. 4) in the following table:
1. PROPOSED RULES

2. sensitivity 'angiitis, Wegener's granulomatosis, Takayasu's (puliseless) disease, Cogan's syndrome and giant cell arteritis (including polymyalgia rheumatica)).

3. E. Amyloidosis F. Others (see also rheumatoid arthritis, I. A. above; Sjogren's syndrome, VI. G. below).

4. III. RHEUMATIC FEVER

5. IV. DEGENERATIVE JOINT DISEASE (OSTEARTHRO-THETIC, OSTEOARTHRITIS)

6. A. Primary B. Secondary

7. V. NONARTICULAR RHEUMATISM

8. A. Fibroitis B. Intervertebral disk and low back syndromes C. Myositis and myalgia D. Tendinitis and periarticular (bursitis) E. Tenosynovitis F. Facitis G. Carpal tunnel syndrome H. Others (see also shoulder-hand syndrome, VII. C. below).

9. VI. DISEASES WITH WHICH ARTHRITIS IS FREQUENTLY ASSOCIATED


11. VII. ASSOCIATED WITH KNOWN INFECTIOUS AGENTS

12. A. Bacterial (gonococci, meningococci, pneumococci, streptococci, staphylococci, salmonella, brucella, streptobacillus moniliformis (Harverfell fever), mycobacterium tuberculosis, treponema pallidum (syphilis), treponema pertenue (yaws), and others) and others (see also rheumatic fever, III. above.)

13. B. Rickettsial

14. C. Viral (Bubella, Mumps, Viral hepatitis, and Others)

15. D. Fungal

16. E. Parasitic

17. VIII. TRAUMATIC AND/OR NEUROGENIC DISORDERS

18. A. Traumatic arthritis (the result of direct trauma)

19. B. Neuropathic arthritis (Charcot joints syndrome), synovitis (tarsal coalon), diabetes mellitus (diabetic neuropathy), syringomyelia, myelomingingocele, gonadal insensitivity to pain (including familial dysautonomia) and others

20. C. Shoulder-hand syndrome

21. D. Mechanical derangement of joints E. Others (see also degenerative joint disease, IV. above; carpal tunnel syndrome, V. G. above.).

22. IX. ASSOCIATED WITH KNOWN OR STRONGLY SUSPECTED BIOCHEMICAL OR ENDOCRINE ABNORMALITIES

23. A. Gout B. Chondrocalcinosis articularis ("pseudo-gout")

24. C. Alkaptonuria (ochronosis)

25. D. Hemophilia

26. E. Sickle cell disease and other hemoglobinopathies

27. F. Psammomulbain sensicia (hypogammaglobulinemia) E. Gaucher's disease G. Gaucher's disease

28. H. Hyperparathyroidism

29. I. Acromegaly J. Thyroid acropathy

30. K. Hypothyroidism L. Scurry, hypovitaminosis C.

31. M. Hyperlipoproteinemia type II (xanthoma tuberculoidum and tendinosum).

32. N. Fabry's disease (angiokeratoma corporis diffusum or lipogranuloid lipidosis).

33. O. Hemochromatosis P. Others (See also inherited and congenital disorders, XII. below).

34. X. NEOPLASMS

35. A. Synovial tumors and neoplasms (including polyostotic fibrous dysplasia and chondroblastoma).

36. B. Primary juxta-articular bone tumors C. Metastatic malignant tumors D. Leukemia E. Multiple myeloma F. Benign tumors of articular tissue G. Others (See also hyperneoplastic osteoarthropathy, X. below).

37. XI. ALLERGY AND DRUG REACTIONS

38. A. Arthritis due to specific allergens (e.g., serum sickness)

39. B. Arthritis due to drugs

40. C. Others (See also systemic lupus erythematosus, I. above for drug-induced lupus-like syndromes, e.g., hyalurazine and procainamide syndromes; hyper-neoplastic osteoarthropathy, X. above).

41. XII. INHERITED AND CONGENITAL DISORDERS

42. A. Marfan syndrome

43. B. Homocystinuria

44. C. Ehlers-Danlos syndrome

45. D. Osteogenesis imperfecta

46. E. Pseudoxanthoma elasticum

47. F. Cutis laxa

48. G. Mucopolysaccharidosis (including Hurler's syndrome)

49. H. Arthropoglojus multiplex congenita

50. I. Hypermobility syndromes

51. J. Myatosis (or fibrosediasia) osteomas progressiva

52. K. Tumoral calcinosls

53. L. Werner's syndrome

54. M. Congenital diplasia of the hip N. Others (See also arthropathy associated with known biochemical or endocrine abnormalities, IX. above.).

55. XIII. MISCELLANEOUS DISORDERS

56. A. Pigmented villonodular synovitis and tenosynovitis

57. B. Ebecht's syndrome

58. C. Erythema nodosum

59. D. Relapsing pancreatitis (Weber-Christian disease)

60. E. Avascular necrosis of bone

61. F. Juvenile osteochondritis

62. G. Osteochondritis dissecans

63. H. Erythema multiforme (Stevens-Johnson syndrome)

64. I. Hypertrophic osteoarthropathy

65. J. Multicentric reticulohistiocytosis

66. K. Disseminated lipogranulomatosis (Farber's disease, Faber's disease).

67. L. Familial lipochromie pigmentary arthritis

68. M. Tietze's syndrome

69. N. Trombophlebitis thrombocytopoietic purpura

70. O. Others

71. 3. Incidence of rheumatic diseases. Many different population studies have been conducted to determine the incidence of rheumatic diseases. However, as pointed out by Hollander (Ref. 3): Large scale surveys are inaccurate because they depend on answers to set questions, permitting guesswork by the people surveyed. Smaller population samplings, with strict diagnostic criteria and medical examination, are far more accurate but represent such a local segment that doubt is thrown on the projection of the figures to cover the general population. In spite of the handicap, the realization that rheumatic diseases form a tremendous segment of chronic disability all over the world has become more widespread in recent years.

72. The impact of these diseases in the U.S. is discussed elsewhere in this document. (See part V. paragraph A. 5. below—Economic and social impact of rheumatic diseases in the U.S.) On the basis of a U.S. survey (Ref. 7), Hollander (Ref. 3) further states that: From the National Health Survey figures it appears that 23 percent of those having rheumatic disease were limited in their activities, and 10 percent were grossly disabled. This means that more than a million persons are rendered unemployed by arthritis and rheumatism.

73. About 27 million work days are lost annually because of arthritis. About 1 in every 9 chronically housebound invalids had arthritis. Arthritises and rheumatism were the second greatest cause of chronic limitation of major activity with a relative incidence of 16 percent. Heart disease, with an incidence of 17 percent, was the only disease group exceeding arthritis.

74. Although arthritis cripples a tremendous number of persons each year, it kills relatively few. There is no other group of diseases which causes so much suffering by so many for so long. Because of the tendency to cripple without killing, arthritis and rheumatism belong at the head of the list of chronic diseases from the standpoint of social and economic importance.

75. The Panel finds that the insidiousness of this group of diseases makes it all the more important that extraneous factors be eliminated so as not to result in delayed diagnosis or treatment. Factors which allude to arthritis as a "minor disease", such as the misrepresentation that the alleviation of symptoms, e.g., joint and muscle pain or stiffness with "extra strength aspirin" or other salicylates will control the disease, are clearly misleading.

76. According to the Arthritis Foundation (Ref. 8), the incidence of the most common rheumatic diseases in the United States during 1974 (the latest figures available) is as follows:

77. Incidence of rheumatic diseases in the United States during 1974

78. Number of persons

79. Rheumatic disease: (million)

80. Osteoarthritis

81. 12

82. Rheumatoid arthritis

83. 5

84. Gout

85. 1

86. Systemic lupus erythematosus

87. 4.100.5

88. Juvenile rheumatoid arthritis

89. 0.25

90. Since the above listed diseases are the most prevalent, the Panel has included a more detailed description of their clinical features and the recommended treatment program below. As will be evident from the discussion, adequate treatment requires the advice and supervision of a physician.

91. 4. Comments on the more common rheumatic diseases in the U.S. a. Osteoarthritis.—(1) Clinical features—Osteoarthritis (degenerative joint disease) is a very common disease especially among elderly individuals. It probably begins as degeneration of joint cartilage in all people by the end of their second decade of life. It is rarely accompanied by evidence of inflammation in and around the joints, yet pain and swelling of the joints are present due to destruction of

92. FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

93. 35455
PROPOSED RULES

the vertebral bodies) which are diarthrodial self-medicate for degenerative disease of the joints; and the intervertebral articulations which constitute an synovial process known as a synovial process. Symptoms of osteoarthritis of the hip include localized pain and stiffness and radiating pain to the hip. Spontaneous remissions and exacerbations occur. Slight pain and tenderness of the neck may also be involved frequently.

Twenty-three percent of those persons having osteoarthritis have moderate or severe disease (Ref. 10).

Clinical features of the disease (Ref. 11) include joint sounds (crepitus) with crunching feeling in the joint, atrophy of the surrounding muscles, limitation of motion, malalignment of the extremity and changes in the shape of the joint which are detectable on physical examination. Tenderness to palpation may be observed, but signs of inflammation are relatively uncommon, except the joint may be present after episodes of trauma following overly vigorous usage of the involved joint.

The Primer on the Rheumatic Diseases has described the clinical features and course (Ref. 11):

Special forms of degenerative disease involve particular joints in a characteristic manner. (Bony nodes, termed Heberden's nodes, are common.) These consist of a deforming bony protuberance at the margins and on the dorsal surface of the distal interphalangeal joints (joint next to the nail) of the fingers, and are often associated with flexion and angulation of the distal phalanx. Local pain and tenderness with some warmth may be present early in the course of their development. Heberden's nodes are more frequent in women, tend to occur in families, and are often associated with degenerative changes in other joints, although the association is not invariable. Involvement of the proximal interphalangeal finger joints (Bouchard's nodes) is not at all uncommon in osteoarthritis and may rise to confusion with rheumatoid arthritis.

Degenerative disease of the hip, although less common than knee disease, is the most disabling form of osteoarthritis.* Pain on motion or weight-bearing is the main complaint, usually begins progressively more severe and is often referred to the groin or to the medial (inner) side of the knee. Later, the pain may become continuous, and be especially difficult to bear at night. On physical examination there is a global loss of range of motion of the involved hip.*

The changes (in the knee) may involve the softening of the posterior surface of the patella (kneecap) and its adjacent patellar ligament as well as the weight-bearing surfaces of the femoral and tibial condyles. The former is often observed in young persons and is considered by many to be related to trauma. Degenerative disease of the knees is most commonly observed in women and is associated with loss of motion, crepitus, and flexion deformity.

Degenerative disease of the spine affects two distinct regions: The degenerative changes in the vertebral arch (and, in the case of the cervical vertebrae, between the vertebral bodies) which are diarthrodial行

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

Aspirin, in moderate dosage (Ref. 12), "Active treatment may retard the course of degenerative disease progression and is of further value in protecting contralateral joints which may be exposed to increased stress." Thus, it is apparent that such active treatment as described below is desirable in patients with self-medication for a long period of time for the relatively minor symptoms, such as pain and stiffness, without consulting a physician and, therefore, are subject to disease progression which can be retarded by proper medical management.

(2) Treatment. The management of osteoarthritis is dependent on the aetiological factors involved and the degree of joint involvement. The joint destroyed by a degenerative process, but disability can be minimized. The principal objectives of treatment are the relief of pain, restoration of function, the prevention of avoidable disability, and the prevention of disease progression. Diagnosis by a physician and continued medical supervision in preventing the development of unnecessary disability is therefore essential. Since the degree of disability and the extent of joint involvement may vary among patients, the treatment must be individualized by a physician.

Orthopedic surgical management is often effective in severe cases. This is the only rheumatic disease affecting a large portion of the population in which aspirin is used as an analgesic rather than as an antipyretic. Therapy. Proper medical management includes not only analgesic therapy but such modalities as physical therapy, orthopedic devices, weight reduction if necessary and possible orthopedic reconstructive surgery which may be extremely effective in severe hip disease. Many patients accept pain as inevitable. Many individuals, who self-medicate for degenerative disease of the hip, could be totally relieved of the pain and disability they endure, and in addition, prevent degenerative changes if they went to a physician for treatment of their arthritis.

The use of corticosteroids has been shown to retard the development or progression of degenerative joint disease (Ref. 13). Pharmacologic agents play a relatively minor role in the management of osteoarthritis. As has been noted in the Primer on the Rheumatic Diseases (Ref. 14):

It remains to be determined whether drug therapy can slow the development or progression of osteoarthritis. As has been noted in the Primer on the Rheumatic Diseases (Ref. 14):

It has been stated by Christian (Ref. 13):

Corticosteroids should not be used with the exception of intra-articular injections which may provide relief of pain for several weeks and permit graded exercises to be started with less discomfort. Repeated injections of corticosteroids should be avoided. However, as the course of the degenerative process is not changed and may even be accelerated, there is no reason to continue and thus unwittingly contribute to the progressive degeneration of their joint disease.

The Primer on the Rheumatic Diseases (Ref. 14) also notes that:

Corticosteroids should not be used with the exception of intra-articular injections which may provide relief of pain for several weeks and permit graded exercises to be started with less discomfort. Repeated injections of corticosteroids should be avoided. However, as the course of the degenerative process is not changed and may even be accelerated, there is no reason to continue and thus unwittingly contribute to the progressive degeneration of their joint disease.

It remains to be determined whether drug therapy can slow the development of degenerative joint disease, although there are some interesting preliminary findings from experimental studies. Some seem to reduce the development of degenerative changes in scarified cartilage in rabbits and there is an extract of calf cartilage which has been shown to stimulate cartilage proteoglycan and chondroitin by articular cartilage.

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(11) Physical measures and surgical management. The use of drugs is only one method of treatment. Osteoarthritis is treated by several methods in an attempt to relieve pain, restore joint function and prevent avoidable disability or progression of the disease. The Panel refers to the statement in the Primer on the Rheumatic Diseases (Ref. 14), "It is helpful to emphasize the value of continued medical supervision in preventing the development of unnecessary disability."

Hence, the disability that results from the disease can be minimized by a physical therapy program and by orthopedic surgical treatment. The two general goals in the design of a physical medicine program for degenerative joint disease are minimizing the forces of work and weightbearing that apply to musculoskeletal system.

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fect joints, and maintenance of normal joint alignment and motion. Christian recommends that:

General physical measures include daily periods of rest and support during recumency, particularly in spondylitis (patients with spinal disease in which case a good mattress with underlying board is needed. When weight-bearing joints are affected, local support is of great value, including the use of casts, crutches, or other mechanical devices. Avoidance of unnecessary walking and stair-climbing, wearing of proper shoes, rest or building a platform one side of a shoe to shift the line of weight-bearing often prove helpful. Correction of abnormal posture is done the type of snugness this is more effective before advanced disease has developed. Weight reduction is advised when indicated, although not often accomplished. Local measures include heat and specific exercises designed to avoid or correct muscle atrophy, since weakness aggravates joint instability. This is useful when there is muscle spasm, particularly for hip or cervical vertebral disease. Pain is relieved by wearing a cervical collar.

It is clear to the Panel that these measures will not be undertaken unless the patient is under medical care. A self-medicating patient will obviously not receive adequate treatment for his disease even though their pain may be relieved by OTC doses of analgesics.

As has been described in the Primer on the Rheumatic Diseases (Ref. 14):

In adults, surgical treatment is often necessary for persistent pain and the correction of serious deformity. Obviously, many considerations influence the selection of procedures. The type of surgery to be performed is determined by the extent of the disease, the position of the patient, and the results of physical examination. Thus, it is important to note that the patient must be able to cooperate physically and emotionally with the necessary postoperative rehabilitation. If a good end result is to be achieved, surgical treatment of osteoarthritic joints includes (1) debridement; (2) arthrodesis (joint fusion); (3) arthroplasty (the formation of a prosthetic articulating surface); (4) osteotomy (a general term for section of bone to alter weight-bearing surfaces); and (5) total joint replacement. Specific procedures usually have predictable end-results with respect to pain relief, mobility, and deformity. However, if the procedure is selected with this knowledge in mind. Thus, intertrochanteric osteotomy for osteoarthritis involves the hip joint; the case of early disease when relatively good motion (at least 60° to 70° of flexion) is present. With early severe osteoarthritis, hip prosthesis, or with the recently developed and highly encouraging total hip replacement, pain relief is often obtained with good stability and mobility. Surgery for knee disease is perhaps less well defined, but there are patients who benefit markedly from high tibial osteotomy, patelloplasty and debridement, interposition arthroplasty, or arthrodesis. Rarely does spondylitis of the thoracic or lumbar spine require surgical intervention. Occasionally, however, resection of cervical osteophytes or cervical arthrodesis is necessary to relieve impingement on neural or spinal cord.

(3) Summary and conclusions. Osteoarthritis is an extremely common rheumatic disease affecting more than 6 percent of the U.S. population. Hip disease alone affects 175,000 Americans aged 64 or older. The Panel concludes that self-medication with analgesics by these patients is undesirable because they will thus deny OTC dose and proper medical management. Self-medicating patients will not receive proper treatment for their disease because they will not receive treatment such as physical therapy, arthrocentesis, and surgical management by physicians may arrest further disease progression whereas patients who self-medicate, only relieve their joint pain temporarily, while allowing their diseased joint to progressively degenerate.

b. Rheumatoid arthritis. (1) Clinical features.—The second most common rheumatic disease is rheumatoid arthritis which affects 3 percent of the female population and 1 percent of the male population (Ref. 15). The disease occurs in both adults and juveniles. Juvenile rheumatoid arthritis begins before the age of 16 and can occur as early as 6 weeks of age. The disease is characterized by inflammation of the synovial joints (movable joints which possess a cavity and are lined by a synovium or joint lining which is a specialized connective tissue). Inflammation of the synovium results in pain, swelling, tenderness and may lead to limitation of the motion of the involved joints. Such joints may become eroded by the inflamed proliferating synovium and this process may eventually lead to severe destruction of the joint.

The clinical features of the disease are described in the Primer on the Rheumatic Diseases (Ref. 16) as follows:

Rheumatoid arthritis is defined clinically by joint involvement but this is often preceded by constitutional symptoms, and, in children particularly, by "unexplained" high fever. In the majority of cases the onset is insidious, with aching and stiffness often poorly localized to joints. This followed by the gradual appearance of frank articular inflammation in the form of pain, swelling, redness, warmth, and tenderness. Stiffness of the joints, particularly noticeable on awakening in the morning, is a regular and often prominent early complaint.

The characteristic morning stiffness of patients with rheumatoid arthritis is very common in these patients. The Panel concludes that advertisements which promise relief from morning stiffness may give these consumers the belief that the OTC dose of aspirin is the recommended therapy for their symptoms. The Panel is concerned that both the labeling and mass media advertising (through television and magazines), primarily directed toward women and the elderly, give the consumer the misleading impression that aspirin in the OTC dose is the therapy of choice for individuals with OTC dose of aspirin is the recommended therapy for their symptoms. The Panel is concerned that both the labeling and mass media advertising (through television and magazines), primarily directed toward women and the elderly, give the consumer the misleading impression that aspirin in the OTC dose is the therapy of choice for individuals with OTC dose of aspirin is the recommended therapy for their symptoms. The Panel is concerned that both the labeling and mass media advertising (through television and magazines), primarily directed toward women and the elderly, give the consumer the misleading impression that aspirin in the OTC dose is the therapy of choice for individuals with OTC dose of aspirin is the recommended therapy for their symptoms. The Panel is concerned that both the labeling and mass media advertising (through television and magazines), primarily directed toward women and the elderly, give the consumer the misleading impression that aspirin in the OTC dose is the therapy of choice for individuals with OTC dose of aspirin is the recommended therapy for their symptoms. The Panel is concerned that both the labeling and mass media advertising (through television and magazines), primarily directed toward women and the elderly, give the consumer the misleading impression that aspirin in the OTC dose is the therapy of choice for individuals with OTC dose of aspirin is the recommended therapy for their symptoms.

The Panel concurs with the above statement regarding the need for evaluation by a physician in the early stages of the disease. However, in some cases, experience relief of pain, they may tend to con-
tinue to self-medicate intermittently for a prolonged time at intervals for 10-day periods as stated in the OTC labeling. In the early stages of the disease, the OTC dosage may give relief of pain for the period of three to four days. It is taken. The patient will not seek out a physician because the pain will have been relieved. The Panel is also aware that at least three-quarters of the patients with rheumatoid arthritis who have the symptoms of the disease for less than 1 year will improve for a time, and that 15 to 20 percent may show a complete remission (Ref. 19). Such remission would only tend to reinforce the belief by the consumer that aspirin and the salicylates are completely effective for this disease. Clearly, it is the Panel's conclusion that the patient should be seen by a physician so that an adequate dosage of aspirin or other salicylate can be recommended along with appropriate physical therapy or other measures discussed above. The Panel concurs with the statement of the Rheumatic Disease Association that in the early stages of the disease is important (Ref. 16) and considers that self-medication is to be avoided even at the early stage of disease.

The patient should not self-medicate because an adequate physical examination and history of the disease should be made by a physician. In addition, the physician brings the patient to the diagnosis of rheumatoid arthritis if he is experienced in dealing with patients with this disorder. The physician will perform a thorough evaluation of all joints for swelling, heat, synovial thickening, deformities, and note the range of motion of all joints. All the tests should be recorded for future reference, and laboratory tests may be needed. Mild anemia and an elevated erythrocyte sedimentation rate are often observed with active rheumatoid arthritis. A number of tests rule out systemic lupus erythematosus may be employed since this disease is infrequent has an onset similar to rheumatoid arthritis. If fluid is present within the knee or another single large joint, analysis of the fluid may be done to rule out infection. The physician inserts a needle into the knee and withdraws fluid which can be examined for crystals, calcification of gouty arthritis and a culture can be obtained to determine whether or not the swollen knee is due to an infection of the joint.

Clearly, the patient with a single swollen knee cannot determine the cause of the swelling. The most common diseases are those discussed above, i.e., osteoarthrosis, and rheumatoid arthritis. These two conditions cannot be distinguished by the patient. Since the treatment of the two diseases, the prognosis, and the management are different, it is to the patient's advantage to seek medical advice rather than to self-medicate. Since infectious arthritis is frequently present as a single swollen knee, the patient may be harmed by self-medication for this disease. The Panel concurs with the following statements made in the Primer on the Rheumatic Diseases (Ref. 18):

- Clearly, the major concern on the part of the patient as well as the physician is not for a mild arthritis that may last for a few weeks or months and leaves no impairment. Rather, the difficult problem is recurrent or sustained disease, in which, over the course of a few to many years, there is an increasingly serious and permanent disturbance in function. At some point in time one finds swollen, boggy joints that are the result of intra-articular effusion, edema of periarticular structures, and particularly the overgrowth of the hyperplastic synovial membrane and variable degrees of periarticular lesions.

- The joint deformities which develop in rheumatoid arthritis are thought to originate in muscle spasm, the flexors maintaining involuntary contracture, with accompanying extensor relaxation, such as occurs reflexly with injury of the extremity. Inflammation and subsequent edema cause the capsule, tendons, and musculotendinous apparatus to lead to fixed deformity. Subluxation, or the slipping of one articular (joint) surface past the other, is usually preceded by erosion of cartilage and bone and destruction of soft tissues, particularly ligaments and tendons. Among the most characteristic deformities in the hand are an ulnar drift or deviation of the fingers, subluxation (dislocation) of the metacarpophalangeal joints, and enlargement of the proximal interphalangeal joints. More disabling is the "boutonniere" deformity in which the proximal interphalangeal joint is forced through the extensor hood like a button through the buttonhole.

- Any diarthrodial joint (moveable joint) may be affected in rheumatoid arthritis. Rheumatoid (and other) effusions of the knee may be complicated by the development of large popliteal cysts, (Baker's cyst) that often extend into the calf. Serious, indeed life-threatening complications may occur from involvement of the atlanto-axial (one of the neck) joints leading to subluxation and spinal cord compression with sensory and/ or pyramidal signs and disease of the coccycgeal joint of the larynx, which, when fixed with the vocal cords ab ducted, can cause laryngeal obstruction.

- The joints most frequently involved are those at the fingers, knees, wrists, ankles, shoulders, elbows, and hips although any joint may be affected. The course and prognosis depend on several factors. Laboratory tests are often required.

The Primer on the Rheumatic Diseases also makes the following observations (Ref. 19):

- The combination of typical joint deformities, subcutaneous nodules, and high titers of rheumatoid factor constitute a classic disease. After observing a patient with active rheumatoid arthritis, the physician (can) evaluate the prognosis and discuss this cautiously yet realistically with the patient. A poor prognosis, in respect to joint function involving disease of more than one year's duration, age below 30 when the patient is first seen by a physician, sustained disease, and the presence of subcutaneous nodules and high titers of rheumatoid factor.

With regard to the long-term outlook for patients followed for periods of many years, based on the course of diseases seen in various arthritis clinics, the Primer on the Rheumatic Diseases notes that about 50 percent of the patients are in the "stationary" or "improved" categories after 10 years (Ref. 19).

It also goes to note:

Without an improvement by this time, there is little likelihood of recovery, and thereafter more patients begin to appear in the "worse" category. Nevertheless, it should be noted that in observations extending for 10 to 15 years, 50 percent to 70 percent of the patients remained capable of full-time employment and that after 15 to 20 years those completely incapacitated constituted only about 10 percent of the group.

(2) Treatment. In planning a treatment program for the patient with rheumatoid arthritis, the Primer on the Rheumatic Diseases states that the physician should be guided by the following factors (Ref. 20):

- (1) the status of joint function, particularly range of motion, with respect to the patient's ability to function in all areas of life; (2) the patient's experience of disease activity, from slight, with mild complaints confined to a few joints, to most severe, with extra-articular manifestations especially vascular; (3) (the use of antiarthritis medications except aspirin, the patient's advantage to seek medical advice rather than to self-medicate. In judging the stage of disease and the degree of the patient's disability in estimating and reporting response to treatment, it is helpful to utilize criteria for the classification of progression of rheumatoid arthritis and of functional capacity developed for these purposes by a committee of the American Rheumatism Association.

- (See part V. paragraph 2. above—Classification of rheumatoid arthritis.)

The Panel believes that conservative measures should be used at the outset of treatment and continued as long as indicated. In addition, the Panel concurs with the following statement made in the Primer on the Rheumatic Diseases (Ref. 19):

When discussing the nature of the disease with the patient who has had arthritis of a few weeks to months' duration the prudent physician avoids promises of quick relief or cures, and usually refrains from prescribing any antiarthritis medication except aspirin. This is a strong opinion, and clearly a personal one, but appears to be the prevailing view of those experienced physicians who have treated patients with this disorder for many years. There is no cure for rheumatoid arthritis, there is no certain way to arrest or produce a remission of disease. There is no evidence that the more potent drugs can relieve symptoms fully and regularly. On the other hand, there is ample evidence that if such agents temporarily ameliorate joint complaints, severe rebound of inflammation may occur when they are withdrawn.

The Panel has heard expert testimony of physicians brought in by the drug industry (Ref. 20). It was stated
by industry spokesmen that arthritic patients will be better off self-medicating than going to the physician because the physician will treat them with corticosteroids. However, the Panel concurs with the statement in the Primer on the Rheumatic Disease (Ref. 21), "Aspirin is the mainstay of therapy." In addition, the Panel concurs with the following statement (Ref. 21):

Adults should take a total of at least 3.6 gm of aspirin per day, in divided doses after each meal and before bedtime; often 4.8 gm per day or more will be tolerated without gastrointestinal, loss of appetite, acid, or tinnitus. With active disease aspirin should be taken on a regular daily basis rather than at will. There is considerable variation from person to person in the plasma level of salicylate produced by a constant quantity of it as is necessary to think in terms of a "standard" dose. If need be, each patient should be given increasing amounts of aspirin to tolerance (Ref. 21). Adults who have shown a much higher tolerance to the side effects of aspirin than do the elderly.

In order to achieve anti-inflammatory efficacy, a higher daily dose and a much more prolonged administration is required than that which is required for analgesic efficacy. Since the dose and duration of therapy should be regulated for analgesic efficacy, a higher daily dose and a much more prolonged administration is required than that which is required for ant-inflammatory efficacy, a higher daily dose and a much more prolonged administration is required than that which is required for ant-inflammatory efficacy. Individuals with inflamed joints who self-medicate with aspirin or other salicylates to relieve the pain without consulting a physician will probably take daily dosages which will achieve analgesia but will not produce an anti-inflammatory effect. Such individuals will suffer continuous deterioration of their inflamed joint conditions unless they consult a physician for proper diagnosis and treatment. The daily dosage of aspirin or other salicylates needed to produce an anti-inflammatory effect may vary between patients and is frequently far above the OTC analgesic dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effects.

c. Gout. (1) Clinical features. Another common condition is a rheumatic disease associated with a biochemical abnormality, i.e., gouty arthritis. Acute gouty arthritis is more prevalent among males (Ref. 23).

The Primer on the Rheumatic Diseases (Ref. 21) notes that:

At all stages of the disease physical measures must be considered in the comprehensive program of management. Local application of heat by means of moist compresses or infrared irradiation, followed by directed exercises, is often helpful in relieving joint pain and muscle spasm. These exercises are designed to preserve the range of motion of joints and to strengthen muscles.

The cooperative efforts of professional personnel in orthopedic surgery, rehabilitation medicine, and physical therapy are necessary to ensure recovery. By individualizing the physical measures according to the needs of the patient, the physician can be of the greatest help in the management of arthritis.

At the present time the most effective and widely used of all medical measures is the use of salicylates. Salicylates at very low dosage levels as analgesics and as anti-inflammatory agents are the mainstay of therapy. The treatment of rheumatoid arthritis requires the administration of aspirin or other salicylates at high dosage levels that will achieve an anti-inflammatory therapeutic effect. Such daily dosages are higher and require more prolonged use than is needed for self-medication. Individuals with inflamed joints who self-medicate with aspirin or other salicylates need to relieve the pain without consulting a physician will probably continue on the same dosage for several years. The high dosage levels that will achieve analgesia but will not produce an anti-inflammatory effect. Such individuals will suffer continuous deterioration of their inflamed joint condition unless they consult a physician for proper diagnosis and treatment. The daily dosage of aspirin or other salicylates needed to reach an anti-inflammatory effect may vary between patients and is frequently far above the OTC analgesic dosage level. Only a physician can individualize the salicylate dosages needed for anti-inflammatory effects.

Gout is a disease of ancient lineage which is characterized by recurrent episodes of violent arthritis associated with the presence of monosodium urate monohydrate crystals in the synovial fluid (fluid in the joint space), and in many cases, the eventual appearance of gross uric acid deposits called tophi (deposits of uric acid crystals) in and about the joints, in the kidneys and in certain subcutaneous sites. Gouty arthritis is a complication of prolonged hyperuricaemia (high blood uric acid levels), the origin of which is frequently found to be markedly diverse. Hyperuricemia is the result of a heritable error of metabolism leading to low retention of uric acid due to abnormalities in purine biosynthesis and/or renal excretion of uric acid. Acute gout is a type of arthritis characterized by swelling and tenderness of joints. This acute attack is followed by low-grade fever and leukocytosis which often accompany the attack frequently give rise to the mistaken impression of cellulitis or thrombophlebitis.

In the United States uric acid stones (calculi) represent about 10 percent of all urinary calculi. Such stones account for approximately 15 to 20 percent of all patients with gout. Patients with gout have a high frequency of arterial hypertension (high blood pressure) and kidney malfunction than do nongouty individuals and are often found to have nephrocalcinosis. Fibrinoid arthritis associated with urate deposits in the tissues of the kidney and obstruction by stone may contribute to the renal disease.
treatment of gouty arthritis must clearly be carried out by a physician.

(2) Treatment. Treatment of this form of arthritis is based firstly on an accurate diagnosis. Once the physician has made the diagnosis, treatment aimed at (1) control of the acute joint inflammation and (2) prevention of future attacks and the long term reduction in hyperuricemia should be considered. The objectives of treatment cannot be avoided by patients taking these drugs or by self-medication with aspirin since they will suppress pain and may also suppress signs of arthritis. This may lead to their not seeking care from a physician and therefore may lead to the infection leading to venereal disease to others during the period of self-medication, increased risk of gonococcal arthritis due to self-medication, and the possibility of significant restriction of joint function due to permanent damage to the joint because of delay in diagnosis and therapy. Sharp describes two patients who had permanent damage to infected wrists due to delay in treatment for 18 and 28 days (Ref. 34). He states "diagnostic studies should be completed with haste and treatment commenced as soon as possible, and have been obtained to minimize the risk of residual articular damage." Although no severe joint damage may occur in patients with gonococcal arthritis who self-medicate with aspirin for less than 10 days, such individuals are clearly not receiving adequate treatment. Some loss of joints (cartilage) space and lytic changes in bone may be noted within 1 to 2 weeks after onset of infection. It is important that "effective treatment of septic arthritis requires early recognition, prompt arthrocentesis and the administration of antibiotic therapy as soon as possible, and sensitivity tests on the infection organism. Treatment should be initiated as soon as adequate cultures are obtained and altered as required after the antibiotic sensitivities are available." (Ref. 35).

e. Other diseases—(1) Rheumatic fever. Rheumatic fever is a serious illness manifested by arthritis, and involves the heart and other organs. Prophylaxis is recommended for all patients. Involvement of the heart particularly during the acute phase of the disease may occasionally have fatal consequences. Rheumatic fever is an in-
flamatory disease which occurs as a sequel to infection with group A streptococci (Ref. 36). Salicylates are of considerable value in controlling the toxic manifestations, in contributing to the comfort of the patient, and in combating anemia and other constitutional symptoms (Refs. 37 and 38). Salicylates, usually aspirin, are given in an initial daily dose of approximately 0.1 g/kg of body weight or 6 to 8 g in children up to 6 to 8 g in adults, trying to achieve a plasma salicylate level of 35 to 30 mg/100 ml. (Compared to an OTC analgesic dosage limit of 4 g/24 hours for aspirin). The symptoms of rheumatic fever typically appear as an acute polyarthritis (swelling and pain of the joints) which may subside in one joint after a few days only to appear in another joint (migratory polyarthritis). Fever is a frequent accompanying feature of the disease. It is entirely possible that where fever is not present or is of low grade, an individual who has unknowingly contracted rheumatic fever may treat the arthritic symptoms with OTC analgesic products. The illusion of having success is reinforced when the symptoms disappear. When the arthritic symptoms reappear in another joint (migratory polyarthritis), aspirin or other salicylates are again, ingested by the consumer. During this period the disease progresses to include the serious and, perhaps, permanent heart manifestations described above. It is clear that patients with this type of arthritis should prompt prompt physician consultation and care. The physician's care and should not self-medicate with aspirin even for 10 days.

(2) "Connective tissue" disorders. Another group of rheumatic diseases is the "connective tissue" diseases which are acquired rather than congenital diseases. These disorders include systemic lupus erythematosus, progressive systemic sclerosis, polymyositis, necrotizing arthritis, and other forms of vasculitis and are serious disorders which may be life-threatening. These patients must be diagnosed and treated. This is particularly important since some of these patients may have severe kidney disease that is usually asymptomatic. Urine and blood chemistry studies are essential for diagnosis and subsequent assessment of the patient's status and response to treatment.

(3) Miscellaneous diseases. Other diseases which may be associated with arthritis may be classified as fibrositis, low back syndromes, myositis, tendonitis and others. These more common complaints which may be acutely painful, however, must be distinguished by a physician from other more serious and life-threatening conditions as described above. For example, gonococcal arthritis may be associated with tendinitis due to infection with gonococci. Myositis may occur in systemic lupus erythematosus and polymyositis and gout may involve bursa leading to acute bursitis.

A variety of miscellaneous disorders also involve joints and should also not be treated by the consumer without the care of the physician and should not self-medicate. These disorders include viliillar nodular synovitis, Behcet's Syndrome, erythema nodosum, avascular necrosis of the bone and others.

Serious traumatic and nonregenerative disorders involving joints should also be treated under the care of a physician. Diseases other than gout with known or strongly suspected biochemical or endocrine cause, are serious disorders which may be life-threatening. These patients must be diagnosed and treated. This is particularly important since some of these patients may have severe kidney disease that is usually asymptomatic. Urine and blood chemistry studies are essential for diagnosis and subsequent assessment of the patient's status and response to treatment.

The Panel concludes that it is absolutely essential that the individual seek proper medical attention when arthritis is suspected. It is essential that the individual consult with a physician for medical care. They stated:

- In 1973, a report of the Arthritis Foundation where it was concluded that most individuals with rheumatic disease go untreated or delay medical care. They stated: Of the more than 20 million individuals afflicted with rheumatic diseases, well over 12 million are not receiving medical care, even though many of these experience some degree of disability.

- Other arthritic diseases are of such severity that the individual seek proper medical advice as early as possible. Because symptomatic self-medication for arthritis of unknown etiology may lead to some instances to some relief of pain and yet allow the disease to progress, the Panel recommends that aspirin and aspirin-containing agents not be labeled for the treatment of arthritis. The use of aspirin and aspirin-containing products as antirheumatic agents is not recommended.

In a survey described by Zollander (Ref. 3), conducted during 1957 to 1959, 30,000 persons were found to be unable to work because of arthritis for a minimum of 6 months. These individuals believe the diagnosis for Social Security benefits. Of these, 78 percent were over 50 years of age, and 20 percent were women. Osteoarthritis was present in 55 percent and rheumatoid arthritis in 27 percent. Rheumatoid arthritis is felt to be related to death directly, but is still the greatest cause of crippling deformity from disease. These patients form a great proportion of the population attending arthritis clinics because of the pain and disability that the individual seek proper medical advice as early as possible.

Because symptomatic self-medication for arthritis of undetermined and undiagnosed etiology may lead to some instances to some relief of pain and yet allow the disease to progress, the Panel recommends that aspirin and aspirin-containing agents not be labeled for the treatment of arthritis. The use of aspirin and aspirin-containing products as antirheumatic agents is not recommended.
and the duration of treatment is longer than when aspirin is used as an OTC analgesic for the relief of pain.

The Panel concurs with a leaflet published by the Arthritis Foundation (Ref. 2), where it is emphasized that aspirin is the best Santos to treat the symptoms of arthritis but points out that its use is widely misunderstood. In addition, it is the conclusion of the Arthritis Foundation that it is a misused drug. It is stated, "There is the general impression in the minds of American consumers that aspirin is an innocuous medication and that arthritis is a minor disease. The labeling and advertising of OTC aspirin products have reinforced this mechanistic impression. This disease condition is not rare and the degenerative nature of the disease if proper medical diagnosis and treatment are not instituted can have a severe debilitating effect on the individual. The labeling and advertising that downplay the seriousness of this disease do the American consumer a gross injustice."

The Panel concludes that all OTC analgesic-antipyrhetic-antirheumatic products be labeled with the warning, "Do take aspirin, if the doctor prescribes it." Strictly according to the "aspirin program" he gives you.

1. DON'T change your aspirin dosage schedule without first asking your physician.
2. DON'T try to diagnose your own arthritis problem or pick your own remedies from over-counter medicines available at the local drugstore.
3. DON'T be misled by aspirin advertising into self-treating yourself on a homemade schedule. Even though arthritis may begin with "minor aches and pains," it is no disease to fool around with. DO get qualified medical advice and get it early.

The Panel has recommended that all OTC analgesics-antipyrhetic-antirheumatic products be labeled with the warning, "Do not take this product for more than 10 days. If symptoms persist, or new ones occur, consult your physician." The Panel concludes that even if temporary self-medication is limited to 10 days, pain may be relieved, but will recur and the disease may progress if not properly diagnosed by a physician.

1. Labeling of antirheumatic products. In his chapter on "Salicylate Therapy for Rheumatoid Arthritis" in "Arthritis and Allied Conditions," Dr. R. B. Beyer (Ref. 35) states, "All patients with active rheumatoid arthritis, mild to severe, should receive salicylates regularly in the largest tolerated dosage excluding only those with a past history of adverse gastrointestinal symptoms or bleeding, peptic ulcer, or allergic manifestation due to salicylates" (Ref. 35).

Suggested labeling doses for self-medication provide only analgesic effect and deprive the patient of the benefit of a physician's care as discussed above. Permanent disability may occur if self-medication occurs intermittently or over prolonged periods of time for certain types of arthritis.

In a brochure distributed by the Arthritis Foundation for patients with arthritis (Ref. 2), the following is stated:

"Most adults make arthritis sound like nothing more than a disease of "minor aches and pains." The truth is arthritis can be a serious disease. The pain can be excruciating and result in severe crippling unless the victim starts full and proper medical treatment in the early stages. How often do aspirin advertisements tell you this? And how often do aspirin advertisements tell you that your dosage schedule should be prescribed by a doctor? Don't let advertising lead you to self-diagnosis and self-medication for arthritis. There is more to controlling arthritis than getting wonderful "relief!" Arthritis isn't a disease to fool around with. While you are seeking the panel of the druggist's cabinet and staying away from the doctor, irreversible damage may be taking place in your arthritic joints.

In another more recent position by the Arthritis Foundation (Ref. 40), the following is stated:

"Aspirin is frequently the drug of choice in the treatment of arthritis. The Panel fully concurs with the leaflet published by the Arthritis Foundation that it is a misused drug. It is stated, "There is a special way to take aspirin..." There is the general impression in the minds of American consumers that aspirin is an innocuous medication and that arthritis is a minor disease. The labeling and advertising of OTC aspirin products have reinforced this mechanistic impression. This disease condition is not rare and the degenerative nature of the disease if proper medical diagnosis and treatment are not instituted can have a severe debilitating effect on the individual. The labeling and advertising that downplay the seriousness of this disease do the American consumer a gross injustice."
A double-blind study was carried out by the Cooperating Clinics Committee of the American Rheumatism Association in which placebo or eight 5 gr aspirin tablets daily were taken by 541 patients with rheumatoid arthritis. The results showed that aspirin had significantly more antirheumatic effect than placebo (Ref. 1). Fromon-Smith and Bayles reported that after withdrawal of aspirin in a total dose of from 3.5 to 7.5 g daily given in 5 divided doses, objective evidence of exacerbation of rheumatoid arthritis appeared. This was demonstrated by a significant decrease in the grip strength and increased circumference of the interphalangeal joints (Ref. 2).

Boardman and Hart measured grip strength and circumference of proximal interphalangeal joints in a double-blind study of the effectiveness of aspirin in patients with rheumatoid arthritis. The data showed that a low dose of aspirin, 2.6 g daily given in 4 equal doses, was not significantly superior to acetaminophen or placebo but a high dose of 5.3 g daily, was (Ref. 3).

Calabro and Paulus performed a double-blind crossover study comparing aspirin, salicylamide and placebo in patients with rheumatoid arthritis. Each patient was treated with 18 tablets daily of each drug every 4 hours. All tablets contained 300 mg of aspiraglace or placebo. The results showed a statistically significant greater improvement of objective parameters of joint inflammation in patients receiving aspirin than in those receiving either salicylamide or placebo (Ref. 4).

Aspirin is effective in the treatment of some patients with rheumatoid arthritis at a dose of 2.4 g daily in divided doses. However, most patients require more than this minimally effective dose (Refs. 5, 6, and 7).

Extensive studies by Ansell, Bywaters and Leake have demonstrated that aspirin is effective in the suppression of juvenile rheumatoid arthritis (Ref. 8). Initial doses ranged from 1.5 g daily at age 2 years to 6 g daily for older children. Maintenance dosage ranged from 1.5 to 6 g daily.

Manifestations of acute rheumatic fever such as fever, arthritis, elevated erythrocyte sedimentation rate and reactive protein disappear faster in patients receiving aspirin therapy than in untreated controls (Ref. 9).}

Ankylosing spondylitis should be treated with aspirin and more potent agents added only when aspirin does not suffice (Ref. 10). Godfrey, Calabro, Mills and Maltz conducted a double-blind crossover trial of aspirin and the anti-inflammatory drugs indomethacin and phenylbutazone. Each drug was used for 6 weeks. They found that indomethacin and phenylbutazone were clearly superior to aspirin in increasing the range of motion. However, aspirin proved more effective than the other two medications in 5 of the 41 patients (Ref. 11).

Psoriatic arthritis may also be treated with aspirin (Ref. 12).

Aspirin is generally recommended for treatment of fibrositis syndromes (Ref. 13).
Aspirin is helpful in the treatment of systemic lupus erythematosus, especially when arthritis is associated with the disease. A minimal dose of 2.4 g daily in four divided doses is required (Ref. 18). Aspirin was also recommended in the treatment of osteoarthritis (Ref. 15). Harth and Bonyd performed a crossover trial using objective measurements rather than relief of pain to study the effects of 1.3 g aspirin taken 3 times daily with the effects of indomethacin 50 mg taken 3 times daily. Objective measurements of hip muscle strength and isometric strength of knee muscles were evaluated prior to therapy and during each trial of medication. These results revealed that aspirin is effective in the treatment of osteoarthritis (Ref. 16).

Effectiveness of Other Forms of Aspirin as Antirheumatic Agents

The problem of managing the adverse effects of aspirin in the gastrointestinal tract are a particular concern in patients with rheumatoid arthritis where large doses are generally employed over extended periods of time. The addition of antacids, buffering agents and enteric coating have been used among others to reduce gastrointestinal irritation. The Panel has discussed the effects of finding the dosage form of aspirin which best matches the activity of the active ingredients elsewhere in this document. (See part II, paragraph J above—Effects of Product Formulations on Drug Absorption and Pharmacologic Effectiveness.)

Buffered aspirin has been proven effective in the treatment of rheumatoid arthritis (Refs. 2 and 4). Aspirin combined with magnesium and aluminum hydroxides has not specifically been shown to have antirheumatic efficacy; however, if the product contains 325 mg (or gr) aspirin it should be considered to be as effective as aspirin at the same dosage.

A study by Battmer (Ref. 17) analyzed the analgesic but not the antirheumatic effects of this combination. The drug is well tolerated, but some cases of upper gastrointestinal hemorrhage and clearly should not be self-medicating with aspirin using antirheumatic doses of aspirin.

Patients with a history of gastric or duodenal ulcers who have symptoms of ulcers should be under the care of a physician and antirheumatic therapy prescribed by the physician. These symptoms are at times influenced by gastrointestinal hemorrhage and clearly should not be self-medicating with aspirin using antirheumatic doses for prolonged periods to control their arthritis. In addition, the daily dose of aspirin should be individualized for each patient and monitored by the physician at specific intervals. For example, only a physician can make the efficacy of aspirin therapy in rheumatoid arthritis patients by determining diminution of swelling, increase in range of motion, decrease in joint tenderness, increased grip strength, etc. Based upon the physician’s assessment of the patient the physician may increase, decrease or continue the same dose of aspirin or add additional medication. In addition, evidence of side effects such as ulcer symptoms and a history of ulcer disease or a history of bleeding ulcers can only be noted by the physician. Patients who are to undergo surgery are told to withhold aspirin for an appropriate period prior to surgery. In addition, the physician may institute other therapy such as gold injections, antimarial therapy, etc. The physician also prescribes specific physical therapy, may order such measures as splints, paraffin baths, hot packs, and change the lifestyle of the patient to include periods of rest. All of these measures cannot be prescribed or ordered by the patient under the care of the physician.

The Panel concludes that aspirin is safe for use as an OTC antirheumatic only under the advice and supervision of a physician.

(3) Dosage. There is no recommended dosage except under the advice and supervision of a physician.

(4) Labeling. The Panel recommends the Category I professional labeling for antirheumatic active ingredients. (See part V, paragraph B.I. below—Category I Labeling.)

b. Calcium carbonate. The Panel concludes that calcium carbonate is a safe and effective OTC antirheumatic when taken in the dosages recommended by a physician for specific rheumatic diseases. The dose required for antirheumatic effectiveness usually exceeds the dose recommended for analgesia (4,968 mg in 24 hours) and the duration of therapy required is longer than 10 days. The therapeutic indications require prior diagnosis by a physician and therefore suitable claims are limited to professional labeling.

1. Effectiveness. No data on effectiveness as an antirheumatic agent are available. However, earlier in this document, its dissolution rate and analgesic efficacy have been studied and found to be similar in action to aspirin. (See part V, paragraph B.I. below—Category I Labeling.)

2. Safety. The safety of calcium carbonate has been previously discussed earlier in this document. (See part V, paragraph B.I. below—Category I Labeling.)

3. Dosage. There is no recommended dosage except under the advice and supervision of a physician.

4. Labeling. The Panel recommends the Category I professional labeling for antirheumatic active ingredients. (See part V, paragraph B.I. below—Category I Labeling.)

c. Choline salicylate. The Panel concludes that choline salicylate is a safe and effective OTC antirheumatic when taken in the dosages recommended by a physician for specific rheumatic diseases. The dose required for antirheumatic effectiveness usually exceeds the dose recommended for analgesia (5,220 mg in 24 hours) and the duration of therapy required is longer than 10 days. The therapeutic indications require prior diagnosis by a physician and therefore suitable claims are limited to professional labeling.

1. Effectiveness. A study performed in 1960 by Nevinny and Gowans (Ref. 1) described the systemic index (dose of the treatment of five patients with rheumatoid arthritis with liquid choline salicylate but did not describe the dose and duration of therapy. Four of the five patients showed a reduction of "systemic indexes," which are a series of subjective and objective parameters of joint inflammation (Ref. 2).

A well-designed double-blind, crossover study comparing equicomparable concentrations of choline salicylate and aspirin as antirheumatic agents was performed by Golden, Tesar and Schmid (Ref. 3). The amount of salicylate used was a mean of 5,800 mg per patient per day. The patients took tablets of one ingredient during the first 2 weeks and then took tablets of the second ingredient during the second 2 weeks. Patients were examined weekly during the test period. Duration of morning stiffness; grip strength; ring size; time to complete a measured walk; and subjective pain severity. Statistical analysis showed no difference in therapeutic effectiveness between choline salicylate and aspirin.

(2) Safety. The safety of choline salicylate has been previously discussed earlier in this document. (See part III, paragraph B.I. below—Category I Labeling.)

The Panel concludes that choline salicylate is safe for use as an OTC antirheumatic only under the advice and supervision of a physician.

(3) Dosage. There is no recommended dosage except under the advice and supervision of a physician.

4. Labeling. The Panel recommends the Category I professional labeling for antirheumatic active ingredients. (See part V, paragraph B.I. below—Category I Labeling.)

d. Sodium salicylate. The Panel concludes that sodium salicylate is a safe and effective OTC antirheumatic when taken in the dosages recommended by a physician for specific rheumatic diseases. The dose required for antirheumatic effectiveness usually exceeds the dose recommended for analgesia (4,000 mg in 24 hours) and the duration of therapy required is longer than 10 days. The therapeutic indications require prior diagnosis by a physician and therefore suitable claims are limited to professional labeling.

1. Effectiveness. Sodium salicylate was tested in 27 patients with rheumatoid arthritis by Hollander and Harris (Ref. 1). Patients were given 4 g (1 g 4 times daily) for at least 1 week. Antirheumatic effectiveness was measured by subjective parameters as relief of stiffness and measurement of the erythrocyte sedimentation rate before and after 1 week of therapy. A change in the sedimentation rate was observed, while stiffness occurred. The data were compared with the efficacy of para-aminobenzoic acid at a dose of 4 g daily for 1 week. Sodium salicylate was found to give substantially more relief of stiffness than para-aminobenzoic acid. The study, however, did not actually measure antirheumatic effect on an objective scale and the results, therefore, do not permit a conclusion as to the efficacy of sodium salicylate as an antirheumatic.

A similarly inconclusive study was carried out by Smith (Ref. 2) who studied the analgesic effect of sodium salicylate in doses of 0.6 to 1.3 g every 4 hours during the day. Although the drug was found to be an effective analgesic, no objective parameters of its antirheumatic effect were measured.

Other studies in the literature are poorly designed and describe only analgesic effect of sodium salicylate in patients with rheumatoid arthritis and use of the agent as an antirheumatic who have advanced chronic renal insufficiency (Ref. 1). Use of this agent in patients with advanced chronic renal insufficiency may lead to toxic levels of magnesium.

The Panel concludes that magnesium salicylate is safe for use as an OTC antirheumatic only under the advice and supervision of a physician.

4. Labeling. The Panel recommends the Category I professional labeling for antirheumatic active ingredients. (See part V, paragraph B.I. below—Category I Labeling.)

REFERENCES

(1) Brown, H. "Magan-7 Day Variability Study," draft of unpublished paper is included in OTC Volume.


other forms of arthritis (Refs. 3, 4, and 5).

An excellent study was carried out by Dick et al., (Refs. 6 and 7) in which the antirheumatic effect of sodium salicylate was compared with that of indomethacin and placebo. The study was carried out in 13 patients with rheumatoid arthritis who entered a 3 week, double-blind trial during which they received the following three courses of treatment each lasting for 1 week: Enteric-coated sodium salicylate 1.5 g 4 times daily; indomethacin 25 mg 4 times daily; and lactose as placebo. The order of treatment was randomized. The Ritchie index (Ref. 8) was used as a measure of total articular status. This index is based on the response of the patient to firm pressure over the joint margins. Thus, 0=no pain, +1=patient complains of pain, +2=patient complains of pain and winces, +3=patient complains of pain, winces, and withdraws). The maximal score is -78. The mean value of the Ritchie index of 4 patients treated with either sodium salicylate or placebo was -80. The difference between observed values obtained while the patients received placebo than those treated with either sodium salicylate or placebo was shown to be significantly better as placebo according to articular index (Ritchie index), knee score, and technetium peak count. Significant differences were shown using joint size measurement as well.

The effectiveness of sodium salicylate as an antirheumatic has been clearly established. The effective dose is at least 4.8 g daily in divided doses.

(2) Safety. The safety of sodium salicylate has been previously discussed in another document (see part III, paragraph 2 above—Safety). The long-term administration of sodium salicylate preparations may be hazardous in patients with chronic renal insufficiency or heart disease due to the sodium in the preparation.

The Panel concludes that sodium salicylate is safe for use as an OTC antirheumatic only under the advice and supervision of a physician.

(4) Labelling. The Panel recommends the following Category I professional labeling for antirheumatic active ingredients.

[Refer to Part V, paragraph B.1 below—Category I Labeling.]

In addition, the Panel recommends the following specific labeling:

(1) For products containing more than 5 mEq (125 mg) sodium per dosage unit, the labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 mEq (5 mg) or higher.

(2) For products containing more than 5 mEq (125 mg) sodium in the maximum recommended daily dosage. Warning. "Do not use if you are on a sodium restricted diet except under the advice and supervision of a physician."

REFERENCES


PROPOSED RULES

The use of OTC antirheumatic agents for the treatment of the symptoms of specific rheumatic diseases requires prior diagnosis by a physician and the establishment of a suitable recommended dosage. The Panel believes that labeling conditions such as those which require medical intervention may mislead the consumer who attempts to self-diagnose and self-treat serious disease. Therefore, there are no suitable labeling claims for use on OTC marketed products. Suitable labeling claims are limited to professional labeling.

The Panel recommends the following Category I professional labeling (labeling of the product for health professionals but not for the general public) for antirheumatic active ingredients to be generally recognized as safe and effective and not misbranded as well.

Acametominophen Phenacetin Acetanilid Quinoline Todypronyl Salicylamide

a. Acemetaminophen. The Panel concludes that acemetaminophen is not an effective OTC antirheumatic.

(1) Effectiveness. Acemetaminophen is not considered to have effective antirheumatic properties (Refs. 1 and 2). A study by Boardman and Hart compared the efficacy of 8 g acemetaminophen daily to 8 g sodium salicylate given 4 times daily compared to placebo given in the same manner (Ref. 3). Each drug was given for 7 consecutive days, and quantitative measurements of joint size using standard "jewellers" rules under double-blind controlled conditions, in addition to measurements of grip strength were made at the beginning of the study and at the end of each of the 7 day trials. All patients had classical or definite rheumatoid arthritis of at least 1 year's duration, had synovitis of the small joints of the hands, and in all patients it was possible to stop all treatment for 24 days before the trial. The results showed that there was no significant difference in joint size and grip strength between patients on acemetaminophen compared with placebo. Patients had a mean improvement of grip strength from 303 mm Hg on placebo to 326 mm Hg on acemetaminophen. This difference was not significant (t=0.57, n=20; P is greater than 0.05).
The Panel concludes that acetaminophen is not effective as an antirheumatic.

(2) Safety. The Panel has discussed the safety of acetaminophen earlier in this document. (See part III, paragraph B.1.b.(2) above—Safety.)

(3) Evaluation. The Panel concludes because there are no data demonstrating the effectiveness of acetaminophen as an antirheumatic that the ingredient is not effective for use as an OTC antirheumatic.

b. Acetanilid. The Panel concludes that acetanilid is not an effective OTC antirheumatic and is not safe for OTC use.

(1) Effectiveness. The Panel has discussed the safety of acetanilid earlier in this document. (See part III. paragraph B.2.a.(1) above—Effectiveness.)

The Panel concludes that acetanilid is not effective for use as an OTC antirheumatic.

(2) Safety. The Panel has discussed the safety of acetanilid earlier in this document. (See part III. paragraph B.2.a.(2) above—Safety.)

(3) Evaluation. The Panel concludes because there are no data demonstrating the effectiveness of acetanilid as an antirheumatic and because of the high incidence of toxic effects that the ingredient is not safe and not effective for use as an OTC antirheumatic.

c. Iodopyrine. The Panel finds that there are no data to demonstrate effectiveness and there are data showing it is not safe and therefore concludes that iodopyrine is not safe and not effective for use as an OTC antirheumatic.

(1) Effectiveness. No studies were found concerning the effectiveness of this iodide salt of antipyrine for use as an OTC antirheumatic. The lack of demonstrated effectiveness for use of iodopyrine as an OTC analgesic has been discussed earlier in this document. (See part III. paragraph B.2.c.(1) above—Effectiveness.)

(2) Safety. The safety of iodopyrine has been discussed earlier in this document. (See part III. paragraph B.2.c.(2) above—Safety.) The Panel concludes that iodopyrine is not safe for use as an OTC antirheumatic.

(3) Evaluation. The Panel finds that iodopyrine is not safe for OTC use because of the significantly high availability of iodide following oral administration and increased likelihood of iodism. Accordingly, the Panel concludes that the risks from use of iodopyrine outweigh any possible benefit and classifies the ingredient unsuitable for use as an OTC antirheumatic.

d. Phenacetin. The Panel concludes that phenacetin is not an effective OTC antirheumatic and is not safe for OTC use because of the high potential for abuse, the high potential for harm to the kidneys and the possibility of hemo-lytic anemia and methemoglobinemia resulting from abuse and the lack of compensating benefits of the drug. The benefit-risk ratio of phenacetin compounds compares unfavorably with other single agents and combination antirheumatic preparations available to target populations.

(1) Effectiveness. The Panel notes that "Acetaminophen and phenacetin have analgesic and antipyrine effects similar to those of aspirin. However, they have only weak anti-inflammatory effects and do not share the antirheumatic uses of the salicylates" (Ref. 1).

(2) Safety. The Panel has discussed the safety of phenacetin earlier in this document. (See part III. paragraph B.2.d.(2) above—Safety.)

(3) Evaluation. The Panel concludes because there are no data demonstrating the effectiveness of phenacetin as an antirheumatic and because of the significant high risk level with long-term use that the ingredient is not effective and not safe for use as an OTC antirheumatic.

REFERENCES


b. Acetanilid. The Panel concludes that acetanilid is not an effective OTC antirheumatic and is not safe for OTC use.

(1) Effectiveness. The Panel has discussed the safety of acetanilid earlier in this document. (See part III. paragraph B.2.a.(1) above—Effectiveness.)

The Panel concludes that acetanilid is not effective for use as an OTC antirheumatic.

(2) Safety. The Panel has discussed the safety of acetanilid earlier in this document. (See part III. paragraph B.2.a.(2) above—Safety.)

(3) Evaluation. The Panel concludes because there are no data demonstrating the effectiveness of acetanilid as an antirheumatic and because of the high incidence of toxic effects that the ingredient is not safe and not effective for use as an OTC antirheumatic.

REFERENCES


REFERENCES


CATEGORII II LABELING

The Panel has examined the submitted labeling claims for antirheumatics alone and for combination products with non-antirheumatic ingredients and concludes that there are no labeling claims suitable for OTC labeling of antirheumatic agents. Other labeling including unacceptable claims related to product performance have been clearly defined elsewhere in this document. (See part III. paragraph B.2. above—Category II Labeling. All labeling claims must be deleted from the labeling of OTC antirheumatic products. Therefore, the following submitted claims are classified as Category II and should be removed from the OTC antirheumatic product labeling.

a. Claims that refer to diseases requiring prior diagnosis by a physician:

The Panel considers the use of any indication for the treatment of arthritic conditions not to be suitable for OTC labeling and recommends that such indications be deleted from the labeling of OTC antirheumatic products. Therefore, the following submitted claims are classified as Category II and should be removed from the OTC antirheumatic product labeling:

- "arthritis", "rheumatism", "pain of arthritis", "pain of rheumatism",
- "minor aches and pains of arthritis", "minor aches and pains of rheumatism", "minor pain of arthritis", "minor pain of rheumatism", "low back pains", "bursitis", "chronic minor pain of arthritis", "minor aches and pains of bursitis," and "lumbago.

b. Claims that are unnecessarily descriptive:

The Panel has recommended...
that the indications for antirheumatic OTC products be limited to professional labeling. Therefore, the Panel feels that labeling claims such as "body aches" and "minor muscle aches" are unnecessary. Such claims are included in the simple term, aches. Likewise, the claim "sore, stiff aching muscles" can be adequately described and understood by the terms, aches and pains. The consumer will not be confused by the cause of the ache but will merely treat the ache. The consumer perceives a muscle ache after exercise as an ache and will take the appropriate ingredient. Since the Panel wishes to avoid multiple descriptions of the terms, aches and pains, such descriptions as "due to fatigue" and "sore, stiff muscles" should be deleted from the labeling. The following submitted labeling claims have been classified as Category II by the Panel and should be removed from OTC antirheumatic products: "minor muscular pains and aches", "minor muscular aches", "minor muscle aches", "aches and pains due to fatigue", "sore, stiff aching muscles", "muscular fatigue", "muscular tensions", "low body ache and fatigue", "body aches", and "sprain". The ingredients listed in this document are not obtained within a reasonable time. If adequate effectiveness and/or safety data are not obtained within 3 years, however, the ingredients listed in this category should no longer be marketed in OTC products.

Aluminum aspirin

Antipyrine

Salaslate (salicylsalicylic acid)

a. Aluminum aspirin. The Panel concludes that aluminum aspirin is safe but that there are insufficient data to determine effectiveness as an OTC antirheumatic.

(1) Effectiveness. No data on the effectiveness of aluminum aspirin as an antirheumatic were found or submitted in this document. The Panel believes it reasonable to provide 3 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 3 years, however, the ingredients listed in this category should no longer be marketed in OTC products.

b. Antipyrine. The Panel concludes that there are insufficient data to determine safety and effectiveness of antipyrine as an OTC antirheumatic.

(1) Effectiveness. No study has been found or submitted in which the anti-inflammatory efficacy of antipyrine has been evaluated (Ref. 1). The effectiveness of antipyrine as an analgesic has been discussed earlier in this document (see part III. paragraph B.3.b.(1)).

(2) Safety. The safety of antipyrine has been discussed earlier in this document (see part III. paragraph B.3.b.(2)).

3. Category III. Conditions for which the available data are insufficient to permit final classification at this time.

CATEGORY III ACTIVE INGREDIENTS

The Panel has concluded that the available data are insufficient to permit final classification of the following claimed antirheumatic active ingredients listed below. The Panel believes it reasonable to provide 3 years for the development and review of such data. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness and/or safety data are not obtained within 3 years, however, the ingredients listed in this category should no longer be marketed in OTC products.

Aluminum aspirin

Antipyrine

Salaslate (salicylsalicylic acid)

a. Aluminum aspirin. The Panel concludes that aluminum aspirin is safe but that there are insufficient data to determine effectiveness as an OTC antirheumatic.

(1) Effectiveness. No data on the effectiveness of aluminum aspirin as an antirheumatic were found or submitted to the Panel.

(2) Safety. The safety of aluminum aspirin has been discussed earlier in this document. (See part III. paragraph B.3.a. (2))

(3) Proposed dosage. There is no recommended dosage except under the advice and supervision of a physician.

(4) Labeling. The Panel recommends the Category I professional labeling for antirheumatic active ingredients. (See part V. paragraph C.1. above—Category I Labeling.)

(5) Evaluation. Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for antirheumatic drugs. (See part V. paragraph C. below—Data Required for Evaluation.)

C. DATA REQUIRED FOR EVALUATION

The Panel recommends the Category I professional labeling for antirheumatic active ingredients. (See part V. paragraph B.1. above—Category I Labeling.)
VI. ADJUVANT AND CORRECTIVE AGENTS

A. GENERAL DISCUSSION

The Panel considered several nonanalgesic ingredients as "active", because they were submitted as such pursuant to the notice published in the Federal Register of July 21, 1972 (37 FR 14633) and the Panel classifies these as adjuvant and/or corrective agents because they do not affect the activity of the active ingredient(s) of the preparation.

The Panel is of the opinion that these ingredients, which are commonly found in marketed products, can be properly reviewed as a separate group, i.e., as components of a drug delivery system. Their activity is not directly involved in the action of the therapeutic ingredient, and therefore may affect the activity or safety of the analgesic component(s) of the submitted preparation(s).

The components of the drug delivery system can be defined as follows:

1. Adjuvants. Adjuvants are agents which, in the acid monograph, do not have significant analgesic effect by themselves, but contribute to the therapeutic effect of the active agent either directly or indirectly.

a. Direct acting. A direct acting adjuvant is one which enhances the pharmacologic response directly by synergistic or additive effects at the site of action. For example, caffeine is added to some analgesics to decrease the incidence of gastrointestinal adverse effects of aspirin which have been extensively discussed earlier in this document.

b. Indirect acting. An indirect acting adjuvant is one which does not have effects at the site of action, but indirectly increases the activity of the active agent(s) of the preparation by modifying the disposition (absorption, metabolism, excretion or distribution) of the active agent. Examples include benzoic acid and sodium bicarbonate, which are claimed to compete for metabolizing systems affecting the elimination (benzoic acid) or absorption (sodium bicarbonate) of aspirin. Buffering systems may act as an indirectly acting, correctives and excipients.

The components of the drug delivery system can be defined as follows:

2. Correctives. A corrective is an agent in the drug delivery system intended to reduce some undesired effect of the therapeutically active agent. An example would be the addition of buffering agents to aspirin formulations to reduce the incidence of gastric distress.

3. Excipients. Formulation considerations of the manufacture of the finished dosage form, many inert ingredients are required, such as starch or other agents to aid disintegration, or magnesium stearate as the lubricant. In the tabletting process. Not only should these agents be inert pharmacologically but, inactive from the point of view of adversely affecting the bioavailability of aspirin or the propensity for absorption of the active agents. It is important to recognize that some of the agents above may have effects relating to two components, for example, buffering agents may be added to serve as an indirectly acting adjuvant to enhance the absorption rate of aspirin or as a corrective to decrease the incidence of gastrointestinal adverse effects of aspirin. In these cases each effect should be considered as a separate effect since the mechanism of action and the clinical endpoint are likely to be different.

B. CATEGORIZATION OF DATA

1. Antacid or buffering ingredients. The Panel has classified the following as ingredients of buffering systems for use as antacids or correctives:

- Aminoacetic acid (glycine, glycocol)
- Calcium carbonate
- Calcium phosphate dibasic (monocalcium phosphate)
- Citric acid
- Dihydroxyaluminum aminoacetate (aluminoni glycinate)
- Dried aluminum hydroxide gel
- Magnesium carbonate
- Magnesium hydroxide
- Sodium bicarbonate
- Sodium carbonate

The Panel notes that these ingredients are generally recognized as safe and effective antacid active ingredients and are identified in § 331.11 of the OTC antacid monograph. The Panel finds that there are three major types of marketed products containing these ingredients that have been submitted to the review:

a. Buffered aspirin. Products containing aspirin combined with buffering ingredients (correctives).

b. Buffered aspirin with solution. Products containing aspirin combined with antacids.

c. Antacid-aspirin products. Products containing nonaslicylic acid ingredients combined with antacids.

2. Alkaline buffers. Alkaline buffers are included in marketed products, can be properly classified as antacids.

The Panel concludes that aspirin tablets may be labeled as "buffered aspirin" providing they meet the following minimum requirements: Each dosage unit contains antacid active ingredients and/or corrective agents because they are generally recognized as antacids or buffering ingredients.

Buffered aspirin is defined in this document as a solid dosage form which consists of aspirin plus a sufficient quantity of alkaline or buffering agents to significantly increase the dissolution rate of the product relative to a standard aspirin tablet without necessarily increasing the pH of the gastric fluid. The Panel recommends that specific standards be established, through appropriate testing procedures, that each product shall meet in order to be recognized as a safe and effective "buffered aspirin" preparation.

The product should have dissolution characteristics equivalent to the buffered aspirin tablet that has been used in most comparative clinical studies (Refs. 1 through 6). The dissolution test used should be capable of detecting significant differences in the initial rate of dissolution which correlates with the in vivo rate of absorption. This problem of evaluating suitable dissolution methodology is likely to involve significant experimental development to establish in vitro/ in vivo correlations and is therefore, beyond the scope of this Panel. The dissolution tests should be established by the appropriate compendial and/or Governmental Agency. A tentative methodology is described below for illustrative purposes. (See part VI.)
paragraph C.I.b. below.—Aspirin (plain and buffered) and other analgesics containing aspirin are most effective in relieving pain or reducing the fever and rigors associated with flu-like symptoms. While these are desirable formulation characteristics, the Panel has placed claims relative to these effects in Category III because of the potential of these statements to mislead the general public. Evaluation of individual claims is necessary to assure that the claims do not imply that increased rate of absorption has been proven to result in improved clinical effectiveness. Therefore, decreased incidence of gastric distress is significant for most people or that increased incidence of recurring gastric distress following aspirin ingestion in a small set of patients implies greater safety from serious gastrointestinal effects associated with aspirin products.

Current evidence indicates that properly formulated preparations, those meeting the proposed antacid and dissolution standards, can be expected to (1) increase the rate of absorption of aspirin relative to a plain aspirin tablet; and (2) reduce incidence of subjective gastrointestinal intolerance in some of the relatively small percentage of persons in the general population who regularly experience intolerance with plain aspirin tablets.

In the presence of buffers, an increase in dissolution rate of aspirin tablets has been demonstrated. Even though the amount of buffer in buffered aspirin tablets is not sufficient to markedly affect the pH of gastric fluids, it does increase the pH immediately around the dissolving particles causing an increased rate of dissolution of aspirin from the particles (Refs. 7 through 9). Since dissolution is usually the rate-limiting process for gastrointestinal absorption of salicylates given in solid dosage form, the greater dissolution rate of aspirin in the presence of buffers results in a more rapid rate of absorption (Ref. 10). However, other aspirin formulation variables, such as the tablet compression and choice of tablet excipients, can also have significant effects on the rate of dissolution of aspirin (Refs. 7 and 8). Thus, the inclusion of a buffer in buffered aspirin tablets will not necessarily result in an increase in the dissolution rate and, therefore, the absorption rate of aspirin. Buffered aspirin tablets with slower rates of dissolution than plain aspirin tablets have been reported (Refs. 7 and 8). Therefore, it is important to evaluate the actual dissolution rate of products claiming rapid absorption. The Panel believes that a suitably designed dissolution test would obviate the necessity of requiring in vivo blood level studies for all buffered aspirin products in order to establish increased absorption. Buffered aspirin tablets have noted that a clear relationship between absorption rate and clinical effects (onset, intensity or duration of clinical effects) has not been definitively established. (See part III. paragraph A.l.a.(2) above—Onset, duration and intensity of pharmacological effects.)

Buffered aspirin has been claimed to reduce symptoms of gastric intolerance (dyspepsia, stomach upset, gastric distress, etc.) associated with aspirin ingestion. The evaluation of this effect in gastric intolerance is given to a number of persons who regularly experience subjective symptoms of gastric distress is relatively small in the general population. However, the evidence seems to indicate that some individuals in this small subset of the general population may experience less gastric intolerance with some buffered aspirin tablets compared to plain aspirin tablets. Thus, the above-mentioned aspirin, buffered aspirin and aspirin-phenacetin-cafeine products in a prisoner population. Twenty-nine percent or 476 of the total population of 1,629 prisoners listed a history of the use of aspirin or buffered aspirin products. The effects of the 3 types of aspirin products were studied in 236 of these 476 prisoners. The 236 prisoners in this "double-blind" study were selected at random. Sher claims that 94 percent of these 236 subjects had one or more complaints of gastric intolerance during the study period. Sher claimed that subjects tolerated more often with an aspirin-phenacetin-cafeine combination (33 percent) and with aspirin alone (18.3 percent) than with buffered aspirin (39 percent).

Paul (Ref. 3) also claimed that buffered aspirin produced less gastric distress.

Fremont-Smith (Ref. 2) found 70 percent of patients who were intolerant to unbuffered aspirin could take buffered aspirin and 30 percent were intolerant to both forms. Unpublished double-blind, crossover, multiple-dose studies by Paul (Ref. 4) submitted to this Panel provide evidence that a buffered aspirin tablet and highly buffered aspirin tablet may produce less incidence of gastric intolerance than either unbuffered aspirin tablets or a product containing aspirin and caffeine when multiple doses are administered.

Some investigators have failed to show a difference between buffered and unbuffered aspirin in controlled studies. Battenman (Ref. 5) used a crossover study to compare buffered aspirin tablets and hospitalized patients who received repeated doses for 1 day, 1 week, 1 to 3 weeks and greater than 5 weeks. Intolerance increased with duration of therapy and was 30 percent more significant for the difference between the two. There is a question whether the tablets used in this study were representative of the usual marketed preparations used in most other studies in the literature.

Cronk (Ref. 6) states that in a well-controlled study only 8 of 397 patients showed gastric intolerance with no difference between buffered aspirin or plain aspirin. Patients who EXPERIENCE intolerance to regular aspirin did not complain when repeatedly given unidentified aspirin. These latter two studies did not evaluate drug intolerance in patients usually intolerant to aspirin and the authors did not demonstrate the sensitivity of their methods.

Thus, the evidence although apparently conflicting seems to indicate that buffered aspirin produces a lower incidence of gastric intolerance in some patients but not in all patients who experience gastric intolerance with regular aspirin products. The number of patients who might benefit from buffered aspirin compared to standard aspirin is probably small. (See part III. paragraph B.l.a.(2) (1) above—Adverse effects on the gastrointestinal tract.)

The results of a study on subjective gastrointestinal intolerance obtained with a given buffered aspirin product cannot necessarily be extrapolated to all other buffered aspirin products. It is not clear whether an observed decrease in gastrointestinal distress is related to the buffering effect of the pH of the microenvironment surrounding the dissolving particles, an increased dissolution rate, or both. However, it is the opinion of the Panel that claims of less gastric intolerance if valid for one buffered product would also be justified for other buffered aspirin tablets which contain the same neutralizing capacity and show similar dissolution characteristics. A suitably designed dissolution procedure as determined by this Panel will be required.

Evaluation of individual formulations is within the scope of the Panel's review. It is the Panel's opinion that if a buffered aspirin formulation meets the requirements for buffer capacity and dissolution rates outlined above, the claims described below may be used. (See part VI. paragraph B.l.d. below.—Labeling claims for marketed products containing analgesics combined with antacid or buffering ingredients.)

In spite of this apparent superiority in terms of blood salicylate studies there is no evidence on the basis of controlled clinical analgesic assays that buffered or highly buffered aspirin provides a more rapid onset, a greater peak intensity, or a more prolonged duration of analgesia than unbuffered aspirin (Ref. 9).

REFERENCES


c. Products containing aspirin combined with antacids—(1) Introduction. Highly buffered aspirin for solution contains a variety of buffers which conforms to the specifications for antacids established in the OTC monograph (21 CFR Part 331) and therefore, will increase the pH of the gastric fluid. Such products, which have a neutralizing capacity of at least 20 mEq of hydrochloric acid, have been shown to significantly decrease gastric acid output that results from the direct effects of aspirin on the gastric mucosa. Such products also have the most rapid rate of aspirin absorption. The Panel notes that there is current OTC marketing of aspirin combined with antacids for use as an effervescent solution with labeling for use in the symptomatic relief of concurrent symptoms requiring both an antacid and an analgesic-antipyretic.

The Panel finds it essential to include aspirin with any antacid preparation intended to provide claims for an antacid effect, e.g., "For the treatment of heartburn, sour stomach and acid indigestion" since the effectiveness of these preparations will be reduced if they are administered with meals. The serious adverse effects of aspirin on the gastrointestinal tract occur more frequently in individuals who have existing gastrointestinal disorders which are often characterized by the recurring gastric symptoms described above.

Therefore, the Panel concludes that it is rational to market such an aspirin product for use only as an analgesic-antipyretic to be used as a concurrent symptom requiring an antacid. The Panel has identified such products as highly buffered aspirin for solution. The Panel has discussed products as highly buffered aspirin. The Panel discussed the basis for these conclusions that any potential increased analgesic benefits derived from combining aspirin and an antacid for concurrent symptoms is not justified by the increased risk of serious adverse effects in this population relative to other analgesic ingredients that are available to the target population. (See part III, paragraphs B.4.a, (2) (ii) above—Adverse effects on the gastrointestinal tract.)

The highly buffered aspirin for solution products discussed above contain aspirin combined with a neutralizing active ingredient(s) identified in §331.11 of the OTC monograph such that the finished product contains at least 20 mEq of acid neutralizing capacity per 325 mg (6 gr) aspirin and results in a pH of 5 or greater at the level of the initial 10-minute period as measured by the method established in §331.23 of the OTC monograph. These products shall be identified as "highly buffered aspirin for solution" or as "specially buffered aspirin" with labeling only as an analgesic and/or antipyretic.

The Panel is limiting claims for these products to "For the temporary relief of occasional minor aches, pains and headaches, and for the reduction of fever". In addition, any claims for highly buffered aspirin products for solution than for buffered aspirin tablets. However, these claims would carry the same benefit to risk considerations for highly buffered aspirin for solution as for other buffered aspirin preparations and must therefore be considered as Category III.

Currently marketed highly buffered aspirin formulations are claimed by the drug manufacturer to be safe for self-medication by individuals with symptoms of peptic ulcer, indigestion and heartburn and to be safe for occasional use in occasional dosage forms, e.g., tablet, highly buffered aspirin solution, etc., can potentiate symptoms of peptic ulcer, occult bleeding and in some predisposed individuals massive gastrointestinal bleeding. The serious adverse effects of aspirin on the gastrointestinal tract occur more frequently in individuals who have existing gastrointestinal disorders which are often characterized by the recurring gastric symptoms described above.

Therefore, the Panel concludes that it is rational to market such an aspirin product for use only as an analgesic-antipyretic to be used as a concurrent symptom requiring an antacid. The Panel has identified such products as highly buffered aspirin for solution. The Panel has discussed products as highly buffered aspirin. The Panel discussed the basis for these conclusions that any potential increased analgesic benefits derived from combining aspirin and an antacid for concurrent symptoms is not justified by the increased risk of serious adverse effects in this population relative to other analgesic ingredients that are available to the target population. (See part III, paragraphs B.4.a, (2) (ii) above—Adverse effects on the gastrointestinal tract.)

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The Panel has also reviewed all available epidemiological data implicating highly buffered aspirin solution preparations from the above point of view that several mechanisms are involved. Many of the inconsistencies in the arguments used in the drug manufacturer's submission are resolved by the concept that aspirin in any dosage form can potentiate massive bleeding in certain individuals with existing "griped" (red or slightly bleeding) bleeding sites.

Based upon the total evidence now available to the Panel, it concludes that the evidence is insufficient to substantiate the claims that buffered or highly buffered aspirin solution is safe for use in patients who should not take regular, unbuffered (plain) aspirin. Furthermore, based upon current knowledge of the risk groups such as individuals who drink alcohol excessively, the benefit to risk ratio for individuals with symptoms of gastric distress, particularly with concomitant headache, does not warrant the use of aspirin in any dosage form. Therefore, the Panel does not recommend any exception to the current proposed labeling wording which states, "Caution: Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician".

The Panel's conclusions, which are discussed more fully below, are based in part on a thorough evaluation of all submissions that support the concurrent antacid-analgesic claims, including the
arguments relating to assumptions on the mechanism of aspirin-induced bleeding and the properties of highly buffered aspirin for solution preparations on animal and clinical experimental studies, including published and unpublished studies on occult bleeding in normal and peptic ulcer patients; on the analysis of published epidemiological studies; and on marketing experience data. 

(2) Arguments submitted to the Panel to support concurrent analgesic-antacid labeling claims for highly buffered aspirin for solution. All arguments given in the extensive materials provided to the Panel directly relate to the following basic contentions: (i) The acid-mediated single mechanism theory. The first contention relates to the primary mechanism involved in the gastric damage produced by aspirin. It is asserted that massive bleeding, erosive gastritis and occult (unseen) bleeding, all result from the same (universal) gastric acid-mediated (Davenport) mechanism and only this single mechanism can be involved in the causation of aspirin-induced bleeding. The presence of gastric acid is required for aspirin to produce the primary lesion involved in massive or occult bleeding. The primary lesion must be produced by the absorption of unionized aspirin into the mucosal cell and at some critical concentration increases the permeability of the gastric barrier which facilitates backflow of hydrogen ion to produce subsequent erosion and hemorrhage. This postulate is referred to by the Panel as the "acid-mediated single mechanism theory.

(ii) The alleged pharmacological properties of highly buffered aspirin for solution. The second contention relates to proposed properties of highly buffered aspirin solutions. It is asserted that the direct effects of aspirin, and therefore gastric bleeding, are not possible with highly buffered aspirin for solution because in these solutions only sodium acetate is present. Acetate ionize, the ionized form of aspirin, is not absorbed into the mucosal cell. Therefore, critical concentrations are not reached in the cell for local effects of aspirin. Gastric bleeding therefore cannot occur. Hydrogen ion is not available to damage the mucosa, thus erosion and massive bleeding cannot occur.

The Panel concludes that submitted and published experimental information which is discussed in more detail below does not support any of these contentions. In the evaluation of statements in the extensive submissions to the Panel, it found that in the final analysis, the validity of the claim for use of highly buffered aspirin for solution preparations for concurrent use in normal subjects, i.e., for use as an antacid and analgesic, is dependent on an unproven argument that there is only one single mechanism involved in massive bleeding. Virtually all the arguments in the submission are dependent upon the validity of the "acid-mediated single mechanism theory."

(iii) Data submitted to the Panel to support concurrent analgesic-antacid labeling claims for highly buffered aspirin for solution. The acid-mediated single mechanism theory has been the basis of the additional arguments which have been used to justify the proposed use of highly buffered aspirin for solution products in individuals with stomach distress, gastritis, peptic ulcer, etc.

The allegation that occult bleeding studies demonstrate the safety of highly buffered aspirin for solution. In the data submitted, it is contended that since aspirin-induced massive bleeding and occult bleeding involve the same mechanism, studies of occult bleeding are adequate to establish safety relative to major (massive) gastrointestinal bleeding (Refs. 1, 2 and 3).

This assertion is the basis of the use of occult bleeding studies in normal subjects and experimental animals in place of clinical studies. The Panel finds that this assertion and the use of these studies are not consistent with available experimental evidence. Occult blood studies in normal individuals are not adequate as good models for the effects of aspirin in "primed" individuals with preexisting gastrointestinal pathologies and potentially bleeding acute lesions.

(i) The absence of highly buffered aspirin for solution associated erosion and occult bleeding. In the data submitted to the Panel, it is contended that because highly buffered aspirin can potentiate massive bleeding, it is safe for use in individuals with a history of signs and symptoms including gastric distress, gastritis, peptic ulcer or massive bleeding (Refs. 2 and 3).

All initial experimental studies with highly buffered aspirin for solution submitted to the Panel involved short-term exposure of normal subjects or animals in which no increased occult blood loss was claimed as proof of safety for highly buffered aspirin for solution (Refs. 1 and 2). However, upon the recommendation of the Panel for further examination, the argument on occult blood loss in humans or animals with existing lesions, new information was obtained showing that pre-existing lesions potentiate aspirin's effects. Therefore, highly buffered aspirin for solution use was actually increased (Refs. 11, 12 and 14). 

(iii) The argument against aspirin-associated massive bleeding in the absence of gastric erosion. In the data submitted to the Panel, it is contended that since aspirin-induced massive bleeding and gastric erosion occur only through the acid-mediated gastric erosion, any cases of massive bleeding not involving aspirin-induced acute erosion cannot be considered to have been caused by aspirin (Refs. 5, 15, 16 and 17). This argument is used to dismiss the few epidemiological studies which have specifically considered highly buffered aspirin for solution preparations as a separate entity and found the proposed use with cases of massive bleeding to the same extent as regular aspirin preparations (Refs. 15 and 16).

The Panel concludes that the studies of Brown and Jennings (Ref. 16), which were criticized by Langman (Ref. 17) on the basis of the above invalid argument, actually support the use of highly buffered aspirin for solution like other aspirin formulations can potentiate massive bleeding from existing lesions in individuals with a variety of gastrointestinal disorders.

The Panel concludes that several types of evidence (experimental and epidemiological) clearly show that the effects of aspirin on the gastrointestinal tract cannot be explained by one mechanism and that the acid-mediated acute lesion produced by aspirin is not the only mechanism by which aspirin can contribute to massive bleeding (Refs. 4, 9 through 12, 14, 16, and 19). There is good evidence that all aspirin products can precipitate bleeding from existing acute lesions.

The Panel finds that there is conclusive evidence that aspirin can and does produce acute erosions and occult bleeding by the acid-mediated mechanism, but that gastric acid is not essential for massive bleeding. The Panel also concludes that in view of the evidence now available it is impossible and illogical to attempt to explain all effects of aspirin on the gastrointestinal tract with a single mechanism. The effect must involve a lesion produced by aspirin mediated through gastric acid. Thus, the Panel concludes that aspirin in any form can potentiate major gastrointestinal bleeding in certain individuals with new or preexisting mucosal lesions. The bleeding lesions may be either caused by aspirin in some cases, or by other factors (alcohol, stress, gastrointestinal disease) and may be simply triggered or potentiated by aspirin. This mechanism explains and correlates many otherwise inconsistent clinical and experimental observations.

(4) Analysis of data submitted to the Panel—(i) Evidence for and against a universal acid-mediated mechanism. A recent submission on highly buffered aspirin for solution (Ref. 3) illustrates the sequence of invalid reasoning repetitively used to show that highly buffered aspirin for solution cannot produce massive bleeding. The argument that massive gastrointestinal bleeding must occur from erosions caused by aspirin is discussed in the submission to reinforce arguments given in previous submissions (Refs. 1 and 2). The recent submission states: "For massive gastrointestinal bleeding to occur in response to aspirin, there must be sufficient erosions of the gastric mucosa." Information is also summarized in the submission to show that aspirin can cause gastric erosions and that the direct effect of aspirin is consistent with the acid-mediated Davenport mechanism. The Panel notes that it is unwarranted to conclude that because (a) erosions are needed for bleeding, (b) aspirin causes lesions, and (c) aspirin can act through the acid-mediated Davenport mechanism, therefore, all gastric bleeding involves erosions produced by the Davenport mechanism. Such a conclusion assumes that there is evidence that only one mechanism exists for each of the three observed events.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
It is stated (Ref. 3) that "Dagradi et al. confirmed that aspirin is capable of causing massive gastrointestinal bleeding because of its ability to initiate acute gastric erosion." The Panel further states that erosions will be prevented if acid is eliminated from the stomach and cite animal studies to support this statement as follows: "Evidence that there is only a single mechanism whereby aspirin may produce gastric damage and blood loss is the fact that * * * even under conditions where aspirin will produce severe hemorrhagic erosions, these erosions will be prevented from occurring if conditions are varied by eliminating the presence of acid in the stomach, citing the animal studies of Brodie and Chase (Refs. 19 and 20) and Dagle et al. (Ref. 21) and concluding that "regardless of the severity of the gastric damage or bleeding response, the presence of acid in the stomach is an essential element for this effect." Finally, the submission (Ref. 3) quotes Cooke (Ref. 22) who reiterates the key argument that "only one mechanism is involved with all adverse aspirin effects on the gastrointestinal system: "Primarily, the basis of aspirin damage to the gastric mucosa, i.e., erosions, occult and overt bleeding is the presence of acid in the lumen of the stomach." However, the studies of Brodie and Chase (Refs. 19 and 20) and Dagle et al. (Ref. 21) clearly show that gastric acid is not required for aspirin to produce gastric erosions.

As noted above, even if each statement regarding experimentally observed phenomena were valid, the Panel concludes that it is not valid to extrapolate that each event is causally related to the other to the exclusion of all other possible contributing or causal factors.

In the Panel's review of the data of Dagradi et al. (Ref. 21), the Panel agrees that, indeed, evidence is provided that would support the contention that aspirin may cause massive bleeding by virtue of initiating acute gastric erosions. However, this same study also provides evidence that aspirin may produce or potentiate bleeding from lesions that were quite unlikely to have been caused by the acute effects of aspirin.

Thus, the basic fallacy in virtually all arguments given in the submissions is the unproven, and in the Panel's opinion, highly unlikely argument that aspirin can cause massive gastric bleeding only if aspirin directly produces the acute bleeding lesion (with the further constraint that aspirin can produce the lesion only through the acid-mediated mechanism).

There are now several lines of recent evidence which strongly indicate that massive bleeding related to aspirin ingestion does not involve only one type of acute gastric erosion but at least two, with some of which may have been present before aspirin was administered. These potentially bleeding erosions may have been caused by a variety of initiating factors, including mechanical irritation." as well as aspirin and other drugs.

Although morphologically different, these lesions have the same clinical characteristics and prognosis in cases of massive bleeding. These lesions may be increased by acute gastric erosions, and involve excessive secretion or the absence of gastric acid (Refs. 24 and 25). The feature they have in common, however, is an abrasion mucosa with an exposed engorged capillary bed which by virtue of the unique vascular arrangement are very prone to an oozing type of bleeding dependent on platelet plugs for hemostasis (Ref. 26). The Panel has discussed the effects of aspirin on platelet aggregation and hemostasis elsewhere in this document. (See part III, paragraph B.3.a.(2) (i) (e) above-Relationship between systemic effects and gastrointestinal bleeding.) There is now considerable evidence that the primary effects of aspirin on these lesions is a prolonged impairing effect on hemostasis (Ref. 27) and involvement of the microcirculation, although this has not been proven.

The submission dismisses the effect of aspirin on occult bleeding by Leonard and Levy (Ref. 27) who showed that aspirin given intravenously increased template bleeding time but decreased increased template bleeding time and occult bleeding has also been noted by the Panel (see part III, paragraph B.3.a.(2) (ii) (e) above-Occult bleeding). 

Thus, in the use of this study as an argument to conclude that the systemic aspirin hemostatic effect does not relate to massive bleeding, again results from the unwarranted adherence to questions raised in a single acid-mediated mechanism theory. This conclusion is again not valid unless it is assumed that massive bleeding and occult bleeding are identical, or that the individuals studied by Leonard and Levy had preexisting lesions which precipitated massive bleeding episodes and, therefore, they served as realistic models to determine the effects of the sublesions (within bleeding time) and gastric bleeding from preexisting potentially bleeding sites.

The Panel reemphasizes that a study which shows no difference should not be interpreted to mean that the study was properly designed relative to the question at hand and that the study had sufficient sensitivity to detect real differences if they did exist. The design of this study of occult bleeding in normal subjects is totally unrelated to the question of whether systemic aspirin effects on platelet function and thus the increased template bleeding time in patients who have existing potentially hemorrhagic gastrointestinal lesions. Indeed, the studies of Grossman showed that intravenous aspirin caused significant prolongation of the bleeding time in only the two "primed" individuals who had pre-existing lesions (Ref. 19). This information was noted in the submission but dismissed because it conflicted with their single acid-mediated mechanism theory.

The evidence supporting the potentiating role rather than the initiating role of aspirin in bleeding from existing erosions is reviewed below. The Panel concludes that there is now significant evidence from experimental and clinical studies strongly supporting a mechanism in which aspirin can potentiate a gastrointestinal lesion in certain individuals with preexisting mucosal lesions. The possibility that bleeding lesions may be either caused by aspirin in some cases but also may have been caused by other factors and simply triggered or potentiated by aspirin, provides a unifying mechanism that explains clinical and experimental observations, although there is no challenge dose of aspirin is given to individuals who have recently experienced massive hemorrhage following aspirin ingestion or who may have peptic ulcers which may have been produced by aspirin ingestion or who may have preexisting gastrointestinal disease (Refs. 28, 29, and 30). (See part III, paragraph B.3.a.(2) (ii) (g) above-Massive gastrointestinal bleeding.) However, massive bleeding is more likely in individuals with existing gastrointestinal disease (Refs. 31). Those who contend that aspirin contributes to massive bleeding only by its direct mucosal erosive effect, claim that this is proof that there must be other modifying factors in order for local erosion and occult bleeding to progress to massive hemorrhage. For those who argue that there can be no effect of aspirin other than the direct local effect, these modifying factors must of course be assumed to be independent of aspirin. Current evidence indicates that aspirin is a modifying factor which can increase bleeding from certain types of bleeding lesions (acute mucosal lesions) (Refs. 19 and 32). Langman (Ref. 17) claims that the absence of proof that such modifying factors commonly occur must be equivocally evidence that the inhibition of aspirin to massive bleeding must be limited. The validity of this conclusion is also of course dependent on the assumption that aspirin acts by only one mechanism.
gastrointestinal effects of aspirin are limited to one single mechanism. The evidence offered by proponents of this theory (Refs. 1 through 4, and 33) is based on the contention that in order to contribute to massive bleeding aspirin must cause the production of the same mechanism that it causes occult bleeding. An important part of their basic assertion is that this common mechanism involves an acidosis of gastric acid since part of the process involves the reduction of occult bleeding by a highly buffered aspirin preparation. Evidence has been given previously that occult bleeding and massive bleeding are unlikely to be due to the same effects of aspirin and that the direct erosive effects of aspirin and occult bleeding can occur in the absence of gastric acid. Furthermore, the development of erosions associated with massive bleeding can occur in the absence of either acid or aspirin, for example as a result of alcohol or stress (Ref. 24 and 26).

While this may be a reason to rule out the possibility that aspirin may initiate acute erosions or increase the bleeding from existing erosions by direct mucosal effects, it does not mean that this is the only mechanism possible or that the mechanism requires gastric acid since massive bleeding following aspirin ingestion may occur in patients with achlorhydria (Refs. 25 and 26).

(b) Potentiation of bleeding from existing erosions. Although aspirin at times causes acute mucosal erosions, in many cases reported bleeding took place after only a few aspirin ingestions in patients with gastric conditions in which acute erosions were highly likely to exist, such as chronic gastritis and chronic atrophic gastritis. This is true also, however, in the four studies cited by Langman (Ref. 17) in which aspirin had a greater probability of being involved in bleeding in the presence of a peptic ulcer because mucosal lesions are also associated with peptic ulcer. The typical lesion involved in most acute bleeding cases is described by Katz and Siegel (Ref. 26).

Katz and Siegel (Ref. 26) have discussed in detail the interactions between gastrointestinal hemorrhage and the occurrence of the acute gastric mucosal lesion which is involved in bleeding from acute erosive gastritis (localized or diffuse small erosions a few millimeters in diameter), acute gastric ulcer (single or multiple erosions 10 mm or more in diameter), and hemorrhagic gastritis (which may appear to “weep” blood without recognizable erosions or ulcers). The latter category is not generally detected by gastroscopy but is observed during surgery.

The acute gastric mucosal lesion is characterized histologically by the presence of three features which are: denudation of superficial epithelium; hemorrhage to the capillary-rich area of the neck of the glands; and hemorrhage in the lamina propria which has diffused throughout the gastric gland area. The degree of involvement of each of these features may vary from one biopsy to another, and multiple biopsies are made. In 93 patients with upper gastrointestinal bleeding, the acute mucosal erosions were present in histological studies in 69.6 percent of patients with gastroscopically observed localized erosions, in 69.7 percent of patients with diffuse gastric erosions, and in 89 percent of patients in whom the cause of upper gastrointestinal hemorrhage was undiagnosed by gastroscopic examination indicating to the authors the possible involvement of central or diffuse erosions.

The histological acute mucosal lesion is thus the common denominator for a variety of gastric conditions associated with massive gastrointestinal bleeding. The diagnosis actually reported and the incidence in different studies depends upon whether examination was carried out by radiology (x-ray) only, or whether gastroscopic examination was done at all, done on all patients who bled (including x-ray positive cases) or done only in x-ray negative cases. Gastroscopy must be done rapidly as erosions can disappear in a few days after bleeding. Further characterization of the lesion depends upon whether single or multiple biopsies were taken for histological studies (Refs. 24 and 26). Finally, recent studies by Langman of mucosal lesions are frequently associated with bleeding in the duodenum and jejunum and upper parts of the stomach and esophagus in hiatus hernia and esophageal varices. These lesions are not seen unless special endoscopic procedures (duodenoscopy or esophagoscopy) or surgery are performed.

Several authors concluded that many cases of x-ray and gastroscopically negative massive bleeding are probably due to acute mucosal lesions (Refs. 25 and 26). The categorization by different authors will also depend on the age group surveyed, the proportion of women and men studied, the proportion of cases involving different inciting agents (aspirin, alcohol, stress) and the precipitating factor (alcohol, stress, aspirin, other drugs).

The acute mucosal lesion is the histological picture seen in hemorrhagic gastritis in which erosions are not seen gastroscopically. This diagnosis is usually not possible gastroscopically but is observed during gastroscopy (Ref. 26). The acute mucosal lesion is seen in 69 percent of localized acute erosive gastritis and 70 percent of diffuse acute erosive gastritis and acute gastric ulcers. The acute mucosal lesion was also observed by Katz and Siegel (Ref. 26) in 80 percent of radiologically and gastroscopically negative cases of overt hemorrhage. It has been shown during surgery that similar erosions can be found concurrently in the gastric and duodenal mucosa and that bleeding may occur from the latter, a possible explanation for the high frequency of diagnosed cases. A control group had acute lesions in only 6.6 percent of 80 patients which was significantly different from all other groups. The relationships between gastrointestinal bleeding and acute mucosal lesions are shown in the following table by Katz and Siegel (Ref. 26):

### Relationship between gastroscopically diagnosed erosions, histologically diagnosed gastritis and frequency of histologically characterized acute mucosal lesions

<table>
<thead>
<tr>
<th>Type of erosion, gastroscopic diagnosis</th>
<th>Number of cases</th>
<th>Cases with acute mucosal lesions (In percent)</th>
<th>Histological diagnosis—type of hemorrhage gastritis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diffuse erosive gastritis</td>
<td>35</td>
<td>69.6</td>
<td>Type of gastritis</td>
</tr>
<tr>
<td>Undiagnosed (x-ray and gastroscopically negative)</td>
<td>25</td>
<td>69.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>69.7</td>
<td></td>
</tr>
</tbody>
</table>

The findings of Katz and Siegel described in the above table are of particular importance showing the high incidence (80 percent) of acute mucosal lesions found in the undiagnosed (x-ray and gastroscopically negative) group. Langman in his critical review erroneously concluded that the incidence of aspirin associated bleeding should be smaller in the latter group with bled some of his further conclusions.

(1) **Acute lesions in peptic ulcer and other x-ray positive conditions.** Even when a positive radiological diagnosis of a chronic ulcer that smaller type (x-ray gas-

troscopic or surgical examination frequently shows that bleeding actually occurs from an acute mucosal lesion (erosion or acute ulcer) and not from the chronic ulcer. A number of studies have been reviewed by Katz and Siegel (Ref. 26) and others showing that the majority of patients with a diagnosis of gastric ulcer are found to be from coexisting acute gastric mucosal lesions (Ref. 24). Back diffusion of hydrogen ion from gastric acid is generally assumed to be a primary factor in the production of acute gastric erosions, presumably by direct and indirect effects on capillary blood flow through liberation of histamine or other substances from the mast cells in the lamina propria. However, acute mucosal erosions can occur in the stomach with reduced or absent gastric acid (Ref. 26).

The etiology of acute mucosal erosions is acromegaly the end product of several possible interactions of both genetic factors which can directly or indirectly affect the mucosal blood supply. Although duodenal ulcer is most often cited as the cause of upper gastrointestinal bleeding, several studies in which early gastroscopy is carried out in all patients have shown that acute gastric erosions are a more frequent site of bleeding than duodenal ulcers (Ref. 35).
It has also been shown that the assumption that alcoholics bleed most often from esophageal varices is false since in one series 43 percent bled from acute gastric mucosal lesions while only 13 percent bled from varices (Ref. 26). Acute erosions were found in 20 of 34 men during acute alcohol intoxication who exhibited abnormal mucosa on histological examination in all 34 cases and acute gastritis in 30 of 34 cases (Ref. 26). Erosions and histology returned to normal after abstinence. It is claimed that the erosions can probably develop in the absence of gastric acid. They also occur in chronic alcoholics in the absence of alcohol ingestion which indicates that alcohol plays a role but is not essential for production of acute mucosal erosions (Ref. 26).

Similarly in hiatus hernia in which the upper portion of the stomach is strangulated, an acute mucosal lesion, similar to those seen lower in the stomach, occurs presumably due to venous traction from occlusion by the diaphragm. Although aspirin apparently is not the cause of the erosion, bleeding is often precipitated immediately following aspirin ingestion (Ref. 26). Bleeding from acute mucosal erosion in patients with hiatus hernia was involved in 2 percent of all massive bleeding in the series of Katz and Siegel (Ref. 26). Although aspirin is in 30 of 34 cases are frequently involved in bleeding from acute mucosal lesions, it is now clear that acute mucosal erosions can be the end product of a variety of other interacting endogenous and exogenous potential etiological variables which directly or indirectly affect the mucosal circulation.

Histamine produced overt bleeding in one of 17 patients. Histological examination showed minimal denudation of superficial epithelium in only three patients but moderate or severe hemorrhage in three patients and hemorrhage in the neck of all patients. Several studies in animals have indicated the probable role of histamine release from degranulation of mast cells in the lamina propria as a factor in stress ulcers. Other factors including vagal and sympathetic stimulation, epinephrine release, and ACTH release have been shown as possible factors in acute hemorrhagic erosive gastritis associated with a variety of types of physical and emotional stress, infections and hypovolemic shock (Refs. 24 and 26).

In 1961, Kossower and Kaplan (Ref. 32) stated that for more than a decade, controversy has existed regarding the role of salicylates in gastrointestinal bleeding. They stated: "There are those who feel that salicylates are responsible for the bleeding; those more skeptical who are awaiting additional evidence, and finally the group who ridicule the idea" and further noted: "Then some do believe that aspirin can cause bleeding; there is divided opinion between the local gastric irritation theory and the hypothesis that the effect is from varices as a result of good coagulation." It is interesting that the same controversy still exists even though 15 years ago based upon data available to them, Kossower and Kaplan reached conclusions on the role of aspirin and the mechanisms involved which are essentially the same as the conclusions presented here based on different, more recent experimental evidence. Based upon information from the literature, from the first report of gastrointestinal bleeding after salicylate medication by Baly in the study of Kossower and Kaplan conducted in 1959, the following conclusions were reached (Ref. 32):

1. Histamine produced overt bleeding in patients with existing occult bleeding. They stated: "There are those who feel that aspirin and salicylic acid can both precipitate bleeding from existing lesions and that aspirin has effects which cannot be explained on the basis of the acid-mediated (Davenport) mechanism. Based upon the Davenport mechanism, salicylic acid would be expected to be essentially equivalent to aspirin in producing occult bleeding based on its ability to break the gastric barrier." (See part III, paragraphs B.1.a.(2) (ii) (c) above—Acid-mediated erosive gastritis.) There are significant differences, however, between the two drugs in the degree of occult bleeding when given intravenously and orally, and in the duration of increased bleeding after dosing is terminated. In the Grossman study, patients with recent gastrointestinal bleeding who are more susceptible to the effects of salicylates, were given aspirin or salicylic acid orally or intravenously for 3 days followed by a 3-day collection period. These data are summarized below.

**Comparison of occult blood loss (milliliter per day) of aspirin and salicylic acid given intravenously and orally to patients with past history of bleeding**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Control before drug</th>
<th>Treatment period 1 (d)</th>
<th>Treatment period 2 (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin intravenous</td>
<td>0.6 ± 0.2</td>
<td>1.14 ± 0.3</td>
<td>1.70 ± 0.6</td>
</tr>
<tr>
<td>Aspirin, enteric coated</td>
<td>0.6 ± 0.5</td>
<td>1.52 ± 0.9</td>
<td>2.03 ± 0.6</td>
</tr>
<tr>
<td>Salicylic acid, intravenously</td>
<td>0.52 ± 0.2</td>
<td>1.52 ± 0.9</td>
<td>2.03 ± 0.6</td>
</tr>
<tr>
<td>Salicylic acid, oral</td>
<td>0.6 ± 0.2</td>
<td>1.52 ± 0.9</td>
<td>2.03 ± 0.6</td>
</tr>
</tbody>
</table>

**Comparison of occult blood loss (milliliter per day) of aspirin and salicylic acid effects in patients with bleeding (primed) lesions**

<table>
<thead>
<tr>
<th>Patient with existing occult bleeding</th>
<th>Aspirin</th>
<th>Sodium salicylate</th>
<th>Sodium salicylate</th>
<th>Sodium salicylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jejunal ulcer</td>
<td>4.0</td>
<td>72.0</td>
<td>10.9</td>
<td>10.9</td>
</tr>
<tr>
<td>Duodenal ulcer</td>
<td>4.0</td>
<td>72.0</td>
<td>10.9</td>
<td>10.9</td>
</tr>
<tr>
<td>Esophageal varices</td>
<td>0.1</td>
<td>11.0</td>
<td>4.7</td>
<td>4.7</td>
</tr>
<tr>
<td>Sodium salicylate</td>
<td>2.0</td>
<td>21.7</td>
<td>4.7</td>
<td>4.7</td>
</tr>
</tbody>
</table>

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**

The effects of aspirin were usually prolonged into the second and third postadministration period of 3 days per period. Sodium salicylate did not exert its effect beyond the first postadministration period even in the "primed" patients with existing erosions. Oral sodium salicylate did have a greater increase in blood loss in "primed" patients bleeding from duodenal ulcer and esophageal varices. Oral aspirin greatly increased bleeding in jejunal ulcer, duodenal ulcer and esophageal varices. It is obvious that this effect is not dependent upon the acid-mediated mechanism (Davenport) in the jejunum or esophagus. Thus, part of the action of aspirin as to be due to local effects of salicylic acid on existing erosions. There is an additional effect which can be exerted from systemic aspirin since it occurs after intravenous administration and is not due to salicylic acid. This aspirin effect persists longer than the effect of an equivalent salicylic acid dose. The aspirin effect also increased bleeding longer than salicylic acid in patients with existing bleeding lesions.

The clinical results seen by Grossman et al. (Ref. 19) in patients are virtually identical to the experimental results of Brodie and Hooke (Ref. 37) in rats who showed a difference between aspirin and salicylic acid in the mechanism of inducing bleeding in the fasted rat stomach. Salicylic acid (sodium salt) produced gastric hemorrhage only by the oral route, requiring twice the dose of aspirin to produce this effect (the 50 percent effective dose (ED₅₀)). The safety for salicylic acid and aspirin was 36 mg/kg and 16 mg/kg, respectively. In contrast to salicylic acid which produced gastric lesions only on direct contact, aspirin produced gastric effects also by the intravenous route at the higher dose (36 mg/kg) (Ref. 37).

Both aspirin and salicylic acid potentiate bleeding from existing acute erosions. There is evidence that aspirin has an additional effect that is different from that of salicylic acid. This effect is observed after systemic administration of aspirin but only when potential bleeding from acute erosion exists. It is clear that the potentiation of aspirin is not dependent upon gastric acid since...
potentiation of bleeding also occurs from duodenal and jejunal ulcers. If the primary effect of aspirin is to enhance bleeding from existing lesions it would be expected that increased occult bleeding would be observed after intravenous administration of aspirin in normal subjects. This is in fact what has been shown by the data of Leonards and Levy (Ref. 27). Thus, the primary factors in producing bleeding in normal subjects appear different from potentiation of bleeding from acute mucosal lesions.

Aspirin-induced occult bleeding in normal aspirin users can be significantly reduced or eliminated when given as highly buffered aspirin solutions. However, recent studies submitted at the request of this Panel, in patients or animals with existing gastrointestinal lesions, show that increased occult bleeding continues to occur even with highly buffered aspirin preparations. These effects persist even after aspirin is discontinued, similar to the results seen by Grossman et al. (Ref. 19). The role of aspirin in potentiating bleeding from existing erosions is not dependent upon gastric acid secretion, because the renal or bile route of excretion is thought to stimulate histamine release. In existing acute lesions histamine has probably already been stimulated by other factors, the most likely being stress, according to some authorities (Refs. 5, 16, 26, and 32).

Increased occult bleeding is produced by aspirin in patients with achlorhydria which is further evidence that some facts of on abnormal gastric mucosa do not require the presence of gastric acid. This has been shown in several studies in patients with achlorhydria due to atrophic gastritis and pernicious anemia. St. John and McDermott (Ref. 34) have shown, in patients with achlorhydria, that aspirin can induce bleeding in the absence of stomach acid. There are several possible mechanisms by which precipitate potentiate bleeding from existing acute mucosal lesions. The effects of aspirin on platelet function will be seen only when exposed oozing capillaries are involved such as acute gastric or duodenal mucosal ulcer.

Thus, the study by Leonards and Levy (Ref. 27) in normal subjects showing increased bleeding time after intravenous aspirin administration, but no increase in occult bleeding, is what would be expected if the effect of systemic aspirin was to potentiate bleeding from existing acute gastritis erosions rather than to cause lesions. Therefore, the Panel concludes that the use of the Leonards and Levy study in the submission to refute the possibility that effect of aspirin on platelet function cannot contribute to massive bleeding is totally inappropriate.

(2) Effect of highly buffered aspirin for solution on gastric mucosa. The arguments that highly buffered aspirin for solution does not directly produce gastric-mucosal lesions or occult bleeding in the stomach, in contrast to other aspirin solid dosage forms, are based on the acid-mediated single mechanism theory and a series of contentions (Ref. 1) listed below. These contentions are not consistent with experimental data from animals or humans. These erroneous allegations are based upon which is contained in the dry tablets of an effervescent aspirin preparation is entirely converted to the water-soluble salt, sodium acetylsalicylic acid; "A solution of an effervescent aspirin preparation does not contain aspirin;" and "Sodium acetylsalicylate possesses chemical and pharmacological properties which distinguish it in fundamental ways from aspirin.

A national news release dated June 6, 1973 cited a subcommittee hearing (Ref. 36) in which it was stated that, "Much of the testimony before the subcommittee is founded on a mistaken premise. Many people do not realize the analgesic as taken in an effervescent aspirin preparation is not aspirin."

The Panel strongly disagrees with these statements. The aspirin in highly buffered aspirin for solution is physicochemically or pharmacologically different from any other aspirin. This assumption is totally ungrounded and clinically misleading.

All aspirin whether administered as an effervescent buffered solution, tablet, or sodium salt always exists in solution either as the unionized molecules or as the unionized species. Both species are always present. The relative abundance of each species is dependent upon the pH (a measure of acidity) of the solution, and therefore, changes almost instantly whenever the pH of the solution changes. The ratio of ionized to unionized aspirin in 100-fold. When the pH is raised to pH 6 (the initial pH after highly buffered aspirin is administered) the ratio of ionized to unionized is only 0.001.

Since the ratio of ionized to unionized drug is a function only of pH, it should be clear that regardless of the form administered, when aspirin gets into the cell it will exist almost completely as the unionized acetylsalicylate as the cell has a constant pH between about 5 and 6. The ratio of ionized to unionized aspirin in the gastric cell, the blood, or cells where it exerts therapeutic effects is totally independent of the form of aspirin administered.

Another argument is that the gastric mucosal cell acts as a lipid barrier and hence is impervious to sodium acetylsalicylate which is ionized and therefore not lipid soluble. Therefore, gastric absorption of aspirin occurs when aspirin is ionized but not sodium acetylsalicylate (ionized) (Ref. 1). The earlier concept that ionized drug is not absorbed can no longer be considered valid. The data of Davenport clearly shows that ionized species of aspirin is absorbed in the stomach at about one-fifth the rate of unionized species.

Davenport states that at high gastric pH the rate of absorption is by no means negligible. In a surgically prepared dog, the absorption rate of aspirin was found to decrease from 342 µmol/min at pH 1 to 65 µmol/min at pH 6.5 even though the fraction of aspirin unionized decreased from 0.97 to 0.01. He found a 10-fold decrease. He suggests that absorption of the ionized species may occur at the same gastric mucosa or and that the gastric barrier prevents access to the cell to the capillaries.

Morris et al. (Ref. 30) correlated gastric lesions with the absorption of radioactive (14C) sodium acetylsalicylic acid administered to albino rats at a dose of 0.28 µmol/kg of body weight dissolved in 0.15 M citrate buffer. The final pH was 4.6 at this usually obtained with highly buffered aspirin for solution. In the stomach no content was absorbed after 1 hour. This content is a half-life of about 20 minutes or less. Absorption from the rumen portion is very slow. Lesions were produced in the corpus region only by sodium acetylsalicylate which absorbed more rapidly than sodium acetylsalicylic acid.

Anderson (Ref. 40) also found that the addition of buffering did not produce gastric lesions when gastric emptying was prevented the decreased gastric damage observed with highly buffered solutions is largely due to increased gastric emptying rather than decreased gastric absorption. He showed in guinea pigs that when gastric emptying was prevented (pyloric ligature) the gastric absorption of aspirin was prevented. The fraction of aspirin absorption at a solution of pH 7.0 was only reduced to about 50 percent of the amount absorbed when the pH was 1.3. When they were both at the high pH (pH 7.0).

Anderson concludes that the critical rate of absorption is of low order in the guinea pig and if a similar low rate occurs in man the avoidance of gastric erosions would be different with any formulation where the whole dose was immediately available for absorption. The latter statement would, of course, be true if highly buffered aspirin for solution preparations.

The mechanism by which aspirin exerts its effects may simply be a result of combination of unionized acid in the cell to cause damage by directly interfering with biochemical processes. The accumulation of total salicylate in the cell will be increased when the gastric content is acidic and the gradient of unionized aspirin outside the cell to the unionized aspirin in the cell (Ref. 41).
Other mechanisms involving delayed gastric acid effects can be postulated. Ethanol, which can damage the hydrogen ion barrier in an alkaline medium, is potentiated by salicylates (Ref. 42). It is not known how long these effects last but they might persist after the buffering capacity of highly buffered aspirin for solution is gone. This might be particularly true for hypersecretors of gastric acid. As is discussed in the next section, the effects may persist for several days after dosing has stopped. In prolonged effect cases, the immediate occurrence of highly buffered aspirin in solution for obvious is of no value if, as the submission contends, these effects are really mediated by gastric acid.

The many inconsistencies in the data and arguments reviewed do not permit the Panel to accept the argument that the use of highly buffered aspirin for solution will obviate all direct mucosal effects of aspirin.

It has been argued that the presence of the buffer not only decreases aspirin absorption but also reduces excess hydrogen ion which is a necessary component in the production of gastric damage and bleeding. Therefore, the argument continues, "highly buffered acetylsalicylate causes no damage." The Panel finds that although gastric acid undoubtedly plays a role in the bleeding, the availability of gastric acid is not essential for aspirin to cause gastric erosions or occult bleeding as has been discussed earlier. (See part XII, paragraph B.l.a(2) (i) above—Other mechanisms of aspirin damage.)

The study of Dagle et al. (Ref. 22) in vaginized rats indicates that microscopic lesions can be produced in the absence of hydrochloric acid. If hydrochloric acid is later added, more severe damage and hemorrhage occurs. Several authors have noted reduced but statistically significant occult bleeding in patients with achlorhydria from a variety of causes including pernicious anemia and atrophic gastritis (Ref. 25 and 26).

(3) Experimental data submitted to the Panel. Evidence to support the contentions regarding the mechanism of aspirin effects and each effect of highly buffered aspirin for solution has come from occult bleeding studies in normal subjects or in experimental preparations. The studies of Leonards and Levy were cited to substantiate the following statement: "In all studies where meaningful protocols were employed, it has been consistently found that an effervescent aspirin preparation does not cause occult blood loss since in every-study the occult blood loss was higher when buffered with highly buffered aspirin for solution was not statistically different from that found habitually occurring in the same subjects or were well within the normal limits." (Refs. 11, 12, and 43 through 46).

However, analysis of submitted data show that average occult bleeding loss produced by highly buffered aspirin for solution is less than that produced by regular aspirin but significant compared to controls receiving placebo or no aspirin and significant when multiple doses are given or when patients with peptic ulcer are used (Refs. 11 and 14). The Panel is not concerned with these minor increases in occult bleeding from a clinical point of view. They are significant, however, from the point of view of evaluating mechanical assumptions. Of additional importance in these studies are certain patterns that can be seen in several different occult bleeding studies which lend support to the involvement of other mechanisms. In particular, the occurrence of unusually greater occult blood loss in a few individuals is consistently noted in several studies. The prolongation of effects for several days after the drug dosing has stopped is also significant (Refs. 11 and 14).

Average increases or decreases in occult bleeding losses shown below: In the initial submission to the Panel, it was stated that "..." subjects N on some days had fecal blood loss well in excess of the range of the other subjects. Applying statistical analysis ("United States Pharmacopeia," 16th Ed., p. 878); these aberrant values may be rejected." As a result it was claimed that no statistical difference existed. The notion of omitting the "outliers" which were excessive bleeders therefore atypical, in a study designed to assess this potential following drug treatment is in the Panel's view not only erroneous from a statistical point of view but totally illogical from a clinical point of view. Exclusion of outliers obscures the obvious fact that some patients bleed significantly after receiving highly buffered aspirin effervescent solution. In each of the outliers, cases where significantly increased bleeding occurred, it was only during the highly buffered aspirin for solution drug treatment period. The most dramatic example was the outlier, subject 8, who had no appreciable bleeding in this day control period (average blood loss of 0.4 ml daily; range 0.0 to 0.9 ml daily) but on the 4th, 5th and 6th day of drug treatment experienced daily blood losses of 12.2, 12.7, and 13.5 ml, respectively.

In the opinion of the Panel, the following can be concluded for the population studied in the Goulston study: (1) Highly buffered aspirin for solution given chronically, and in all cases, slightly increases fecal blood loss. This loss is probably less than would have been produced by aspirin tablets and is not significant clinically.

(4) Additional information that appears consistent with other studies. Evidence of increased bleeding occurs only after about 3 to 4 days of multiple dosing but appears to persist for up to 3 days after cessation of drug ingestion. When it compares the bleeding during the control period after drug dosing (1.1 ml daily) with the control period before dosing (0.5 ml daily), there is a statistically significant carryover effect. If one accepts the average blood loss of all controls as 0.79 as given, this value is exceeded in only 3 of 20 subject days in the first 2 days of the drug period. When the control is given first, but in 15 of 20 days when drug is given in the first period (Ref. 4). When one plots the average and individual values as a function of time, this pattern may be repeated.

(4) Review of new studies on occult bleeding in subjects and animal preparations with existing lesions. The Rider study (Ref. 14) measured average daily fecal blood loss in patients receiving no drug (12 day control period), a placebo (7 days) and a highly buffered aspirin for
solution product (7 days), and a post-treatment period (5 days).

The average data are shown below:

<table>
<thead>
<tr>
<th>Occult fecal blood loss in patients with active duodenal ulcer</th>
<th>Average range milliter per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control period (12 d) ---</td>
<td>0.57 (0.23-1.04)</td>
</tr>
<tr>
<td>Placebo period (7 d)</td>
<td>0.71 (0.62-1.22)</td>
</tr>
<tr>
<td>Post placebo period (5 d)</td>
<td>1.18</td>
</tr>
<tr>
<td>Highly buffered aspirin for solution period (7 d)</td>
<td>1.05 (0.67-4.38)</td>
</tr>
<tr>
<td>Post highly buffered aspirin for solution period (5 d)</td>
<td>2.7</td>
</tr>
</tbody>
</table>

1Significance not stated (individual data not given)

2Significance not stated (individual data not given)

The Rider study clearly shows that occult bleeding does increase in patients with active peptic ulcer after administration of the highly buffered aspirin for solution product (mean blood loss 1.58 ml daily) compared to a control period (mean blood loss 0.57 ml daily) and a placebo (mean blood loss 0.71 ml daily).

Perhaps more significant was the finding that the effects of the highly buffered aspirin for solution product persisted for at least 5 days after administration had ceased (mean blood loss 2.7 ml daily compared to mean blood loss of 0.57 ml daily for placebo).

This provides evidence that the increase in bleeding may not involve the direct effects of aspirin. It would be consistent with the long lasting effects (7 days) of aspirin on platelet function which would be expected to be observed only in patients with potential bleeding sites but not in individuals with a normal mucosa. The bleeding lesion may not necessarily be the ulcer but acute gastric erosions which are often associated in patients with peptic ulcer.

Similar results are seen in the recent two studies of Phillip et al. (Ref. 12) in which highly buffered aspirin for solution produced a statistically significant increase in occult bleeding in dogs with chronic ulcer. Excess occult bleeding in some animals (outliers) also occurred in these studies. Further evaluation of these studies was limited because individual data were not available and arbitrary, e.g., "weighting factors" appeared to be applied to the bleeding data in an irregular manner.

(5) Epidemiological studies on massive bleeding. Two epidemiologic studies, the Brown and Mitchell study and the Jennings study were critically reviewed by Langman in an industry submission (Ref. 47). The reasons used by Langman in dismissing the highly buffered effervescent aspirin dosage form as a factor in massive bleeding ignore several important points. For example, the fact that highly buffered aspirin preparations are promoted for use in gastric distress was not considered by Langman in his review.

Brown and Mitchell (Ref. 15) showed that a highly buffered aspirin preparation was more frequently used by individuals who bled from duodenal ulcers whereas plain aspirin was most often used in the treatment of gastric ulcers. Langman concluded from this study that since bleeding from gastritis is more frequently associated with aspirin than the aspsrin dosage forms which have the highest potential to cause bleeding would be associated in this diagnostic category. This conclusion ignores three important points. First, individuals with duodenal ulcer who frequently also have acute gastritis have a higher incidence of gastric distress than individuals with only acute gastritis, particularly of the atrophic variety. Since the Brown and Mitchell study (Ref. 15), highly buffered aspirin for solution preparations claimed and were promoted for the symptoms of gastric distress, in the absence of the study Langman states that a greater number of individuals with duodenal ulcer ingested this type of preparation. Second, the potentiation of aspirin induced bleeding by alcohol is used in those who bled from acute gastritis and Mitchell subgroup when subgroups are analyzed, a point noted, by Langman in the same paper. Highly buffered effervescent aspirin preparations have been claimed and have been heavily promoted for use in concomitant symptoms of headache and gastritis related to overindulgence with alcohol. Therefore, when alcohol ingestion is a factor, these preparations would more likely be associated with bleeding from duodenal ulcer rather than gastritis. Finally, irrespective of the above, the Panel believes that it is not a matter of whether aspirin tablets cause bleeding more frequently than highly buffered effervescent aspirin but whether or not highly buffered effervescent aspirin preparations are associated with aspirin-induced bleeding. Since Langman in his review (Ref. 47) states that if the highly buffered effervescent product were the cause of the bleeding the incidence of use would be higher in the acute ulcer group which is not associated with aspirin-induced bleeding. There are several reasons for questioning the validity of this contention. First, patients with chronic ulcers have a higher incidence of gastric distress than patients with acute ulcer. At the time of the study (1965) highly buffered effervescent preparations were specifically and almost exclusively promoted for gastric distress. It would not be surprising therefore that the group with the highest incidence of gastric distress would have the highest use of highly buffered effervescent aspirin use. Second, even though aspirin is associated more with acute ulcer (to a higher proportion) than with chronic ulcer, it has nevertheless been associated with bleeding in chronic ulcer patients. In fact, Langman states in his review that in four of five studies, aspirin ingestion was more frequently associated with massive bleeding in duodenal ulcer than in acute gastric lesions.

Because the Panel believes the control group, referred to by Langman in his analysis of the Brown and Mitchell study was improperly defined, it has estimated what the control group should have been, based upon data in the submissions (Ref. 1). The data (Ref. 2) show that about 38 percent of the individuals who took one brand of buffered effervescent aspirin from "time to time". This is consistent with the control group of Brown and Mitchell (Ref. 15). However, calculations from the information presented by Langman (Ref. 47) indicate that on any given day less than 5 percent of a random sample would be expected to have consumed the highly buffered effervescent preparations. Using the 5 percent figure rather than the 40 percent as a control upon which to view the Brown and Mitchell study, the Panel concludes that one cannot rule out the possibility that all aspirin preparations regardless of formulation are equally capable of potentiating gastrointestinal bleeding.

Langman (Ref. 47) also reinterpreted the epidemiological data of Jennings (Ref. 15) to show that highly buffered effervescent aspirin products are not implicated in massive gastrointestinal bleeding to the same extent as "insoluble" varieties of aspirin. The Panel does not agree with the assumptions used by Langman in this conclusion.

In the Jennings study, detailed information was provided on the specific types of aspirin used, including highly buffered effervescent aspirin. The distribution of aspirin products in patients with overt gastrointestinal bleeding was as follows: In the radiologically negative group, 42 percent with acute ulceration took ordinary aspirin, 18 percent took soluble varieties, and 7 percent took a buffered effervescent preparation. In contrast, 29 percent of the chronic ulcer patients took ordinary aspirin, 14 percent took soluble varieties, and 21 percent took the highly buffered effervescent preparation. Langman in his review (Ref. 47) states that if the highly buffered effervescent product were the cause of the bleeding the incidence of use would be higher in the acute ulcer group which is not associated with aspirin-induced bleeding. There are several reasons for questioning the validity of this contention. First, patients with chronic ulcers have a higher incidence of gastric distress than patients with acute ulcer. At the time of the study (1965) highly buffered effervescent preparations were specifically and almost exclusively promoted for gastric distress. It would not be surprising therefore that the group with the highest incidence of gastric distress would have the highest use of highly buffered effervescent aspirin use. Second, even though aspirin is associated more with acute ulcer (to a higher proportion) than with chronic ulcer, it has nevertheless been associated with bleeding in chronic ulcer patients. In fact, Langman states in his review that in four of five studies, aspirin ingestion was more frequently associated with massive bleeding in duodenal ulcer than in acute gastric lesions.
This argument is found again in this statement by Langman: "Finally Jenn-
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in lesion is generally considered to be an acute mucosal erosion."

The data of Jennings (Ref. 16), showing a higher incidence of aspirin and alcohol associated with hemorrhage than concurrent gastritis and headache, suggest that the available aspirin product that could be taken. The Panel finds that the use of highly buffered aspirin for solution may increase the risk because it delivers more pure aspirin to the systemic circulation than regular aspirin products (Ref. 49).

Even if a claim was allowed only for use for concurrent symptoms of gastric distress and headache, in the opinion of the Panel, and in fact, the Panel finds that the use of highly buffered aspirin for solution may increase the risk because it delivers more pure aspirin to the systemic circulation than regular aspirin products (Ref. 49).

The Panel concludes that is is un-
proven, and unlikely that highly buffered aspirin for solution is less apt to produce major gastrointestinal hemorrhage than regular aspirin. Neither is there evidence to show that it would be safer to use this aspirin buffered product for concurrent symptoms of headache and gastric distress. Current evidence sug-
gests that alcohol gastritis and stress are the two most likely causes of concurrent symptoms of gastric distress. Alcohol and stress are also two major factors which may produce acute mucosal lesions and thus increase the risk of bleeding from the use of any aspirin product.

The Panel does not believe that cur-
current evidence warrants an exemption from the labeling recommendation for simultaneous use for concurrent symptoms of gastric distress, ulcers or bleeding prob-
lems except under the advice and super-
vision of a physician.

REFERENCES

(1) OTC Volume 030059.
(2) OTC Volume 030121.
(3) OTC Volume 030104.
(4) OTC Volume 030162.

(5) Benefit to risk considerations.

Several benefit to risk considerations were involved in the Panel's recommend-
ation not only to highly buffered aspirin for solution to be indicated for use in individuals with a history of symptoms of gastrointestinal bleeding, ulcer or symptoms of gastric distress with or without concurrent headache. The Panel's conclusions regarding the mech-

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Therefore, the Panel concludes that arguments of Langman cannot be used to dismiss this study as reasonable evidence that highly buffered efferves-
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cent aspirin is as likely to be associated with gastric bleeding as any other form of aspirin.
These advantages have been, in various ways, linked to both the more rapid dissolution resulting in faster absorption into the bloodstream, and consequently preventing the adverse local reactions to the stomach that may be caused by plain (unbuffered) aspirin products. The statements that have most frequently been used on the labeling of buffered and highly buffered aspirin products suggest these advantages in terms or phrases such as "Faster to the bloodstream" or "G Entle to the stomach."

The Panel concludes that these claims give the consumer the impression that buffered and highly buffered aspirin products have a therapeutic advantage over plain aspirin products, and may mislead those consumers who can be adversely affected by buffered aspirin as plain aspirin. Until such statements can be adequately documented, the Panel recommends that claims be limited and restricted on the label to discourage unproven claims of therapeutic advantage.

Therefore, for the reasons discussed below, the Panel recommends that such labeling be restricted to the principal display panel of the product and be limited to the following statements: "Faster to the bloodstream than plain aspirin" and "Provides ingredients that may prevent the stomach distress that plain aspirin occasionally causes but should not be taken by certain individuals with stomach disorders as cautioned elsewhere on the label". The Panel also concluded that any other statement(s) that suggests or represents a product as having a more rapid absorption or as preventing any side effects to the stomach because of the antacid or buffering ingredients in the product should be classified as Category II.

The Panel views the problem of evaluating claims relating to differences in blood levels of drug products as involving several interrelated steps. First is the requirement of well-designed blood level studies which can be shown that the differences in drug absorption with buffered aspirin compared to plain aspirin are due to a more rapid rate of drug absorption into the bloodstream.

The problem is largely due to inadequacies in the available data and the lack of understanding of the relationship between salicylate blood levels and onset of analgesic effects. There is clear experimental evidence based upon well-designed blood level studies which substantiate the claim that buffered aspirin is more rapidly absorbed than plain aspirin (Refs. 1 through 3). Comparisons of the most commonly used plain and buffered aspirin show that salicylate blood levels are twice as high in the first 10 to 20 minutes for the buffered aspirin product compared to regular aspirin. It can be shown that the differences in plasma levels in the first 30 minutes correlate quite well with the amount of drug absorbed (Ref. 4).

The basic problem is that there are no well-controlled clinical studies that unequivocally prove or disprove that these differences in absorption will result in clinically important differences in the onset, intensity or incidence of relief of pain or fever.

In the absence of this definitive information on the clinical significance of the increased rate of absorption, there is a secondary question that was debated by members of the Panel and consultants. This second question pertained to divergent opinions regarding the validity and value to the public of claims regarding differences in drug absorption with buffered aspirin. One argument is that since the information regarding absorption is true and these differences likely relate to real therapeutic advantages, the information should be available to the public for their assessment. The opposite view, held equally strong, is that such information will usually be confusing or misleading to the public. Any statement regarding more rapid absorption will always be interpreted by the public as implying some therapeutic advantage. Else, why would it be made?

The Panel does not believe that questions regarding the public's interpretation of presently undefined promotional statements can be objectively resolved by any practical methods presently available. The Panel's conclusion is that the Panel should carefully formulate an accurate statement. However, regarding the relative rates of aspirin absorption, which would be accurate and informative, the problem of public interpretations of labeling claims relates not only to the current controversy but to the interpretation also of future statements based on new studies. Similar problems have and will occur with statements regarding prolonged blood levels produced with some dosage forms and the inference that prolonged duration of effect will occur.

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PROPOSED RULES

35481

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

a nonlinear dose–response function has been shown by different methods and that a graded time course of pharmacologic activity has also been documented (see part III, paragraph B.I.a.1—Effectiveness.) There are known relationships between dose and plasma concentration. Analysis. It is theoretically and mathematically that some expression does exist and recent advances in computer assisted pharmacokinetic modeling, analytical methodology, and statistical testing will enable elucidation of this function in the future. When an insensitive test does not show clear differences between two products it can only be said that present insensitivity of an assay was administered.

There is some other evidence to indicate that the differences due to rates of absorption. First, from a theoretical point of view, it can be shown by mathematical analysis that because the rate of aspirin is much more rapid than most other drugs (50 percent is eliminated in 15 to 20 minutes), changes in rates of absorption within normal ranges can result in twofold changes in the average plasma levels. Some possible approaches to define the conditions required in a study to move claims from Category III to Category I are in the literature. Feinblatt et al. (Ref. 5) have shown that the peak blood level and relative amount of aspirin absorbed at different absorption rates are the same for the average plasma levels under the blood level-time curves is twice as great for an effervescent preparation as for a simple aspirin tablet. Even greater peak blood levels were observed when the sodium bicarbonate used as a stimulant was administered.

One of the buffered products was tested against the plain aspirin in two crossover studies comparing the peak onset of relief of pain in patients with recurring headaches and pain of rheumatoid arthritis for arthritis pain. Unfortunately, the data were given only as the mean and range of the time of initial onset of relief. It is claimed that the buffered aspirin preparation had a more rapid onset in both headache and arthritis pain relief. The data were not evaluated statistically and individual data were not provided. Therefore, the apparent increased onset of pain relief with buffered aspirin cannot be further evaluated.

However, these two preparations were evaluated with two types of follow-up data which were analyzed to see if they are consistent with the possibility that the rate of absorption could affect the onset. Preliminary biochemical pharmacokinetic analysis by the Panel indicates that with certain assumptions the data are consistent with a low threshold for pain relief requiring only 1 to 3 mg/100 ml to initiate pain relief. Because of the great variability in absorption rates even in the same individual, it is readily seen that differences in onset of pain relief on the order of a 10 minute difference between two products would be very difficult to show statistically because of the large number of subjects that would be required.

The Panel recognizes that the differences in a few minutes in the onset of pain relief may be considered to be meaningless and of little practical value. The Panel believes that this subjective evaluation of effectiveness is best left to the consumer provided that sufficient facts are presented to an informed decision. Claims such as "faster acting" may be scientifically accurate but misleading for example, if the difference is only 1 or 2 minutes in a small percentage of the target population. The Panel recommends, therefore, that claims implying a greater or faster onset of therapeutic effect or claims relating to blood level data showing differences in the time of onset of absorption may be moved from Category III to Category I if the claimed differences of analgesic effect can be quantitated to provide information on the quantitative or average or the change in the peak plasma concentration (Ref. 1). Experimental data on the blood levels of aspirin by Leonard's (Ref. 5) have shown that the peak blood level and relative amount of aspirin absorbed at different absorption rates are the same for the average plasma levels under the blood level-time curves is twice as great for an effervescent preparation as for a simple aspirin tablet. Even greater peak blood levels were observed when the sodium bicarbonate used as a stimulant was administered.

The Panel suggests once the clinical studies are available to adequately demonstrate major differences in the action of different aspirin products that such information be included in labeling. Reference to blood level data or other indirect data inferring a therapeutic advantage is not adequate use for comparative claims. Claims such as safer to the stomach, faster to the blood stream, are of limited or negative value to the consumer unless sufficient information is given to put them in a proper perspective.

The Panel notes that clinical or preclinical data should be meaningful and of little practical value. The Panel believes that this subjective evaluation of effectiveness is best left to the consumer provided that sufficient facts are presented to an informed decision. Claims such as "faster acting" may be scientifically accurate but misleading for example, if the difference is only 1 or 2 minutes in a small percentage of the target population. The Panel recommends, therefore, that claims implying a greater or faster onset of therapeutic effect or claims relating to blood level data showing differences in the time of onset of analgesic that can be expected. Scientifically valid studies must provide some estimate of the degree and incidence of effect that can be expected by the average user for comparative claims. Claims such as safer to the stomach, faster to the blood stream, are of limited or negative value to the consumer unless sufficient information is given to put them in a proper perspective.

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In addition to serving as a means of simulating in vivo performance of the dosage form in the patient, the procedure may be needed as components of a quality control program not only for buffered aspirin but all standard regular aspirin tablets. Therefore, although methodology of development is now beyond the scope of the Panel, preliminary planning with the FDA was initiated to consider possible recommendations to suggest a starting point for methodology development, which is discussed elsewhere in this document. (See part VI, paragraph C.1. below—Aspirin standard testing procedures.) This methodology must be validated before it can be used to screen products which may have poor biological performance. With less extensive modification, it may be useful for quality control programs. The Panel recommends that, if possible, the development of suitable in vitro methodology for aspirin and buffered aspirin be continued by the appropriate FDA staff in collaboration with all interested parties, e.g., industry, academia and the United States Pharmacopoeia.

REFERENCES

(2) OTC Vol. 03139.
(5) Leonard, J. R., "Presence of Acetylsalicylic Acid in Plasma Following Oral In-


2. Benzaldehyde-containing ingredients. The Panel has classified the following active ingredients as ineffective antiphlogistic agents:

- Aminobenzoic acid (para-aminobenzoic acid (PABA))
- Sodium para-aminobenzoate

Further, para-aminobenzoic acid or sodium aminobenzoate may not be included in combinations for safety reasons discussed below.

a. Effectiveness. The Panel concludes that para-aminobenzoic acid (PABA) is ineffective for use as an OTC antirheumatic agent and is classified as Category II. The Panel further concludes that the combination of para-aminobenzoic acid (PABA) or sodium aminobenzoate with any ingredient(s) discussed below in this document are also classified as ineffective antirheumatic agents.

In 1947, Rosenblum and Fraser studied the efficacy of aspirin as acid in nine patients with rheumatic fever and found depression of fever and relief of joint pain in seven patients after 2 days of administration of 1 to 3 g every 2 to 3 hours (Ref. 1). In 1951, Zollander and Harris studied 27 patients with active rheumatoid arthritis. The effect of the drug on relief of pain and stiffness was studied after administration of 4 g of PABA daily for at least 1 week. Slight experienced relief of pain and stiffness whereas relief was noted in patients given 4 g of sodium salicylate for at least 1 week (Ref. 2).

Para-aminobenzoic acid (PABA) in the form of sodium aminobenzoate is a sulfonamide antagonist which competitively counteracts bacteriostasis induced by sulfonamides. Certain microorganisms require PABA for incorporation into folic acid. It is capable of altering the course of experimental and clinical ricketsial disease. In large doses, PABA can increase the blood level of salicylate by competing for glycine and thereby lowering the rate of conversion of salicylate to salicylic acid, as shown by studies of Salassa et al., who demonstrated that PABA in doses of 2.24 g daily with a single dose of 3 g of sodium salicylate produced a sustained, elevated plasma salicylate level (Ref. 3). This observation was confirmed by Hoagland (Ref. 4).

Carski compared the blood salicylate levels after the administration of a single dose of 650 mg sodium salicylate with the blood salicylate level after a single dose of 650 mg sodium salicylate plus 650 mg PABA and found no difference in blood salicylate level (Ref. 5). Similarly, there was no difference in blood salicylate levels after 1 week of the same doses administered 4 times daily.

Hollander and Harris showed that 4 g each of sodium salicylate and PABA raised the plasma salicylate level more than did 4 g sodium salicylate alone (Ref. 2). However, analgesic effectiveness could not be related to the level of salicylate achieved.

The studies on the antirheumatic effectiveness of PABA do not provide objective evidence of analgesic effectiveness. Analgesic effectiveness in relief of arthritis pain is claimed by Barden and Cuneo (Ref. 6), Cass et al. (Ref. 7), Smith (Ref. 6) and Hebert and Renzi (Ref. 9). However, these impressions of effectiveness are generally counteracted bacteriostasis induced by aspirin or sodium salicylate. Similarly, the clinical and experimental evidence of PABA's role in antirheumatic activity has not been duplicated in controlled clinical trials.

Ford and Blanchard compared the analgesic activity of arthritic patients before and after the treatment with aspirin alone and with PABA (Ref. 10). Some patients were also given the combination plus 2.5 mg dextrose. No conclusions regarding either the antirheumatic or analgesic effectiveness of the combination can be reached from this study because the design of the study did not separate the effect of hospitalization and physical therapy from the effect of the drug combination.

The enteric-coated combination of aspirin and PABA may be expected to be as effective as aspirin alone in relieving pain and relieving signs and symptoms of rheumatic fever (Ref. 11).


(2) Zollander, J. L. and T. N. Harris, "Combined Salicylate and Para-Aminobenzoic Acid (Paba) in the Treatment of Rheumatoid Arthritis," *American Journal of the Medical Sciences*, **221**:388–401, 1951.


(5) Carski, "Combination of Individual Active Components: Controlled Study No. 2019," draft of unpublished paper is included in OTC Volume 60009.


FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

PROPOSED RULES
The pharmacologic rationale for the long accepted use of caffeine in APC compound and in other similar products is not clearly understood. The most recognized pharmacological actions of the drug in stimulating the central nervous system, acting on the kidney to produce diuresis, and in stimulating cardiac and relaxing smooth muscle. Perhaps, it is this latter effect which accounts for its popularity. Caffeine has been claimed to be useful in treating certain migraine headaches due to constriction of cerebral blood vessels and has been shown to be important in the treatment of caffeine withdrawal headache. The latter is discussed below. The Panel, therefore, finds that an important historical use for these preparations containing caffeine has been for the treatment of certain types of headache. There is also some evidence that caffeine may contribute to the effectiveness of analgesics, and therefore, the Panel has categorized this possible contributory effect as a potential adjunctive effect of caffeine.

2. Effectiveness

a. Evidence (1) Caffeine as an analgesic adjuvant. As noted above, the Panel finds that there is some inconclusive evidence to suggest that caffeine may enhance analgesia when used in combination with other analgesics. Therefore, the Panel concludes that although caffeine combined with any Category I analgesic is safe, there are insufficient data to demonstrate any additional contribution of caffeine to the action of the Category I analgesic ingredient.

Although there is weak evidence to suggest that the combination is more effective than the analgesic ingredient alone, more clinical studies need to be done to show that caffeine contributes to the claimed effect(s) and to study the interaction of these two compounds in terms of their analgesic and antipyretic effects. As will be discussed below, there is only one well-controlled clinical study to determine aspirin plus caffeine is more effective than aspirin alone and the results of this study are equivocal (Ref. 1). Several other clinical studies provide some support for this hypothesis; and there are also supportive animal data, and data related to sensory changes to suggest that caffeine enhances the analgesic properties of mild analgesics (Refs. 2 and 3).

The reasons for the lack of clinical studies of the potentiating effect of caffeine on other mild analgesics are many and include the difficulty of carrying out controlled studies with mild analgesics. Another possibility is that clinical analgesiometry is sufficiently imprecise in patients so that a biologically significant effect might not be measurable. A third possibility is that the assay is not sensitive to measure changes in pain intensity for the particular type of pain studied. Although the efficacy of mild analgesics has been studied in experimental pain situations with parturient pain, the effects of caffeine would probably be more apparent if, under closely controlled conditions, patients with headache other than migraine headache were the study population. Still another possibility is that mixtures of caffeine and lidocaine may contribute therapeutic benefits beyond those of pain relief, such as mood changes, which are not measured by typical clinical pain relief studies.

One of the earliest reports by Moyer et al. (Ref. 4) compared the effects of aminophylline (theophylline with ethylendiamine) and caffeine on cerebral hemodynamics and cerebral spinal fluid pressure in patients with headache clinically identified as hypertensive headache. The study demonstrated that aminophylline is more effective but that both aminophylline and caffeine cause prompt relief of headache which results from the hypertensive state. There was immediate relief of headaches following aminophylline in seven of nine patients. After caffeine, relief from headache was obtained in five of nine patients.

There have been other studies which have shown that caffeine may exert a beneficial effect on pain relief through an effect on cerebral vasculature. It is known for many years and shown by the work of Leake et al. (Ref. 5) that the production of experimental headache by nictine was accompanied by dilatation of the cerebral vessels. Likewise, Pickering in 1933 (Ref. 6) studied headache produced by intravenous injections of small amounts of histamine. These studies were enlarged by Clark et al. in 1934 (Ref. 7), and by Schummacher et al. in 1940 (Ref. 8) who demonstrated that this experimental headache was accompanied by increased amplification of pulsation of cerebral blood vessels. Thus, there is good evidence to support the theory that some headaches are related to cerebral vascular distension.

A plausible explanation for the biochemical mechanism by which caffeine is effective in treating this vascular smooth muscle spasm has to do with the biologic role of adenosine-3',5'-monophosphate (cyclic AMP.) Caffeine (an inhibitor of a phosphodiesterase) can cause cyclic AMP to be increased and act as a second messenger in initiating a mechanism which would explain, then, the common effect of catecholamines and amphetamines and caffeine on the small blood vessels and thereby serve as the pharmacologic mechanism by which caffeine could be effective in treating headache associated with constriction of cerebral blood vessels.

In studies of other types of headache, De Laude and Pfeffer (Ref. 10) showed that caffeine could be important in the treatment of caffeine withdrawal headache. The authors recognized that many people with occasional headaches to lack of morning coffee had the "feeling down" which may result if this stimulant is withdrawn from habituated individuals. This study of caffeine withdrawal headache in normal volunteers and in their double-blind study in 22 young volunteers, they produced headache by the abrupt withdrawal of caffeine after the administration of up to 0.78 g caffeine daily usually in the morning over a period of 7 to 8 days. It was uniformly noted that headache following caffeine withdrawal was quite different from the migraine syndrome in the five subjects who also suffered from migraine, although the caffeine withdrawal headache was accompanied by nausea in four of the migraine subjects, and vomiting in one of them. The investigators found that in 55 percent of 32 trials in 22 subjects, headache was extreme and severe as the subject had ever experienced was produced by the sudden withdrawal of caffeine. This headache responded to treatment with aspirin. The authors concluded that this study also provides a plausible explanation for the hitherto empirical addition of caffeine to many headache remedies.

The psychotropic effect of caffeine has been studied in detail by Goldstein et al. (Ref. 11). In the study, the effects of caffeine in coffee were compared in two groups of subjects (abstainers and habitual users of coffee). The study was well controlled and well analyzed, and the authors concluded that caffeine had no demonstrable effect upon objectively measured performance, although it made some subjects feel more awake and physically active. There was a strong positive association between the subjects' sensitivity to mood elevating effects of caffeine, and sensitivity to the psychotomimetic effects caused by caffeine. The central nervous system stimulant effects of caffeine have been discussed in detail in the OTG Sedative, Tranquilizer and Sleep-Aid category. The authors concluded that caffeine withdrawal headache is associated with the use of analgesic agents in combination with caffeine may be increased. This study of caffeine withdrawal headache was concluded that this product is taken continuously for central nervous system effects or for caffeine withdrawal headache.

It is of interest to note that in some recent, controlled clinical studies comparing aspirin alone, aspirin in combination with phenacetin, salicylamide and caffeine, or aspirin, phenacetin and caffeine, the combinations produced a mean pain relief score higher than those for aspirin alone (Refs. 1 and 12). Although the difference was not statistically significant for the study on which the results are based (Ref. 12), it seemed to suggest that caffeine was contributing to the pain relief observed. However, this study was not designed to test this hypothesis that caffeine and aspirin were working in a synergistic manner and that the higher scores could have been due to higher total equivalent dosage of analgesics or indeed, as the authors concluded, it does have an analgesic and antipyretic effect.

In a study presented by Houde (Ref. 1), the effect of caffeine is statistically significant. Houde found that a com-
bination of 210 mg aspirin, 150 mg acetaminophen and 30 mg caffeine gave somewhat better pain relief than either aspirin or acetaminophen alone. House concluded, "while our data does not per-
mitt a conclusive statement, there is at
least some evidence in it to show that
caffeine contributes something to the
efficacy of this combination."

We have been studying the analgesic
activity of aspirin in rabbits, when
aspirin combined with caffeine had no
antipyretic action. The investigators postulated
that caffeine may raise levels of 3',5'-
cyclic AMP, a substance reported to raise
body temperature by inhibiting 3',5'-
cyclic AMP phosphodiesterase. They
therefore recommended that these
experiments be repeated in man and if
similar responses are found that caffeine
and mixtures containing caffeine not be
used in man to demonstrate an effect of the single entity
and no interference with this effect when
65 mg caffeine is given concomitantly.
Thus, following the guidelines under
clinical testing the study would contain
placebo, a dose of the single entity both
alone and in combination with caffeine
in a 2x2 factorial design. (See part VI.
paragraph. Combining Caffeine and Aspirin.)

The Panel believes that if combinations
are to claim antipyretic efficacy the
inclusion of caffeine must be shown not
to produce any more effect than the
antipyretic in man. Therefore,
combinations employing caffeine
are placed in Category III for this indica-
tion. To test for such interference, a
study should be done in humans to dem-
strate an effect of the single entity
and no interference with this effect when
65 mg caffeine is given concomitantly.
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clinical testing the study would contain
placebo, a dose of the single entity both
alone and in combination with caffeine
in a 2x2 factorial design. (See part VI.
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The stimulant effects and toxicity of
caffeine were reviewed in detail by Weiss and Laties in
1962 (Ref. 20). They reported that there
was a wide range of behavior with the
exception of intellectual tasks that could
be enhanced by caffeine. They were
unable to find any evidence of physical de-
cyptively. AMP phosphodiesterase. They
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placebo, a dose of the single entity both
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in a 2x2 factorial design. (See part VI.
paragraph. Combining Caffeine and Aspirin.)
a factor in analgesic abuse the Panel finds insufficient evidence to justify a warning at the present time and the potential benefits outweigh this risk.

References


4. Antihistamine-containing ingredients.

The Panel has classified the following as ingredients for potential use as direct acting adjuvants:

Methyprylonum fumurate Phenamnile maleate Phenyltoloximate Pyridylmaleate

The Panel received data only on phenyltoloximate (Ref. 1 through 5) for use as an adjuvant. However, it is the opinion of the Panel that such potential activity is shared by antihistamines in general. Therefore, the Panel has included for consideration other antihistamines submitted to the Panel for review, i.e., methyprylonum fumurate, phenamnile maleate and pyridylmaleate.

a. Methyprylonum fumurate. The Panel concludes that methyprylonum fumurate when used alone in the currently marketed OTC adult oral dosage of 25 mg not to exceed 100 mg in 24 hours is safe but ineffective as an OTC analgesic, antipyretic and/or antirheumatic ingredient and is classified as Category II. However, there are insufficient data available to classify the adjuvant effect of phenyltoloximate when used in combination with Category I analgesic, antipyretic and/or antirheumatic agents as an effective analgesic, antipyretic and/or antirheumatic adjuvant and it is therefore classified in combination as Category III.

b. Phenyltoloximate dihydrogen citrate. The Panel concludes that phenyltoloximate dihydrogen citrate when used alone in the currently marketed OTC adult oral dosage of 25 mg not to exceed 100 mg in 24 hours is effective as an OTC analgesic, antipyretic and/or antirheumatic ingredient and is classified as Category II. However, there are insufficient data available to classify the adjuvant effect of phenyltoloximate dihydrogen citrate when used in combination with Category I analgesic, antipyretic and/or antirheumatic agents as an effective analgesic, antipyretic and/or antirheumatic adjuvant and it is therefore classified in combination as Category III.

c. Phenyltoloximate dihydrogen citrate. The Panel notes that the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasmatic Products, in their report published in the Federal Register of September 9, 1976 (41 FR 38312) concluded that phenyltoloximate maleate is safe and effective as an OTC antihistamine. The Panel recommended an adult oral dosage of 25 mg every 4 to 6 hours to not exceed 150 mg in 24 hours.

D. Combination with Category I Analgesic, Antipyretic and/or Antirheumatic Agents. The Panel notes that the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasmatic Products, in their report published in the Federal Register of December 8, 1976 (40 FR 57229) concluded that the available data were insufficient to make a final determination as to the safety and effectiveness of methyprylonum fumurate for use as a nighttime sleep-aid or daytime sedative. The Panel recommended a proposed dosage of 25 mg single dose at bedtime as a nighttime sleep-aid and a maximum 25 mg single dose up to 4 times daily for the drug as a daytime sedative.

The Panel notes that the Advisory Review Panel on OTC Sedative, Tranquilizer and Sleep-Aid Products, in their report published in the Federal Register of December 8, 1976 (40 FR 57229) concluded that the available data were insufficient to make a final determination as to the safety and effectiveness of methyprylonum fumurate for use as a nighttime sleep-aid or daytime sedative. The Panel recommended a proposed dosage of 100 to a maximum 200 mg single dose at bedtime as a nighttime sleep-aid and a maximum 25 mg single dose up to 4 times daily for the drug as a daytime sedative.
Phenyltoloxamine belongs to the ethanolate group of antihistamines. It is currently marketed in OTC combination products for the treatment of asthma, allergic conditions and for headache and other pain. The drug has been shown to be effective in relieving vascular rhinitis, hay fever, pruritus, eczema, urticaria, asthma and certain other allergic drug reactions. Animal studies have shown that the drug is toxic at anaphylactic doses. However, it may cause drowsiness, dizziness, insomnia, nervousness and epigastric distress in some people.

The Panel was unaware of any OTC marketing of phenyltoloxamine alone as an analgesic, antipyrptic and/or antihistaminic. However, the Panel did receive submissions of the use of phenyltoloxamine in combination with acetaminophen, phenacetin, phynylpropanolamine, and with acetaminophen and caffeine. Labeling for these marketed products includes phrases such as “reduced or enhanced relief of pain”, “relief of moderate to severe pain and discomfort due to simple headaches”, “for temporary relief of such pain associated with colds, sinusitis, toothache, and minor aches and pains of rhematism and arthritis” and “produces mild transitory headache.”

The results of two clinical studies were submitted to the Panel to support the analgesic/adjuvant effects of phenyltoloxamine in combination with acetaminophen. One study was designed to determine the analgesic-calmmative effects of a currently marketed combination product containing acetaminophen and phenyltoloxamine in the treatment of simple nervous tension headaches accompanied by headache and the second study was designed to determine the effectiveness of the combination product in relief of musculoskeletal pain associated with anxiety.

In the single-dose, double-blind crossover study on simple nervous tension accompanied by headache, both acetaminophen and phenyltoloxamine were found to be effective (Ref. 1). There were 200 females and 6 males in the study. Subjects were instructed to take two tablets on the day they developed nervous tension with headaches. Each subject completed four, single-dose trials and received each drug alone, the combination and placebo with a minimum of 48 hours between. The interaction of phenyltoloxamine and acetaminophen was not significant.

The Panel carefully reviewed this study and the additional data submitted (Ref. 1). The Panel finds that problems in the 2x2 factorial analysis prevent a firm conclusion from being reached since it cannot be determined if the combination is significantly more effective than acetaminophen alone in the treatment of headache.

In the other double-blind study on relief of musculoskeletal pain associated with anxiety, both acetaminophen and phenyltoloxamine were reported to be effective (Ref. 2). Patients with acute episodes of mild to moderate traumatic or nontraumatic musculoskeletal pain associated with anxiety were included. There were 73 females and 87 males in the study such that 60 subjects were divided into four medication groups of 15 for each subject. Each patient received two tablets 3 times daily for 3 days.

Both were found to be effective, 225 mg acetaminophen and 60 mg phenyltoloxamine in relieving anxiety. It was reported that after a single dose, and after one day of dosing, the combination, i.e., 225 mg acetaminophen and 60 mg phenyltoloxamine, was equivalent to the combined effects of the two drugs in relieving pain and anxiety. After 2 days of dosing, the analgesic effects of the combination was significantly greater than the effect of acetaminophen alone (p less than 0.01).

The Panel carefully evaluated this study and the additional data submitted (Ref. 1 and 2) and found that while the data suggested the combination of acetaminophen and phenyltoloxamine produced more pain relief than acetaminophen alone, this was statistically significant only when the data were grouped. The Panel finds these data insufficient to classify phenyltoloxamine as an adjuvant in combination with acetaminophen in Category II.

The Panel concludes, upon all the data submitted, that the statistical analysis does not support the conclusion that the combination is effective in the treatment of tension headache or for the relief of 60 mg phenyltoloxamine associated with anxiety. The Panel has classified such claims as Category III (See part III, paragraph B.3. above—Pyrilamine maleate and part IV, paragraph B.3. above—Pyrilamine maleate). The Panel concludes that there is some evidence that salicylamide may effectively contribute to the analgesic effectiveness of combination products in doses (200 mg) considerably below those required when salicylamide is used as a single analgesic agent.

Current evidence, although still incomplete, suggests that salicylamide may be acting on a unique mechanism that enhances the pharmacologic activity of other agents, e.g., increased hypnotic activity of acetaminophen, or possibly indirectly by increasing the amount of the aspirin absorbed possibly by competition or inhibition of metabolizing systems in the intestine or liver. This mechanism provides one possible explanation for the “aspirin sparing” claim submitted for one analgesic combination (Ref. 1).

Salicylamide has been demonstrated to inhibit salicylate metabolism competing with aspirin for the glucuronidation pathway. It has also been shown that it competitively inhibits the metabolism of acetaminophen in the glucuronide and conjugate formation (Ref. 1 and 2).

The mechanisms involved, doses required and effects of formulation variables are not well defined. Claims for adjuvant effects of salicylamide should be evaluated for each product.

Studies on the systemic availability of salicylamide in man at doses of 300 to 600 mg indicate that very little free drug reaches the systemic circulation. In most clinical studies, these doses of salicylamide have provided little or no effect over that obtained with placebo. Doses of 25 to a maximum 50 mg single dose at bedtime as a nighttime sleep-aid and a maximum 25 mg single dose up to 4 times daily for the drug as a daytime sedative.

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(2) Drummond, C. M., “Efficacy of Percocet in Relief of Musculoskeletal Pain Associated with Anxiety,” draft of unpublished paper is included in OTC Volume 030165.

(3) OTC Volume 030163.

(4) OTC Volume 030165.

(5) OTC Volume 030169.

5. Salicylamide. The Panel concludes that there are insufficient data to determine that salicylamide is either safe or effective when used in combination as an OTC adjuvant in the currently marketed dosage either as an analgesic or to identify that salicylamide when used alone at a higher dose (1,000 mg every 4 hours while symptoms persist not to exceed 5,000 mg in 24 hours for not more than 10 days) may be effective but has not been demonstrated to be safe for OTC use. However, the Panel recommends that salicylamide not be made available for OTC use at the higher dosage range until suitable studies have been completed to show safety and effectiveness. (See part III, paragraph B.3. above—Pyrilamine maleate and part IV, paragraph B.3. above—Pyrilamine maleate). The Panel concludes that there is some evidence that salicylamide may effectively contribute to the analgesic effectiveness of combination products in doses (200 mg) considerably below those required when salicylamide is used as a single analgesic agent.

Current evidence, although still incomplete, suggests that salicylamide may be acting on a unique mechanism that enhances the pharmacologic activity of other agents, e.g., increased hypnotic activity of acetaminophen, or possibly indirectly by increasing the amount of the aspirin absorbed possibly by competition or inhibition of metabolizing systems in the intestine or liver. This mechanism provides one possible explanation for the “aspirin sparing” claim submitted for one analgesic combination (Ref. 1).

Salicylamide has been demonstrated to inhibit salicylate metabolism competing with aspirin for the glucuronidation pathway. It has also been shown that it competitively inhibits the metabolism of acetaminophen in the glucuronide and conjugate formation (Ref. 1 and 2).

The mechanisms involved, doses required and effects of formulation variables are not well defined. Claims for adjuvant effects of salicylamide should be evaluated for each product.

Studies on the systemic availability of salicylamide in man at doses of 300 to 600 mg indicate that very little free drug reaches the systemic circulation. In most clinical studies, these doses of salicylamide have provided little or no effect over that obtained with placebo. Doses of 25 to a maximum 50 mg single dose at bedtime as a nighttime sleep-aid and a maximum 25 mg single dose up to 4 times daily for the drug as a daytime sedative.

REFERENCES

(1) Drummond, C. M., “Analgesic/Calming Effects of Acetaminophen and Phenyltoloxamine,” Trenntam in Relief of Musculoskeletal Pain Accompanied by Headache,” draft of unpublished paper is included in OTC Volume 030165.

(2) Drummond, C. M., “Efficacy of Percocet in Relief of Musculoskeletal Pain Associated with Anxiety,” draft of unpublished paper is included in OTC Volume 030165.

(3) OTC Volume 030163.

(4) OTC Volume 030165.

(5) OTC Volume 030169.

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salicylate was given after acetaminophen. Excretion rates of these metabolites in levels rapidly than the formation of acetaminolism. Most likely due to its very rapid metab-
inhibitory effect of salicylamide on lamide is the major determinant in the formation of sodium and salicylamide-acetaminophen (Ref. 2). This is in contrast to the adinistration of- the urine. The inhibition of sulfate formation was counteracted by L-cy-
steine, a source of sulfate, administered concomitantly (Ref. 3). On the other hand, when sodium salicylate was given after acetaminophen administration, there was no apparent mutual inhibition of the formation of metametabolites in the urine, measured directly. Considering the meta-
formation sites to increase intestinal metabolism sites to increase systemic plasma levels of the active forms of the analgesics has not been measured directly. Considering the meta-
 releasings, a rabbit in man at intestinal metabolic sites to increase systemic plasma levels of the active forms of the analgesics has not been measured directly. Considering the metabolic interactions, however, these combinations might be expected to have greater than additive effects. Synergistic pharmacologic effects of combinations of salicylamide with acetaminophen or with phenacetin have been demonstrated in animals and man (Refs. 3, 6, and 7).

Barr et al. (Ref. 5) have shown that salicylic acid can competitively inhibit salicylamide glucuronide formation and noncompetitively inhibit salicylamide sulfate formation in a rabbit in vivo. The extent to which combinations of acetaminophen and salicylamide are given alone. Levy and co-work-
ters have shown that a mutual inhibition of metabolism occurs in man with a combination of salicylamide and sodium salicylate (Ref. 2) and also a combination of salicylamide and acetaminophen (Ref. 3). As was noted by these, however, with the combination of acetaminophen and salicylic acid (Ref. 4).

When 2.32 g sodium salicylate was given to healthy adults 2 hours before the administration of acetaminophen (Ref. 3). As was noted by these, however, with the combination of acetaminophen and salicylic acid (Ref. 4). A similar competitive inhibition in the metabolism of acetaminophen and salicylamide occurred when the drugs were administered to healthy subjects. When 1 or 2 g sodium salicylate was given after the administration of 1 g acetaminophen, a decrease in the formation of acetaminophen sulfate, acetaminophen glucuronide and salicylamide sulfate was observed as the percentage of increased excretion of these metabolites in the urine. The inhibition of sulfate formation was counteracted by L-cysteine, a source of sulfate, administered concomitantly (Ref. 3). On the other hand, when sodium salicylate was given after acetaminophen administration, there was no apparent mutual inhibition of the formation of metabolic conjugates (glucuronides and sulfates) of acetaminophen or the formation of the metabolites of sodium salicylate (Ref. 4). This is in contrast to the meta-
formation sites to increase intestinal metabolism sites to increase systemic plasma levels of the active forms of the analgesics has not been measured directly. Considering the metabolic interactions, however, these combinations might be expected to have greater than additive effects. Synergistic pharmacologic effects of combinations of salicylamide with acetaminophen or with phenacetin have been demonstrated in animals and man (Refs. 3, 6, and 7).

The findings of Berger are corroborated by the studies in mice by White et al. (Ref. 7) who in 1967 found significant differences in the absorption of acetaminophen and salicylamide in rabbits. Workers also noted that with a dose of 240 mg acetaminophen and 600 mg salicylamide, 76 out of 122 animals noted a sedative effect and some patients commented on the adverse effects of acetaminophen. The same dose given 4 times daily to 12 subjects resulted in daytime sedation in 14 pa-
tients and in 7 patients receiving a placebo. No other adverse reactions were recorded.

The effectiveness of two dose levels of a combination of acetaminophen-salicylamide (487.5 mg plus 487.5 mg, and 325 mg plus 325 mg) in the treatment of headaches was compared to a dose of 648 mg aspirin and to placebo in university students, employing a double-blind Latin-square design (Ref. 9). In a total of 94 subjects, with 223 headaches, relief was obtained in 49 subjects on placebo, 78 percent by aspirin and 76 and 69 percent, respectively, by the high and low doses of the acetaminophen-salicylamide combination. The effectiveness of all drug treatments was significantly different from the placebo efficacy, but not differ-
cent from each other.

1. Aspirin standard testing procedures. The studies cited above have shown that buffered aspirin products vary among themselves with respect to rate of dissolu-
tion, rate of absorption and effect on gastric tolerance. (See part II para-
graph J above—Effect of Product Formu-
lization on Drug Absorption and Pharmaco-
logic Effectiveness.) Variations in these characteristics, are also found in plain aspirin products. Although buf-
pered aspirin products generally have faster dissolution rates, are better tol-
erated and are absorbed faster than plain aspirin products, all buffered as-
pirin products cannot be equated to have the same ability to be absorbed and therefore produce comparable blood levels in a specified time. On the other hand, while plain (unbuffered) aspirin products generally dissolve and are ab-
sorbed at a slower rate, and are less well tolerated, buffered aspirin products are comparable to buffered aspirin prod-
ucts in their ability to be rapidly dis-
solved and rapidly absorbed. The simi-
larities and/or dissimilarities between plain aspirin products and buffered as-
pirin products may be accounted for on the basis of formulating procedures of the manufacturers and/or the dissolu-
tion methodology employed by different investigators. To avoid any discrepancies in dissolution methodology and to elimi-
nate products that are, without question, improperly formulated for the safe use of the patient, the Panel adopted set standards for plain and buffered aspirin prod-
ucts. The Panel has proposed a tentative testing procedure for future de-
velopment and implementation.

a. Buffered aspirin acid neutralizing testing procedure. The Panel concludes that aspirin tablets may be labeled as

C. DATA REQUIRED FOR EVALUATION

PROPOSED RULES

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
"buffered aspirin" providing each dosage unit containing the equivalent of 325 mg (5 gr. of aspirin) contains at least 1.9 mEq of acid neutralizing capacity as determined by the following procedure:

(1) Preparation of reagents. (i) pH meter: equipped with glass and saturated calomel electrodes.
(ii) Magnetic stirrer.
(iii) Magnetic stirring bars (about 40 mm long and 3 mm in diameter).
(iv) 50 ml buret.
(v) Buret stand.
(vi) 100 ml beakers.
(vii) 250 ml beakers.
(viii) 10 ml, 20 ml, and 30 ml pipets calibrated to deliver.
(ix) Tablet comminuting device.
(x) A number 20 and 100 U.S. standard mesh sieve.
(xi) Tablet disintegration apparatus.
(xii) 0.1 N, 0.5 N and 1.0 N hydrochloric acid.
(xiii) 0.5 N sodium hydroxide.
(xiv) Standard pH 4.0 buffer solution (0.085 M potassium phthalate).
(xv) 95 percent ethanol.
(xvi) Purified water U.S.P.

(2) Reagent standardization. Standardize the required hydrochloric (HCl) and hydrochloric acid (HClO4) solutions according to the procedures in the United States Pharmacopeia XVIII (NaOH page 1036 and HCl page 1034) or the Official Methods of Analysis of the Association of Official Analytical Chemists, 11th Ed., 1970 (NaOH page 876 and HCl page 873).

(3) Temperature standardization. All tests shall be conducted at 25°C ± 3°C or 37°C ± 3°C.

(4) Acid neutralizing capacity test.-(a) pH meter. Standardize the pH meter at pH 4.0 with the standardizing buffer and check for proper operation at pH 1 with 0.1 N HCl.
(b) Dosage form testing.—(a) Tablet sample. Place an accurately weighed amount of a tablet composite equivalent to the minimum labeled dosage into a 250 ml beaker. (The composite shall be prepared by determining the average weight of not less than 20 tablets and then crushing the tablets sufficiently to pass through a number 20 U.S. standard mesh sieve and held by a number 100 U.S. standard mesh sieve. Mix the sieved material to obtain a uniform sample.) If wetting is desired, add not more than 5 ml of 95 percent ethanol and mix to wet the sample thoroughly (ethanol may affect the acid neutralizing capacity). Add water to a volume of 70 ml and mix on a magnetic stirrer at 300±30 r.p.m. for about 1 minute. Capsules should be tested in the same manner using the sieved capsule powder as the tablet composite according to the procedure set forth in section (5) below.
(b) Effervescent sample. Place an amount of effervescent dosage unit to the minimum labeled dosage into a 250 ml beaker. Add 10 ml water and swirl the beaker gently while allowing the reaction to subside. Add another 10 ml of water, and swirl the beaker gently. Wash down the walls of the beaker with 50 ml of water and mix on a magnetic stirrer at 300±30 r.p.m. for about 1 minute. Analyze the sample according to the procedure set forth in § 331.28.

(5) Acid neutralizing capacity test procedure. (a) Pipette 50 ml of 1.0 N HCl into the sample solution while stirring on the magnetic stirrer at 300±30 r.p.m.
(b) Stir for exactly 15 minutes after addition of acid.
(c) Begin titrating immediately and in a period not to exceed an additional 5 minutes titrate the excess 1.0 N HCl with 0.5 N NaOH to a stable pH of 3.5.
(d) Check the sample solution 10 to 15 seconds after obtaining pH 3.5 to make sure the pH is stable.
(e) Calculate the number of mEq of acid neutralized by the sample as follows:

\[
\text{Total mEq} = \frac{\text{molarity of NaOH}}{\text{molarity of HCl}} \times \text{volume of NaOH} \times 1000
\]

Use appropriate factors, i.e., density, average tablet weight, etc., to calculate the total mEq of acid neutralized per minimum labeled dosage.

(6) Test modification. The formulation and/or mode of administration of certain products may require modification of this in vitro test. Any proposed modification and/or mode will be submitted to the Food and Drug Administration for approval prior to use.

b. Aspirin (plain and buffered) tablet dissolution testing procedure. Each dosage unit containing not less than 325 mg (5 gr) of aspirin shall be suitable for labeling as an "aspirin" or if applicable "buffered aspirin" product if the quantity of aspirin dissolved within *x* minutes is not less than 182.5 mg (2.5 gr) (50 percent of labeled amount) and the quantity of aspirin dissolved in *x* minutes is not less than 292.5 mg (4.5 gr) (90 percent of labeled amount) as determined by the following procedure:

(1) Laboratory technique. Throughout this procedure use scrupulously clean glassware, which previously has been rinsed with dilute hydrochloric acid, distilled or deionized water, and carefully dried. Take precautions to prevent contamination from airborne, fluorescent particles and from metal and rubber surfaces.

(2) Dissolution apparatus. The apparatus consists of a suitable water bath, a 500 ml round bottom glass vessel (Kimble Glass No. 33710-51, or equivalent), a motor, and a stirring blade (Sargent 65-700-060 or equivalent) on a stirring shaft (Sargent S-76637, Size B, 3-in length). The motor is suspended or equivalent). A magnetic stirrer at length. It must run true on the motor and be able to stir the vessel is positioned so that the stirring element is in line with the axis of the vessel. The motor is fitted with a speed-regulating device that allows the motor speed to be held at 50 rpm±2 rpm. The motor is suspended above the vessel in such a way that it may be raised or lowered without altering the position of the vessel.

Stirring blade is 4 mm in inside diameter. The sample shall be considered in de-
mining the total amounts of acetylsalicylic acid and salicylic acid in solu-
tion at the time of each sampling. The
amounts of acetylsalicylic acid and salicylic acid should be converted to ex-
press the total amount of acetylsalicylic acid, in mg, (Ref. 1) resulting from
the dissolution of a dosage unit (tablet) contain-
ing 325 mg (5 gr) buffered aspirin in (x) minutes.

2. Combination products containing an
analgesic, antipyretic and/or antirheuma-
tic adjuvant—General principles. (a) Combinations must demonstrate at
least as much analgesic effectiveness as
650 mg (10 gr) dose of aspirin.
(b) Combinations must be at least as
safe as the recommended
prescription dosage of aspirin.
(c) Studies with a placebo. The analysis must show caffeine
was absent when compared to the standard so-
martic adjuvant—General principles.

(a) Caffeine. This could be determined
by direct measurement of caffeine,
which reduces joint or muscle tenderness
and swelling.
(b) Aspirin (buffered).
(c) Antipyretic drug.
(d) Analgesic.
(e) Agent which, in the
method established in §331.53 of this chapter
such that the
product contains the following active ingredient(s) as identified in
§331.11 of this chapter:
(1) Aspirin (buffered). A solid dosage
form containing 325 mg (5 gr) aspirin
with sufficient buffering capacity with
acid antacid active ingredient(s) identified in
§331.11 of this chapter such that the
finished product contains at least 1.9 mEq of
acid neutralizing capacity per 325 mg
of aspirin and results in a pH of 3.5 or
greater at the level of the initial 10-
minute period as measured by the method
established in §331.25 of this chapter
and provided that product is labeled
as an analgesic and/or antipyretic.
(2) Aspirin (highly buffered) for solution.
A solid dosage form to be dissolved in
water prior to oral administration as a
solution. The product shall contain 325
mg (5 gr) aspirin and sufficient buffering
capacity with antacid active ingredient(s) identified in
§331.11 of this chapter
such that the finished product contains
at least 50 mEq of aspirin and results
in a pH of 3.5 or greater at the level of
the initial 10-minute period as measured
by the method established in §331.25 of
this chapter and provided that product is
identified as highly buffered aspirin
with labeling only as an analgesic and/or antipyretic.

3. Combinations containing adjuvants.
Combinations containing adjuvants
which have been shown to affect the
metabolic pathways of other ingredients
must be shown on repeated dosage
schedules not to inhibit or interfere with
the metabolism in such a way that
toxic levels of any ingredients are achieved.
For example, for a combination containing
salicylamide and aspirin, it must be shown
with repeated dosing that the blood
salicylate level does not exceed 20 mg percent.

Therefore, under the Federal Food,
Drug, and Cosmetic Act (secs. 201, 502,
505, 701, 52 Stat. 1040–1042 as amended,
705–706 as amended by 70 Stat. 919 and
and the
Administrative Procedure Act (secs. 4,
5, 10, 60 Stat. 238 and 243 as amended
(5 U.S.C. 553, 554, 702, 703, 704)) and
under authority delegated to him (21
CFR 6.1), the Commissioner of Food and
Drugs published a notice in the Federal Regis-
ty amended by adding new Part 343 to read as follows:

PROPOSED RULES

PART 343—INTERNAL ANALGESIC, ANTI-
PYRETIC AND ANTI RHEUMATIC PRO-
DUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart B—Active Ingredients

§343.10 Analgesics.
§343.12 Antipyretics.
§343.14 Antiinflammatory agents.
§343.20 Permitted combinations of active in-
gredients.

Subpart C—Reserved

Subpart D—Labeling

§343.50 Labeling of analgesic and antipy-
retic products.

§343.80 Professional labeling.

PART B—Active Ingredients

§343.1 Scope.

An over-the-counter internal analge-
sic, antipyretic, or antirheumatic prod-
cut in a form suitable for oral admin-
istration is generally recognized as safe
and effective and is not misbranded if it meets each of the following conditions:
and each of the general conditions estab-
lished in §300.1 of this chapter.

§343.3 Definitions.

(a) Acetaminophen analgesic equiva-
ience value. The analgesic effectiveness
for a product containing acetaminophen
when compared to the standard aceta-
mphen 325 mg dosage unit.
(b) Acetaminophen (pediatric dosage unit). A single dosage unit containing
80 mg (1.23 gr) acetaminophen for children
under 12 years.
(c) Acetaminophen (standard dosage
unit). A single dosage unit containing
325 mg (5 gr) acetaminophen.
(d) Adjuvant. An agent which, in the
amount used, has no significant analge-
sic effect itself but contributes to the
therapeutic effect of the active agent
either directly or indirectly.

(1) Direct acting. An adjuvant which
enhances the pharmacologic response
directly by synergistic or additive effects
at the site of action.

(2) Indirect acting. An adjuvant which
does not have effects at the site of ac-
tion, but indirectly increases the activity
of the active agent(s) of the preparation
by modifying the disposition (absorption,
metabolism, excretion or distribution)
of the active agent.
(e) Age (dosage) usage. Infant or baby
under 2 years, child (2 years to under
12 years), and adult (12 years and over).
(f) Analgesic drug. An agent useful to
alleviate the symptoms of pain.
(g) Antipyretic drug. An agent used to
reduce fever.
(h) Antirheumatic drug. An agent which
reduces joint or muscle tenderness or
swelling.
(i) Aspirin analgesic equivalence value.
The analgesic effectiveness for a product
containing aspirin or aspirin salts, e.g.,
aluminum aspirin or calcium
barspirin when compared to the standard
aspirin 325 mg (5 gr) dosage unit.
(j) Aspirin (buffered). A solid dosage
form containing 325 mg (5 gr) aspirin

(k) Aspirin (highly buffered) for solu-
tion. A solid dosage form to be dissolved
in water prior to oral administration as a
solution. The product shall contain 325
mg (5 gr) aspirin and sufficient buffering
capacity with antacid active ingredient(s) identified in
§331.11 of this chapter
such that the finished product contains
at least 50 mEq of aspirin and results
in a pH of 3.5 or greater at the level of
the initial 10-minute period as measured
by the method established in §331.25 of
this chapter and provided that product is
identified as highly buffered aspirin
with labeling only as an analgesic and/or antipyretic.

(l) Aspirin (pediatric dosage unit). A single dosage unit containing
80 mg (1.23 gr) aspirin for children
under 12 years.
(m) Aspirin (standard dosage unit). A single dosage unit containing
325 mg (5 gr) aspirin.
(n) Corrective. An agent in the drug
delivery system intended to reduce some
undesirable effect of the therapeutically
active agent.
(o) Sodium salicylate analgesic equiva-
ience value. The analgesic effectiveness
for a product containing sodium salicy-
late or other salicylates, e.g.,
choline salicylate, magnesium salicylate, or
salicylic acid, when compared to the standardizing
dosage sodium salicylate 325 mg dosage unit.
(p) Sodium salicylate (standard dosage
unit). A single dosage unit containing
325 mg sodium salicylate.

Subpart B—Active Ingredients

§343.10 Analgesics.

The active ingredients of the product
must consist of the following within the dosage
limit established for each ingredient:
(A) Aspirin.—(1) For products contain-
ing 325 mg (5 gr) per dosage unit—
(1) Standard schedule. Adult oral dosage is
325 mg (5 gr) to 650 mg (10 gr) every
4 hours while symptoms persist not to
exceed 3,900 mg (60 gr) in 24 hours for
not more than 10 days. Children 11 to
under 12 years oral dosage is
487.5 mg (7.5 gr) every 4 hours while symptoms persist not to
exceed 2,015 mg (31.5 gr) in 24 hours for
not more than 5 days. Children 9 to
under 11 years oral dosage is
406.3 mg (6.25 gr) every 4 hours while symptoms persist not to
exceed 1,625 mg (25 gr) in 24 hours for
not more than 5 days. Children 6 to
under 9 years oral dosage is
325 mg (5 gr) every 4 hours while symptoms persist not to
exceed 1,255 mg (20 gr) in 24 hours for
not more than 5 days. Children 4 to
under 6 years oral dosage is
243.8 mg

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
(7.3 gr) every 4 hours while symptoms persist not to exceed 1,219 mg (18.75 gr) in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 162.5 mg (2.5 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(ii) Nonstandard schedule. Adult oral dosage is 325 mg (5 gr) to 975 mg (15 gr) initially, followed by more than 325 mg (5 gr) but not more than 421 mg (6.48 gr) every 4 hours while symptoms persist not to exceed 3,900 mg (60 gr) in 24 hours for not more than 10 days. Children 2 to under 4 years oral dosage is 65 mg (1.08 gr) initially, followed by more than 65 mg (1.08 gr) but not more than 100 mg (1.75 gr) every 4 hours while symptoms persist not to exceed 2,000 mg (33.75 gr) in 24 hours for not more than 5 days. Children 6 to under 9 years oral dosage is 125 mg (2.12 gr) every 4 hours while symptoms persist not to exceed 1,500 mg (24.6 gr) in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 240 mg (3.9 gr) every 4 hours while symptoms persist not to exceed 2,100 mg (34.5 gr) in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 40 mg (0.66 gr) every 4 hours while symptoms persist not to exceed 575 mg (9.5 gr) in 24 hours for not more than 10 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

(3) For products containing 80 mg (1.23 gr) per dosage unit.

(4) For products containing more than 621 mg (10.38 gr) per dosage unit.

(5) For products containing more than 640 mg (11.12 gr) per dosage unit.

(6) For products containing more than 650 mg (11.5 gr) per dosage unit.
Under 12 years, there is no recommended dosage every 4 hours while symptoms persist not to exceed 2,031.5 mg in 24 hours for not more than 5 days. Children 6 to under 9 years oral dosage is 480 mg (7.46 gr) every 4 hours while fever persists not to exceed 1,600 mg (24.6 gr) in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 240 mg (3.92 gr) every 4 hours while fever persists not to exceed 1,000 mg (15.6 gr) in 24 hours for not more than 3 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

(ii) Sodium salicylate. (1) For products containing 325 mg per dosage unit.—
   (i) Standard schedule. Adult oral dosage is 325 to 650 mg every 4 hours while symptoms persist not to exceed 5,050 mg in 24 hours for not more than 5 days. Children 6 to under 9 years oral dosage is 243.8 mg every 4 hours while symptoms persist not to exceed 1,625 mg in 24 hours for not more than 5 days. Children 4 to under 6 years oral dosage is 126.5 mg every 4 hours while symptoms persist not to exceed 1,000 mg in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 65.3 mg every 4 hours while symptoms persist not to exceed 600 mg in 24 hours for not more than 5 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (ii) Nonstandard schedule. Adult oral dosage is 325 mg to 975 mg initially, followed by 650 mg every 4 hours while symptoms persist not to exceed 3,900 in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

   (2) For products containing more than 325 mg but not more than 421 mg per dosage unit. Adult oral dosage is more than 325 mg but not more than 842 mg initially, followed by more than 325 mg but not more than 421 mg every 3 hours while symptoms persist not to exceed 3,769 mg in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

   (3) For products containing more than 421 mg but not more than 485 mg per dosage unit. Adult oral dosage is more than 421 mg every 4 hours while symptoms persist not to exceed 4,812 mg in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

   (4) For products containing more than 485 mg but not more than 500 mg per dosage unit. Adult oral dosage is more than 485 mg but not more than 1,000 mg initially, followed by more than 485 mg every 4 hours while symptoms persist not to exceed 5,000 mg in 24 hours for not more than 3 days. Children 4 to under 6 years oral dosage is 240 mg (3.92 gr) every 4 hours while fever persists not to exceed 1,000 mg (15.6 gr) in 24 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 65 mg (1.05 gr) every 4 hours while fever persists not to exceed 600 mg (9.9 gr) in 24 hours for not more than 3 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (5) For products containing more than 500 mg but not more than 650 mg per dosage unit. Adult oral dosage is more than 500 mg every 4 hours while symptoms persist not to exceed 3,800 mg (67.6 gr) in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

   (6) For products containing more than 650 mg but not more than 700 mg per dosage unit. Adult oral dosage is more than 650 mg every 4 hours while symptoms persist not to exceed 3,900 mg (69.2 gr) in 24 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 160 mg (2.6 gr) every 4 hours while fever persists not to exceed 1,200 mg (19.6 gr) in 24 hours for not more than 3 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (7) For products containing more than 700 mg but not more than 800 mg per dosage unit. Adult oral dosage is more than 700 mg every 4 hours while symptoms persist not to exceed 4,000 mg (68.5 gr) in 24 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 200 mg (3.3 gr) every 4 hours while fever persists not to exceed 1,300 mg (21.7 gr) in 24 hours for not more than 3 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (8) For products containing more than 800 mg but not more than 850 mg per dosage unit. Adult oral dosage is more than 800 mg every 4 hours while symptoms persist not to exceed 4,300 mg (71.5 gr) in 24 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 250 mg (4.1 gr) every 4 hours while fever persists not to exceed 1,600 mg (26.0 gr) in 24 hours for not more than 3 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (9) For products containing more than 850 mg but not more than 900 mg per dosage unit. Adult oral dosage is more than 850 mg every 4 hours while symptoms persist not to exceed 4,700 mg (78.2 gr) in 24 hours for not more than 3 days. Children 2 to under 4 years oral dosage is 300 mg (4.8 gr) every 4 hours while fever persists not to exceed 2,000 mg (32.0 gr) in 24 hours for not more than 3 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (10) For products containing more than 900 mg but not more than 1,000 mg per dosage unit. Adult oral dosage is more than 900 mg every 4 hours while symptoms persist not to exceed 5,100 mg (83.3 gr) in 24 hours for not more than 4 days. Children 2 to under 4 years oral dosage is 350 mg (5.7 gr) every 4 hours while fever persists not to exceed 2,500 mg (40.0 gr) in 24 hours for not more than 4 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (11) For products containing more than 1,000 mg but not more than 1,200 mg per dosage unit. Adult oral dosage is more than 1,000 mg every 4 hours while symptoms persist not to exceed 5,600 mg (93.8 gr) in 24 hours for not more than 4 days. Children 2 to under 4 years oral dosage is 400 mg (6.5 gr) every 4 hours while fever persists not to exceed 3,000 mg (48.0 gr) in 24 hours for not more than 4 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (12) For products containing more than 1,200 mg but not more than 1,400 mg per dosage unit. Adult oral dosage is more than 1,200 mg every 4 hours while symptoms persist not to exceed 6,100 mg (102.1 gr) in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 450 mg (7.2 gr) every 4 hours while fever persists not to exceed 3,500 mg (57.0 gr) in 24 hours for not more than 5 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

   (13) For products containing more than 1,400 mg but not more than 1,600 mg per dosage unit. Adult oral dosage is more than 1,400 mg every 4 hours while symptoms persist not to exceed 6,600 mg (108.1 gr) in 24 hours for not more than 5 days. Children 2 to under 4 years oral dosage is 500 mg (8.0 gr) every 4 hours while fever persists not to exceed 4,000 mg (65.0 gr) in 24 hours for not more than 5 days. Children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.
 PROPOSED RULES

under 12 years oral dosage is 487.5 mg (7.5 gr) every 4 hours while fever persists not to exceed, 2,031.5 mg (31.5 gr) in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 406.3 mg (6.25 gr) every 4 hours while fever persists not to exceed 2,015.5 mg (31 gr) in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 348.7 mg (5.75 gr) every 4 hours while fever persists not to exceed 2,004.5 mg in 24 hours for not more than 3 days. Children 3 to under 6 years oral dosage is 278.1 mg (4.5 gr) every 4 hours while fever persists not to exceed 1,995 mg in 24 hours for not more than 3 days. Children 2 to under 3 years oral dosage is 207.5 mg (3.3 gr) every 4 hours while fever persists not to exceed 1,265 mg in 24 hours for not more than 3 days. Children 1 to under 12 years oral dosage is 157.5 mg (2.5 gr) every 4 hours while fever persists not to exceed 812.5 mg in 24 hours for not more than 3 days.

Children 6 to under 9 years oral dosage is 243.8 mg (3.75 gr) every 4 hours while fever persists not to exceed 1,552.5 mg in 24 hours for not more than 3 days. Children 2 to under 3 years oral dosage is 207 mg every 4 hours while fever persists not to exceed 1,035 mg in 24 hours for not more than 3 days. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

Choline salicylate. Adult oral dosage is 435 to 870 mg every 4 hours while fever persists not to exceed 5,520 mg in 24 hours for not more than 3 days. Children 9 to under 12 years oral dosage is 435 mg every 4 hours while fever persists not to exceed 3,625.5 mg in 24 hours for not more than 3 days. Children 2 to under 6 years oral dosage is 162.5 mg (2.5 gr) every 4 hours while fever persists not to exceed 812.5 mg (12.5 gr) in 24 hours for not more than 3 days.

For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

Choline salicylate. Adult oral dosage is 435 to 870 mg every 4 hours while fever persists not to exceed 5,520 mg in 24 hours for not more than 3 days. Children 9 to under 12 years oral dosage is 435 mg every 4 hours while fever persists not to exceed 3,625.5 mg in 24 hours for not more than 3 days. Children 2 to under 6 years oral dosage is 162.5 mg (2.5 gr) every 4 hours while fever persists not to exceed 812.5 mg (12.5 gr) in 24 hours for not more than 3 days.

For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

Nonstandard schedule. Adult oral dosage is 325 mg to 975 mg initially, followed by 650 mg every 4 hours while fever persists not to exceed 5,500 mg in 24 hours for not more than 3 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

For products containing more than 2.175 mg (3.75 gr) per dosage unit, Adult oral dosage is more than 325 mg but not more than 421 mg per dosage unit. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

Mg 2 salicylate. Adult oral dosage is 325 mg to 650 mg every 4 hours while fever persists not to exceed 3,900 mg in 24 hours for not more than 3 days. Children 9 to under 12 years oral dosage is 435 mg every 4 hours while fever persists not to exceed 3,625.5 mg in 24 hours for not more than 3 days.

For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

Calcium carbaspirin. Adult oral dosage is 414 to 828 mg every 4 hours while fever persists not to exceed 4,988 mg in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 621 mg every 4 hours while fever persists not to exceed 3,105 mg in 24 hours for not more than 3 days. Children 9 to under 11 years oral dosage is 617.5 mg every 4 hours while fever persists not to exceed 2,987.5 mg in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 414 mg every 4 hours while fever persists not to exceed 2,004.5 mg in 24 hours for not more than 3 days. Children 3 to under 6 years oral dosage is 348.7 mg (5.75 gr) in 24 hours for not more than 3 days. Children 2 to under 3 years oral dosage is 278.1 mg (4.5 gr) every 4 hours while fever persists not to exceed 1,995 mg in 24 hours for not more than 3 days.

For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

Sodium salicylate.—(1) For products containing 325 mg per dosage unit.—

(1) Standard schedule. Adult oral dosage is 325 mg to 650 mg every 4 hours while fever persists not to exceed 3,105 mg in 24 hours for not more than 3 days.

Children 9 to under 11 years oral dosage is 621 mg every 4 hours while fever persists not to exceed 3,105 mg in 24 hours for not more than 3 days. Children 6 to under 9 years oral dosage is 414 mg every 4 hours while fever persists not to exceed 2,004.5 mg in 24 hours for not more than 3 days. Children 3 to under 6 years oral dosage is 348.7 mg (5.75 gr) in 24 hours for not more than 3 days. Children 2 to under 3 years oral dosage is 278.1 mg (4.5 gr) every 4 hours while fever persists not to exceed 1,995 mg in 24 hours for not more than 3 days. Children 1 to under 2 years oral dosage is 210.5 mg (3.5 gr) every 4 hours while fever persists not to exceed 1,035 mg in 24 hours for not more than 3 days.

For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

§ 343.14 Anticipalline.

The active ingredients of the product consist of the following:

FEDERAL REGISTER, VOL 42, NO. 131—FRIDAY, JULY 8, 1977
(a) Aspirin. There is no recommended dosage except under the advice and supervision of a physician.
(b) Calcium carbasmir. There is no recommended dosage except under the advice and supervision of a physician.
(c) Choline salicylate. There is no recommended dosage except under the advice and supervision of a physician.
(d) Magnesium salicylate. There is no recommended dosage except under the advice and supervision of a physician.
(e) Sodium salicylate. There is no recommended dosage except under the advice and supervision of a physician.

§ 343.20 Permitted combinations of active ingredients.

(a) Active ingredients. The active ingredients of combination products consist of two or more of the following at the dosage limit established for each ingredient:

(1) Aspirin 325 mg (6 gr) per dosage unit.
(2) Acetaminophen 325 mg (gr) per dosage unit.
(3) Calcium carbasmir 414 mg per dosage unit.
(4) Choline salicylate 435 mg per dosage unit.
(5) Magnesium salicylate 325 mg per dosage unit.
(6) Sodium salicylate 325 mg per dosage unit.

(b) For analgesic combination products. Adult oral dosage is 1 dosage unit every 4 hours while symptoms persist not to exceed 6 dosage units in 24 hours for not more than 10 days. For children under 12 years, there is no recommended dosage except under the advice and supervision of a physician.

(c) For antipyretic combination products. Adult oral dosage is 1 dosage unit every 4 hours while fever persists not to exceed 6 dosage units in 24 hours for not more than 3 days.

(d) For combination products containing nonanalgesic and/or nonantipyretic active ingredients. (1) Any single active ingredient identified in § 343.10 or § 343.12 or any combination of active ingredients identified in § 343.20(a) may be combined with generally recognized as safe and effective antihistaminic active ingredient(s) provided the product is labeled for the concurrent symptoms involved, e.g. “For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever, and to alleviate, decrease, or temporarily relieve running nose, sneezing, itching of the nose or throat and itchy and watery eyes as may occur in allergic rhinitis (such as hay fever).”
(2) Any single active ingredient identified in § 343.10(b), or § 343.12(b) may be combined with antacid active ingredient(s) which meet the requirements of § 331.10 of this chapter such that the finished product contains at least 20 mEq of acid neutralizing capacity per 325 mg (gr) aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of this chapter.

(e) Aspirin identified in § 343.10(a) or § 343.12(a) may be combined with antacid active ingredient(s) identified in § 331.11 of this chapter such that the finished product contains at least 20 mEq of acid neutralizing capacity per 325 mg (gr) aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of this chapter.

(f) Aspirin identified in § 343.10(a) or § 343.12(a) may be combined with antacid active ingredient(s) identified in § 331.11 of this chapter such that the finished product contains at least 20 mEq of acid neutralizing capacity per 325 mg (gr) aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of this chapter and provided the product is identified as highly buffered aspirin with labeling only as identified in § 343.50(a).

(g) Aspirin identified in § 343.10(a) or § 343.12(a) may be combined with antacid active ingredient(s) identified in § 331.11 of this chapter such that the finished product contains at least 20 mEq of acid neutralizing capacity per 325 mg (gr) aspirin and results in a pH of 3.5 or greater at the level of the initial 10-minute period as measured by the method established in § 331.25 of this chapter and provided the product is identified as highly buffered aspirin with labeling only as identified in § 343.50(a).

Subpart C—[Reserved]

Subpart D—Labeling

§ 343.50 Labeling of analgesic and antipyretic products.

(a) Indications. The labeling shall identify the product pursuant the appropriate definition(s) established in § 343.53 and shall contain the following:
(1) For products containing analgesic ingredients identified in § 343.10 or § 343.20 if applicable under the heading “Indications,” the labeling shall state

“For the temporary relief of occasional minor aches, pains and headache.”
(2) For products containing antipyretic ingredients identified in § 343.12 or § 343.20 if applicable under the heading “Indications,” the labeling shall state “For the reduction of fever.”
(3) For products containing analgesic-antipyretic ingredients identified in §§ 343.10 and 343.12 if applicable under the heading “Indications,” the labeling shall state “For the temporary relief of occasional minor aches, pains and headache, and for the reduction of fever.”

(b) Directions for use. The labeling of the product contains the recommended dosage and appropriate directions identified under §§ 343.10 and 343.12 if applicable.

(c) Warnings. The labeling of the product contains the appropriate warnings under the heading “Warnings” which may be combined to eliminate duplication of warnings or phrases so the resulting warning is clear and understandable as follows:
(1) For products containing any analgesic ingredient identified in § 343.10:
(1) “Adults: Do not exceed dosage for more than 10 days. If symptoms persist, or new ones occur, consult your physician.”
(2) “Children under 12 years: Do not take this product for more than 5 days. If symptoms persist, or new ones occur, consult your physician.”
(2) For products containing any antipyretic ingredient identified in § 343.12:
(1) “If fever persists for more than 3 days (72 hours), or recurs, consult your physician.”
(3) For products containing any analgesic or any antipyretic ingredient identified in §§ 343.10 and 343.12 other than acetaminophen identified in §§ 343.10(b) and 343.12(c):
(1) “Take this product for the treatment of arthritis only under the advice and supervision of a physician.”
(2) “Stop taking this product if ringing in the ears or other symptoms occur.”
(3) For products intended for oral administration as a liquid product:
(a) “Adults: Drink a full glass of water with each dose.”
(b) “Children under 12 years: Drink a full glass of water with each dose.”
(4) “Caution: Do not take this product if you have stomach distress, ulcers or bleeding problems except under the advice and supervision of a physician.”

(4) For products containing any analgesic or any antipyretic ingredient identified in § 343.10 (a) or (c) or § 343.12 (a) or (c) or § 343.20 if applicable:
(1) “This product contains aspirin. Do not take this product if you are allergic to aspirin or if you have asthma except under the advice and supervision of a physician.”

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
(II) "Do not take this product during the last 3 months of pregnancy except under the advice and supervision of a physician".

(iii) For oral product formulations to be chewed before swallowing: "Do not take this product with or under the advice and supervision of a physician except under the advice and supervision of a physician".

(5) For products containing acetaminophen identified in § 343.10(b) or § 343.20 if applicable:

(1) "Do not exceed recommended dosage because severe liver damage may occur".

(II) "Do not take this product for the treatment of arthritis except under the advice and supervision of a physician".

(6) For products containing any analgesic or any antipyretic ingredient identified in § 343.10(d), (e), (f), § 343.12(d), (e), (f), or § 343.20 if applicable: "Do not take this product if you are allergic to salicylates except under the advice and supervision of a physician".

(7) For products containing magnesium salicylate identified in § 343.10(e), § 343.12(e) or § 343.20 if applicable in an amount more than 500 mg of magnesium in the recommended daily dosage: "Do not take this product if you have kidney disease except under the advice and supervision of a physician".

(5) For products containing calcium carbonate identified in § 343.10(c), § 343.12(c) or § 343.20 if applicable:

(1) For products containing 0.2 mEq (5 mg) or higher of sodium per dosage unit: The labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 mEq (5 mg) or higher.

(II) For products containing more than 5 mEq (125 mg) sodium in the maximum recommended daily dosage: "Do not take this product if you are on a sodium restricted diet except under the advice and supervision of a physician".

(d) Statement on dosage unit. (1) For products containing the standard aspirin dosage unit identified in § 343.10(a) or § 343.12(a) (1) shall be clearly labeled on the principal display panel: "Contains the standard strength of 325 mg (5 gr) aspirin per dosage unit".

(2) For products containing aspirin in an amount different than the standard aspirin dosage unit identified in § 343.10(a) (3), (4), (5), (6) or § 343.12(a) (3), (4), (5), (6) shall be clearly labeled on the principal display panel: "Contains the nonstandard strength of X mg aspirin per dosage unit compared to the established standard of 325 mg (5 gr) aspirin per dosage unit".

(3) For products containing calcium carbonate identified in § 343.10(c) or § 343.12(c) shall be clearly labeled on the principal display panel: "Equivalent to X mg per dosage unit of the established standard of 325 mg sodium salicylate per dosage unit". The actual amount of "X" of equivalent analgesic effectiveness for the specific product shall be used. The term "dosage unit" may be replaced by the applicable dosage form such as tablet or capsule.

§ 343.80 Professional labeling.

The labeling of a product provided to health professionals (but not to the general public) containing active ingredients identified in § 343.14 may contain any of the following indications: "For rheumatoid arthritis, juvenile rheumatoid arthritis, and ankylosing spondylitis, psoriatic arthritis, Reiter's syndrome, and fibrositis."

Interested persons are invited to submit their comments in writing (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before October 6, 1977. Such comments should be addressed to the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a memorandum or brief in support thereof. Additional comments replying to any comments so filed may also be submitted on or before November 7, 1977. Received comments may be seen in the above office between the hours of 8 a.m. and 4 p.m. Monday through Friday.

Note—The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an impact statement under Executive Order 11821 and OMB Circular A-107.

Dated: June 7, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 77-19108 Filed 7-7-77; 8:45 am]
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

MEDICARE

Limitations on Provider Costs

Effective July 1, 1977
SCHEDULE OF LIMITS ON HOSPITAL IN-PATIENT GENERAL ROUTINE SERVICE COSTS. UNDER THE HEALTH INSURANCE PROGRAM

Cost-Reporting Periods Beginning on or After July 1, 1977, and Before October 1, 1977.

A revised Schedule of Limits on Hospital Inpatient General Routine Service Costs in the Medicare program, applicable for cost reporting periods beginning on or after July 1, 1977, and before October 1, 1977, is set forth by the Administrator, Health Care Financing Administration, with the approval of the Secretary of Health, Education, and Welfare. Section 1861(v)(1) of the Social Security Act permits the Secretary to set prospective limits on costs to be recognized as reasonable based on estimates of the cost necessary in the efficient delivery of needed health services. The revised Schedule of Limits replaces the Schedule currently in effect which was published in the Federal Register (41 FR 26892) on June 30, 1976. The schedule applies to the total of the cost of hospital inpatient general routine service costs. These limits do not apply to the cost of special care units or ancillary services.

The Secretary of Health, Education, and Welfare is strongly committed to a national policy of containing the rapidly escalating health care costs. Therefore, the Secretary hereby serves notice of his intention to publish in the near future for comment a proposed new schedule of limits which, when published in final form, will become effective for cost reporting periods beginning on or after October 1, 1977. The Secretary also serves notice that either this or the subsequent schedule of limits may be required to be revised to conform with any Federal cost containment legislation enacted subsequent to the effective date of this schedule.

The initial classification system, which is described in the Federal Register (39 FR 20163) published June 6, 1974, was developed to provide for comparison of hospitals of similar size and in similar economic environments. Several refinements of the initial classification system were made effective July 1, 1975, and are described in the Federal Register (40 FR 23292) published May 30, 1975.

An additional refinement was made in the revised schedule of limits effective July 1, 1976. The refinement was the result of changes in the size of units of economic environment, and is described in the Federal Register (41 FR 26892) published June 30, 1976.

A refinement is made in the revised schedule of limits effective July 1, 1977. This limited refinement arose from the definition of metropolitan environments in the New England area. Under the Office of Management and Budget (OMB) definition, which has been used to distinguish between metropolitan and nonmetropolitan areas, Standard Metropolitan Statistical Areas (SMSA's) and Standard Consolidated Statistical Areas (SCSA's) in New England are based on cities and towns rather than on counties, as is the case in the rest of the United States. Because towns and cities are used to delineate SMSA's and SCSA's in New England, a county may be part of more than one SMSA or only a part of a county may be in an SMSA. However, costs in the Medicare program, applicable for cost reporting periods beginning on or after July 1, 1977, and before Income data supplied by the Department of Commerce, Bureau of Economic Analysis (BEA), which are used to group various areas according to economic environment, are available only on a county basis. In order to use the available data, BEA has slightly changed SMSA definitions in New England so that the SMSA's follow county lines.

Therefore, under the classification presently in force, a hospital located in the part of the county not included by OMB in the SMSA/SCSA would be subject to a nonmetropolitan limit even though the income of the hospital's location had been used for SMSA/SCSA classification grouping purposes. This situation is limited to New England and is inconsistent with the classification grouping used in the rest of the United States where the OMB and BEA definitions of SMSA's consistently follow county lines.

In order to rectify this inconsistency, a change is made in the classification of metropolitan environment used in the classification system. The change would alter the requirements for metropolitan status and would deem an entire county to be within an SMSA/SCSA if any part of such county was included by OMB in the SMSA/SCSA. Where a county contains the major city of an SMSA and is considered by OMB to be part of two or more SMSA's, that county would be deemed to be part of the SMSA whose major city it encompasses. Where a county is considered by OMB to be part of two or more SMSA's and does not contain the major city of any of those SMSA's, the county would be included in the SMSA having the highest per capita income. An SMSA's major city is defined as the city from which the SMSA takes its name. Where the application of this provision results in a provider being placed in a group with a limit lower than the limit to which it would have been subject without this change, the change in this limit may be applied in the cost reporting period to which this schedule applies.

An additional refinement is made in the revised schedule of limits effective July 1, 1977, for the per capita income level in nonmetropolitan areas, which are frequently single industry areas, per capita income levels are extremely sensitive to changes in economic conditions from one year to the next. This is especially true where the primary source of income is from agriculture. In these cases, hospital costs usually reflect the trend of the area's economy rather than year to year fluctuations. In order to provide more equitable treatment to nonmetropolitan areas, a change has been made that would base the classification of State nonmetropolitan areas on a 5-year per capita average income instead of a one year base period. In these areas the longer base would be more reflective of the economic environment than a single year's income.

The same change was considered for the metropolitan (SMSA/SCSA) areas. However, these areas do not exhibit the same volatility of per capita income from one year to the next as do the non-SMSA areas. This may be attributed to diversity in economic activity in the SMSA areas plus the additional benefits, such as supplemental unemployment compensation, which are available to the mostly unionized workers in these areas. Therefore, no change is being made in the classification system SMSA/SCSA areas.

The revised Schedule of Limits retains the provision to protect metropolitan area providers, for the period in which such hospital is in the effects of lower limits that might result from circumstances that result in a lower per capita income for the provider's area. Thus, if a metropolitan area's per capita income in a year, or a change in SMSA/SCSA designation during the year, places the area in a group lower than in the previous year, the limit to be applied for that year will be the higher of the current period or the income from the preceding year group. This provision will lessen the effect of unusual short-term fluctuations in area per capita income on reimbursement to individual providers.

For the period in which this schedule is in effect the same provision will be applied to nonmetropolitan providers this schedule which have been placed in a lower group as a result of the new classification methodology. SMSA and non-SMSA areas that are affected by this provision are indicated in the list of groups by an asterisk preceding the area name.

Example: Hospital A, Bed Size: 150. Per capita income in the provider's SMSA during the period on which the classification is based was reduced because of the effects of a natural disaster. Provider A had been classified in Group II effective July 1, 1976, and is now classified in Group III beginning July 1, 1977. The limit to be applied, beginning July 1, 1977, is the higher of the Group II limit or the Group III limit.

All SMSA's and SCSA's have been divided into the following five groups based on per capita income. Counties, rather than SMSA/SCSA areas, are listed for New England States.
### SCSA Group I

**Alaska**

**California**

**Los Angeles-Long Beach-Anaheim (SCSA)**
- Los Angeles-Long Beach
- Anaheim-Garden Grove
- Camarillo-Simi Valley-Ventura
- Riverside-San Bernardino-Ontario

**Salinas-Sonnoma-Monterey**

**San Francisco-Oakland-San Jose (SCSA)**
- San Francisco-Oakland
- San Jose
- Vallejo-Fairfield-Napa

**Colorado**

**Denver-Boulder**

**Connecticut**

**Fairfield County**
- Hartford County
- Litchfield County
- Middlesex County
- Tolland County

**District of Columbia**
- Washington, DC, DC-MD-VA

**Florida**

**Miami-Fort Lauderdale (SCSA)**
- Fort Lauderdale-Hollywood
- Miami
- Sarasota
- West Palm Beach-Boca Raton

**Illinois**

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**Iowa**

- Davenport-Rock Island-Moline, IA-IL

**Michigan**

**Detroit-Ann Arbor (SCSA)**
- Detroit
- Ann Arbor

**Minnesota**

- Minneapolis-St. Paul, MN-WI

**Nevada**

- Reno

**New Jersey**

**New York**

- New York

**New York-Newark-Jersey City, NY-NJ-CT (SCSA)**
- New York, NY-NJ
- Newark, NJ
- Jersey City, NJ
- Patterson-Clifton-Passaic, NJ
- Nassau-Suffolk, NY
- Long Branch-Asbury Park, NJ
- New Brunswick-Parth Amboy-Sayerville, NJ
- Rochester
Ohio
Cleveland-Akron-Lorain, (SCSA)

Cleveland
Akron
Lorain-Elyria

Virginia
Richmond
Washington

Richland-Kentucky

Wisconsin
Milwaukee-Racine (SCSA)

Milwaukee
Racine

Kenosha

SNSA/SCSA Group II

Arizona

Phoenix

California
Bakersfield
Santa Barbara-Santa Maria-Lompoc
San Diego
Stockton

Connecticut
New Haven County
New London County

Delaware

SEE PHILADELPHIA SCSA

Georgia

Atlanta

Hawaii

*Honolulu

Idaho

Boise City

Illinois

Bloomington-Normal
Decatur
Kankakee

*Rockford

Indiana

Fort Wayne
Indianapolis

Iowa

Cedar Rapids
Des Moines
Waterloo-Cedar Falls

Kansas

Topeka
Wichita

Kentucky

Louisville, KY-IN

Maryland

Baltimore

Massachusetts

Berkshire County

*Essex County

*Middlesex County

*Norfolk County

*Plymouth County

*Suffolk County

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<td>Saginaw</td>
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<tr>
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<tr>
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<tr>
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<tr>
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<tr>
<td>Albany-Schenectady-Troy</td>
<td>Houston-Galveston (SCSA)</td>
</tr>
<tr>
<td>Buffalo</td>
<td>Galveston-Texas City</td>
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<tr>
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<td>Midland</td>
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<td>Greensboro-Winston-Salem-High Point</td>
<td>Washington</td>
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<td>Seattle-Tacoma, (SCSA)</td>
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<td>Fargo-Moorhead, ND-MN</td>
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<tr>
<td>Ohio</td>
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<tr>
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<td>Madison</td>
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<td>Toledo, OH-MI</td>
<td>SMSA/SCSA Group III</td>
</tr>
<tr>
<td>Youngstown-Warren</td>
<td>Alabama</td>
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<td></td>
<td>Birmingham</td>
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<tr>
<td>Tucson</td>
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<td>Little Rock-North Little Rock</td>
<td>*Battle Creek</td>
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<td>California</td>
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<td>County/Metro Area</td>
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<td>Bristol County</td>
<td>Michigan</td>
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<td>Muskegon-Norton Shores-Muskegon Heights</td>
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<td>*St. Joseph</td>
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<td>*Great Falls</td>
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<td>Albuquerque</td>
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<td>Utica-Rome</td>
<td>New York</td>
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<td>North Carolina</td>
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<td>Burlington</td>
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<td>Oklahoma City</td>
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<tr>
<td>Eugene-Springfield</td>
<td>Oregon</td>
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<tr>
<td>Johnstown</td>
<td>Pennsylvania</td>
</tr>
<tr>
<td>Wilkes Barre-Scranton-Katleton (Northeast PA)</td>
<td>Pennsylvania</td>
</tr>
<tr>
<td>Williamsport</td>
<td>Pennsylvania</td>
</tr>
<tr>
<td>Columbia</td>
<td>South Carolina</td>
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<tr>
<td>Greenville-Spartanburg</td>
<td>Tennessee</td>
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<tr>
<td>Chattanooga, TN-CA</td>
<td>Tennessee</td>
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<tr>
<td>Clarksville-Hopkinsville, TN-KY</td>
<td>Tennessee</td>
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<tr>
<td>Knoxville</td>
<td>Tennessee</td>
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<tr>
<td>Abilene</td>
<td>Texas</td>
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<tr>
<td>Austin</td>
<td>Texas</td>
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<tr>
<td>Kilgore -Temple</td>
<td>Texas</td>
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<tr>
<td>Longview</td>
<td>Texas</td>
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<td>Lubbock</td>
<td>Texas</td>
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<tr>
<td>Odessa</td>
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<td>San Angelo</td>
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<td>San Antonio</td>
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<td>Sherman-Denison</td>
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<td>Tyler</td>
<td>Texas</td>
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<tr>
<td>Naco</td>
<td>Utah</td>
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<tr>
<td>Salt Lake City-Ogden</td>
<td>Utah</td>
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<tr>
<td>Lynchburg</td>
<td>Virginia</td>
</tr>
<tr>
<td>Parkersburg-Marionette, WV-OH</td>
<td>West Virginia</td>
</tr>
<tr>
<td>Wheeling, WV-OH</td>
<td>West Virginia</td>
</tr>
<tr>
<td>Green Bay</td>
<td>Wisconsin</td>
</tr>
<tr>
<td>La Crosse</td>
<td>Wisconsin</td>
</tr>
</tbody>
</table>

* indicates a leading or co-leading city in the MSA.

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FEDERAL REGISTER, VOL. 42, NO 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>Alabama</th>
<th>Mississippi</th>
<th>North Carolina</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anniston</td>
<td>Biloxi-Gulfport</td>
<td>Fayetteville</td>
</tr>
<tr>
<td>Florence</td>
<td>Panacaoula-Moss Point</td>
<td>Wilmington</td>
</tr>
<tr>
<td>Gadsden</td>
<td></td>
<td>Oklahoma</td>
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<tr>
<td>Huntsville</td>
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<td>Lawton</td>
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<tr>
<td>Mobile</td>
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<td>Pennsylvania</td>
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<td>Tuscaloosa</td>
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<td>Altoona</td>
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<td>Arkansas</td>
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<td>Puerto Rico</td>
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<td>Fayetteville-Springdale</td>
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<td>Lawton</td>
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<td>Fort Smith, AR-OK</td>
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<td>Pennsylvania</td>
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<td>Pine Bluff</td>
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<td>Altoona</td>
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<td>Bloomington</td>
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<td>South Carolina</td>
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<tr>
<td>Terre Haute</td>
<td></td>
<td>Charleston-North Charleston</td>
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<tr>
<td>Louisiana</td>
<td></td>
<td>Tennessee</td>
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<tr>
<td>Alexandria</td>
<td></td>
<td>Johnson City-Kingsport-Bristol, TN-VA</td>
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<tr>
<td>Lafayette</td>
<td></td>
<td>Texas</td>
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<tr>
<td>Lake Charles</td>
<td></td>
<td>Brownsville-Harlingen-San Benito</td>
</tr>
<tr>
<td>Monroe</td>
<td></td>
<td>Bryan-College Station</td>
</tr>
<tr>
<td>Maine</td>
<td></td>
<td>Corpus Christi</td>
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<tr>
<td>Androscoggin County</td>
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<td>El Paso</td>
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<tr>
<td>Minnesota</td>
<td></td>
<td>Laredo</td>
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<td>St. Cloud</td>
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<td>McAllen-Pharr-Edinburg</td>
</tr>
<tr>
<td>Missouri</td>
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<td>Texarkana, TX-AK</td>
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<tr>
<td>Columbia</td>
<td></td>
<td>Utah</td>
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<tr>
<td>Springfield</td>
<td></td>
<td>Provo-Orem</td>
</tr>
<tr>
<td></td>
<td></td>
<td>West Virginia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Huntington-Ashland, WV-KY-OH</td>
</tr>
</tbody>
</table>
Wisconsin

Eau Claire

*Hospitals in areas (SCSA or SMSA) identified by an asterisk will receive the higher of the limit published herein for the group in which the hospital is actually classified or the limit published herein for the group in which the hospital was classified in the immediately preceding cost reporting period.

Non-SMSA areas will be classified according to the per capita income of all non-SMSA counties within a State. The following are the five income groupings, (with States classified according to a 5-year per capita income average) to be used for hospitals located in non-Standard Metropolitan Statistical Areas in those States.

Non-SMSA

Group I
Alaska
Kansas

Group II
California
Connecticut
Delaware

Group III
Colorado
Idaho
Michigan

Group IV
Arizona
Maine

*Hospitals in States identified by an asterisk will receive the higher of the limit published herein for the group in which the hospital is actually classified or the limit published herein for the group in which the hospital was classified in the immediately preceding cost reporting period.

With respect to the Standard Consolidated Statistical Area/Standard Metropolitan Statistical Area groupings, the groupings were developed by combining those SCSA/SMSA's which reflect a similar economic environment as expressed by per capita income data. The SCSA/SMSA's were arrayed in order of the size of their per capita income and groupings were established. The same procedure was followed for grouping the non-SCSA/SMSA areas to arrive at State groups.

The following bed-size categories are used to classify hospitals:

**Standard Metropolitan Statistical Areas**

Groups I and II
Less than 100
100-404
405-604
605 and above

Groups III, IV, and V
Less than 100
100-404
405 and above

**Non-Standard Metropolitan Statistical Areas**

Less than 100
100-169
170 and above

The limits were developed in the following manner:

1. Inpatient general routine service cost data for each participating hospital were obtained from the fiscal intermediaries.
2. The data for hospitals in each class were arrayed in descending order of inpatient general routine service cost.

3. The 80th percentile and the median were computed for each class.

4. For each class, an amount equal to 10 percent of the median was added to the 80th percentile amount.

5. This sum was adjusted to reflect the 14.0 percent annual rate of estimated cost increases in per diem routine service costs following the date of data collection.

6. The amounts calculated in step 5 are rounded to the next highest dollar which establishes the limit for each class, subject to adjustment for hospitals reporting on other than a reporting period beginning July 1, 1977.

Under the authority of section 1861(x) of the Social Security Act, the following cost limitations apply to the total of the hospital inpatient general routine service costs (excluding costs incurred for special care units and ancillary services), adjusted upward as provided for below. The limits are applicable to cost reporting periods beginning on or after July 1, 1977, and will remain in effect until the effective date of a revised schedule.

The limits are applicable to any hospital with a cost reporting period beginning on or after July 1, 1977. Where a hospital has a cost reporting period beginning after July 1, 1977, the published limit will be adjusted upward by a factor of 1.17 percent for each elapsed month between July 1, 1977, and the month in which the hospital's reporting period begins. The result of this calculation is not rounded and is to be given in dollars and cents.
SCHEDULE OF LIMITS ON HOSPITAL INPATIENT GENERAL ROUTINE SERVICE COSTS FOR HOSPITALS WITH COST-REPORTING PERIODS BEGINNING ON OR AFTER JULY 1, 1977 (A)

HOSPITALS LOCATED WITHIN SMSA'S (METROPOLITAN) BED SIZE

<table>
<thead>
<tr>
<th>SMSA group</th>
<th>Less than 100</th>
<th>100 to 404</th>
<th>405 to 684</th>
<th>685 and above</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>$ 139</td>
<td>$ 144</td>
<td>$ 160</td>
<td>$ 211</td>
</tr>
<tr>
<td>II</td>
<td>121</td>
<td>123</td>
<td>126</td>
<td>151</td>
</tr>
<tr>
<td>III</td>
<td>109</td>
<td>110</td>
<td>109</td>
<td>109</td>
</tr>
<tr>
<td>IV</td>
<td>100</td>
<td>105</td>
<td>108</td>
<td>108</td>
</tr>
<tr>
<td>V</td>
<td>89</td>
<td>87</td>
<td>109</td>
<td>109</td>
</tr>
</tbody>
</table>

1Limits apply to all SMSA's except Anchorage, Alaska, and Honolulu, Hawaii, where cost-of-living adjustment (25 percent Anchorage, Alaska; 17.5 percent Honolulu, Hawaii) was made. The limits for these areas are as follows:

<table>
<thead>
<tr>
<th>Anchorage</th>
<th>Less than 100</th>
<th>100 to 404</th>
<th>405 to 684</th>
<th>685 and above</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchorage</td>
<td>$ 174</td>
<td>$ 180</td>
<td>$ 200</td>
<td>$ 264</td>
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</table>

<table>
<thead>
<tr>
<th>Honolulu</th>
<th>Less than 100</th>
<th>100 to 404</th>
<th>405 to 684</th>
<th>685 and above</th>
</tr>
</thead>
<tbody>
<tr>
<td>Honolulu</td>
<td>164</td>
<td>170</td>
<td>188</td>
<td>248</td>
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</tbody>
</table>

HOSPITALS LOCATED OUTSIDE SMSA'S (NONMETROPOLITAN) BED SIZE

<table>
<thead>
<tr>
<th>State group</th>
<th>Less than 100</th>
<th>100 to 169</th>
<th>170 and above</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>$ 103</td>
<td>$ 114</td>
<td>$ 112</td>
</tr>
<tr>
<td>II</td>
<td>119</td>
<td>114</td>
<td>107</td>
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<tr>
<td>III</td>
<td>109</td>
<td>105</td>
<td>103</td>
</tr>
<tr>
<td>IV</td>
<td>92</td>
<td>89</td>
<td>91</td>
</tr>
<tr>
<td>V</td>
<td>84</td>
<td>83</td>
<td>84</td>
</tr>
</tbody>
</table>

2Limits apply to all Group I States except Alaska where cost of living adjustment (25%) was made - limits for Alaska are:

Less than 100 100 to 169 170 and above
$ 129 $ 143 $ 140

3Appplies to all Group II States except Hawaii where cost of living adjustment (12.5%) was made - limits for Hawaii are:

Less than 100 100 to 169 170 and above
$ 134 $ 129 $ 121

(A) The schedule of limits and adjustment factors are only for a 12-month cost reporting period. For providers with other than 12-month cost reporting periods, intermediaries must contact the Health Care Financing Administration for adjustment factors.

The Department finds that there is good cause for dispensing with a notice and comment period for this Notice of Limits because of the need to inform hospitals whose cost reporting year begin July 1 of the limits which will be applicable to them for this year. Continued uncertainty on the part of such hospitals as to the limits to which they will be subject for this cost reporting year would not serve the public interest.

(Secs. 1102, 1851(v)1, 1866(a), and 1971, Social Security Act; 42 Stat 657, as amended; 78 Stat 312, as amended; 78 Stat 322, as amended; 78 Stat 331 (42 U.S.C. 1302, 1395d (v), 1396c (a), and 1398bb));

(Catalog of Federal Domestic Assistance Program No 13 660, Health Insurance for the Aged—Hospital Insurance)

Note: The Health Care Financing Administration has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11921 and OMB Circular A-107.

Dated: June 30, 1977

DAVID W. WEINSTEIN,
Acting Administrator, Health Care Financing Administration

Approved: June 30, 1977

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education, and Welfare

[FR Doc 77-19360 Filed 7-1-77; 5:01 pm]
FRIDAY, JULY 8, 1977
PART IX

DEPARTMENT OF LABOR
Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions
NOTICES

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (48 Stat. 1494, as amended, 49 U.S.C. 276a) and of other Federal statutory provisions prescribed in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor’s Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor’s Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modification and superseded decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rule-making procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

New General Wage Determination Decisions

Alabama

Mississippi

Michigan

North Carolina

Superseded Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the Federal Register are listed with each State.

Arizona: AZ77-5058; AZ77-5059; June 17, 1977.

California: CA77-5039; CA77-5040; April 22, 1977.

Florida: FL77-1005; May 13, 1977.

Georgia: GA-4098; Sept. 27, 1974.

Idaho: ID77-5045; May 13, 1977.

Illinois:

IN76-2120; Oct. 1, 1976.
IN76-2126; Oct. 6, 1976.
IN76-2129; Nov. 28, 1976.
IN76-2133; Dec. 3, 1976.
IN76-2144; Feb. 28, 1977.
IN77-2008; June 10, 1977.

Kansas:

K077-4075; Apr. 8, 1977.

Louisiana:

LA77-4104; May 20, 1977.

Maryland:

MD77-3077; June 3, 1977.

Michigan:

MI76-2149; Nov. 19, 1976.
MI77-2050; MI77-2053; May 8, 1977.
MI77-2054; May 13, 1977.
MI77-2071; June 3, 1977.

Minnesota:

MN77-2047; May 6, 1977.
MN77-2048; May 20, 1977.

Mississippi:

MS77-1033; Mar. 25, 1977.

Montana:

MT77-5097; June 3, 1977.

Nevada:

NV77-6031; Mar. 18, 1977.
NV77-6061; June 17, 1977.

New Mexico:

NM77-4116; Do.

Pennsylvania:

PA77-3020; PA77-3029; Feb. 18, 1977.
PA77-3031; PA77-3039; Apr. 8, 1977.
PA77-3049; Apr. 23, 1977.
PA77-3050; PA77-3053; May 13, 1977.
PA77-3054; PA77-3058; PA77-3057; June 10, 1977.

South Dakota:

SD77-3006; June 17, 1977.

Texas:

TX77-4007; TX77-4008; May 6, 1977.
TX77-4101; May 13, 1977.
TX77-4108; June 3, 1977.

Washington:

WA77-5095; June 17, 1977.

Superseded Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the Federal Register are listed with each State.

Superseded Decision numbers are in parentheses following the numbers of the decisions being superseded.

FEDERAL REGISTER, VOL. 42, NO. 151—FRIDAY, JULY 8, 1977
NOTICES

Alabama:
ALJ7-1099 (ALJ7-1099) --- Jan. 10, 1976
Florida:
FLJ7-1015 (FLJ7-1015) --- Feb 18, 1977
Illinois:
ILJ7-2122 (ILJ7-2122) --- Oct 1, 1976
Kansas:
KJ7-4084 (KJ7-4161) --- Apr 15, 1977
Missouri:
MOJ7-4070 (MOJ7-4160) --- Apr. 8, 1977

Montana:
MTJ7-5020 (MTJ7-5074) --- Mar 11, 1977

Tennessee:
TNJ7-1054 (TNJ7-1082) --- Apr. 1, 1977

Texas:
TXJ7-4171 (TXJ7-4157) --- Dec 28, 1976

Puerto Rico:
PRJ7-5030 (PRJ7-5060); Aug 8, 1976

FRJ7-3090 (FRJ7-5097); FRJ7-3091 (FRJ7-5096).

TXJ7-4053 (TXJ7-4157); TXJ7 - 4056 (TXJ7 - 4153); TXJ7 - 4055 (TXJ7-4154).

TXJ7-4057 (TXJ7-4156) --- Mar 4, 1977

Signed at Washington, D.C., this 1st day of July 1977.

RAY J. DOLAN,
Assistant Administrator,
Wage and Hour Division.

STATE: Alabama
COUNTIES: Madison & Marshall
DECISION No.: ALJ7-1099
DATE: Date of Publication
DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### New Decision

**State:** Michigan  
**Decision No.:** M177-2106  
**County:** Ionia  
**Date of Publication:** 

**Description of Work:** Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>Carpenters</td>
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</tr>
<tr>
<td>Cement Masons</td>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td>Drywall Hangers</td>
<td>8.00</td>
<td></td>
</tr>
<tr>
<td>Drywall Tapers</td>
<td>8.00</td>
<td></td>
</tr>
<tr>
<td>Laborers</td>
<td>4.00</td>
<td></td>
</tr>
<tr>
<td>Painters</td>
<td>5.22</td>
<td></td>
</tr>
<tr>
<td>Plumbers</td>
<td>7.75</td>
<td></td>
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<tr>
<td>Roofers</td>
<td>4.81</td>
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<tr>
<td>Soft Floor Layers</td>
<td>7.08</td>
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### New Decision

**State:** North Carolina  
**Decision No.:** M077-1092  
**County:** Orange  
**Date of Publication:** 

**Description of Work:** Building construction (does not include single family homes and garden type apartments up to and including 4 stories).

<table>
<thead>
<tr>
<th>Trade</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
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<td>Bricklayers</td>
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<td>Carpenters</td>
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<td>Cement Masons</td>
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<tr>
<td>Electricians</td>
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<td></td>
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<tr>
<td>Glassers</td>
<td>5.22</td>
<td></td>
</tr>
<tr>
<td>Ironworkers - structural, ornamental &amp; reinforcing</td>
<td>5.21</td>
<td></td>
</tr>
<tr>
<td>Laborers</td>
<td>3.07</td>
<td></td>
</tr>
<tr>
<td>Painters</td>
<td>4.12</td>
<td></td>
</tr>
<tr>
<td>Plumbers &amp; Pipefitters</td>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td>Roofers</td>
<td>4.00</td>
<td></td>
</tr>
<tr>
<td>Sheet metal workers</td>
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<td></td>
</tr>
<tr>
<td>Tile setters</td>
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<tr>
<td>Truck drivers</td>
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<td></td>
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<tr>
<td>Power Equipment Operators: Backhoe</td>
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<td></td>
</tr>
<tr>
<td>Front end loader</td>
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<td></td>
</tr>
<tr>
<td>Roller</td>
<td>3.75</td>
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<tr>
<td>Welders – rate for craft</td>
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</tbody>
</table>

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*Federal Register, Vol. 42, No 131—Friday, July 8, 1977*
### NOTICE

**Decision No. A277-5058 - Mod. #1**

*(42 FR 31065 - June 17, 1977)*

Statewide, Arizona

#### Changes

**Bricklayers (Tucson Area):**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>$10.02</td>
<td>.90</td>
<td>.95</td>
<td>.05</td>
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<tr>
<td>B</td>
<td>12.24</td>
<td>.96</td>
<td>34.70</td>
<td>3/4/4</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>13.00</td>
<td>.96</td>
<td>34.70</td>
<td>3/4/4</td>
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</table>

**Manhole Builders:**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
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<td>.95</td>
<td>.05</td>
<td>.06</td>
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<td>.95</td>
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<td>C</td>
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<td>.05</td>
<td>.06</td>
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<tr>
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<td>.95</td>
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<td>.06</td>
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</tbody>
</table>

**Electricians (Phoenix, Kingman and Prescott Areas):**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
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<td>.96</td>
<td>34.70</td>
<td>3/4/4</td>
<td></td>
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<tr>
<td>B</td>
<td>14.38</td>
<td>.96</td>
<td>34.70</td>
<td>3/4/4</td>
<td></td>
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<tr>
<td>C</td>
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<td>.96</td>
<td>34.70</td>
<td>3/4/4</td>
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**Electricians (Tucson Area):**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
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<td>34.70</td>
<td>1/2/1</td>
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<tr>
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<td>34.70</td>
<td>1/2/1</td>
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<tr>
<td>C</td>
<td>14.04</td>
<td>.96</td>
<td>34.70</td>
<td>1/2/1</td>
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**Line Construction: Zone 1 (Phoenix and Tucson 30 mile radius from center of town):**

<table>
<thead>
<tr>
<th>Groundmen</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
<tbody>
<tr>
<td>9.67</td>
<td>8%</td>
<td>34.70</td>
<td>1/2/1</td>
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**Equipment Operators; Powdermen; Mechanics; Linemen; Technicians; Crane Operators; Lineman Holders:**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<td>.8%</td>
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### Decision No. A277-5059 - Mod. #1

*(42 FR 31065 - June 17, 1977)*

Maricopa County, Arizona

#### Changes

**Electricians:**

<table>
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<th>Zone</th>
<th>Basic Hourly Rates</th>
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<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
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<td>34.70</td>
<td>3/4/4</td>
<td></td>
</tr>
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<td>B</td>
<td>14.38</td>
<td>.96</td>
<td>34.70</td>
<td>3/4/4</td>
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<tr>
<td>C</td>
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### Decision No. A277-5060 - Mod. #1

*(42 FR 31070 - June 17, 1977)*

Pima County, Arizona

#### Changes

**Bricklayers, Stonemasons:**

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<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tbody>
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<td>.05</td>
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<td>.95</td>
<td>.05</td>
<td>.06</td>
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<tr>
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<td>.05</td>
<td>.06</td>
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<td>.95</td>
<td>.05</td>
<td>.06</td>
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</table>

**Electricians:**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>13.09</td>
<td>.90</td>
<td>34.70</td>
<td>1/2/1</td>
<td></td>
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<tr>
<td>B</td>
<td>13.79</td>
<td>.90</td>
<td>34.70</td>
<td>1/2/1</td>
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</tr>
<tr>
<td>C</td>
<td>14.39</td>
<td>.90</td>
<td>34.70</td>
<td>1/2/1</td>
<td></td>
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<tr>
<td>D</td>
<td>15.09</td>
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### DECISION NO. CA77-5039 - Mod. 2

**(42 FR 20591 - April 22, 1977)**

<table>
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<th>Counties</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alameda, Alpine, Amador, Butte, Calaveras, Colusa, Contra Costa, Del Norte, El Dorado, Fresno, Glenn, Humboldt, Kings, Lake, Lassen, Modoc, Marin, Mariposa, Mendocino, Merced, Modoc, Monterey, Napa, Nevada, Placer, Plumas, Siskiyou, San Benito, San Francisco, San Joaquin, San Mateo, Santa Clara, Santa Cruz, Shasta, Sierra, Siskiyou, Solano, Sonoma, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo and Yuba Counties, California</td>
<td>$ 11.42</td>
<td>$ 1.50</td>
<td>$ 1.10</td>
<td>$ 1.00</td>
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</tr>
<tr>
<td>Fresno, Kings, Madera, Mariposa and Merced Counties Brick Tenders</td>
<td>11.55</td>
<td>95</td>
<td>1.00</td>
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</tr>
<tr>
<td>Fresno, Kings, Madera and Tulare Counties Electricians</td>
<td>10.35</td>
<td>60</td>
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<tr>
<td>Alameda County Electricians</td>
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<tr>
<td>Cable Splicers</td>
<td>14.52</td>
<td>1.05</td>
<td>3×+1.15</td>
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</tbody>
</table>

**Change:**
- Bricklayers; Stonemasons; Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo, Siskiyou, Solano, Sonoma and Trinity Counties

### DECISION NO. CA77-5039 (Cont'd)

<table>
<thead>
<tr>
<th>Counties</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amador, Colusa, Sacramento, Sutter, Yolo, Yuba and those portions of Alpine, El Dorado, Nevada, Placer and Sierra Counties West of the Sierra Mountain Watershed</td>
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<td>Electricians</td>
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<td>95</td>
<td>3×+ 85</td>
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<td>045</td>
</tr>
<tr>
<td>Tunnel: Electricians</td>
<td>14.52</td>
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<td>3×+ 85</td>
<td></td>
<td>045</td>
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<tr>
<td>Cable Splicers</td>
<td>15.97</td>
<td>95</td>
<td>3×+ 85</td>
<td></td>
<td>045</td>
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<tr>
<td>Lake Tahoe Area Electricians</td>
<td>13.98</td>
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<td>3×+ 77</td>
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<td>Cable Splicers</td>
<td>15.20</td>
<td>67</td>
<td>3×+ 77</td>
<td>08</td>
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<tr>
<td>Butte, Glenn, Lassen, Hodoc, Plumas, Shasta, Siskiyou, Tehama and Trinity Counties Electricians</td>
<td>11.98</td>
<td>87</td>
<td>3×+ 705</td>
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<tr>
<td>Cable Splicers</td>
<td>13.18</td>
<td>87</td>
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<tr>
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<td>12.50</td>
<td>87</td>
<td>3×+ 705</td>
<td>04</td>
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<td>13.84</td>
<td>87</td>
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<tr>
<td>Calaveras and San Joaquin Cos Electricians, Technicians</td>
<td>12.15</td>
<td>92</td>
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<td>Cable Splicers</td>
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<td>Contra Costa County Electricians</td>
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<td>3×+1.00</td>
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<tr>
<td>Del Norte and Humboldt Cos Electricians</td>
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<td>80</td>
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<tr>
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<td>80</td>
<td>3×+1.05</td>
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<tr>
<td>Fresno, Kings, Madera and Tulare Counties Electricians</td>
<td>12.91</td>
<td>75</td>
<td>3×+ .95</td>
<td>05</td>
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<tr>
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<td>75</td>
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</table>
### Table: Fringe Benefits Payments

<table>
<thead>
<tr>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
</table>

#### Lake, Marin, Mendocino and Sonoma Counties
- **Electricians**
  - Basic Hourly Rates: $12.65, 13.91
- **Cable Splicers**
  - Basic Hourly Rates: 9.03, 10.01
- **Monterey County Electricians**
  - Basic Hourly Rates: 12.50, 13.81
- **Napa and Solano Counties Electricians**
  - Basic Hourly Rates: 12.07, 13.58
- **San Benito, Santa Clara and Santa Cruz Counties Electricians**
  - Basic Hourly Rates: 13.80, 15.53
- **San Francisco County Electricians**
  - Basic Hourly Rates: 15.58, 17.53
- **San Mateo County Electricians**
  - Basic Hourly Rates: 11.77

#### Other Areas
- **Calaveras and San Joaquin Counties**
  - Basic Hourly Rates: 11.30
- **Line Constructions**
  - Basic Hourly Rates: 11.40, 13.68, 15.20, 16.70

### Table: Fringe Benefits Payments (Cont'd)

<table>
<thead>
<tr>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
</table>

#### Fresno, Kings, Madera and Tulare Counties
- **Groundmen**
  - Basic Hourly Rates: 12.09
- **LINEMEN/Line Equipment Operators**
  - Basic Hourly Rates: 12.91, 14.20
- **Cable Splicers**
  - Basic Hourly Rates: 9.42, 12.56, 13.00
- **Monterey County Groundmen**
  - Basic Hourly Rates: 12.07
- **LINEMEN/Line Equipment Operators**
  - Basic Hourly Rates: 13.50, 13.62
- **Alameda County Groundmen**
  - Basic Hourly Rates: 9.60
- **LINEMEN/Line Equipment Operators**
  - Basic Hourly Rates: 11.62
- **Humboldt County Groundmen**
  - Basic Hourly Rates: 9.00
- **LINEMEN/Line Equipment Operators**
  - Basic Hourly Rates: 11.25, 12.15
- **San Francisco County Groundmen**
  - Basic Hourly Rates: 13.25
- **LINEMEN/Line Equipment Operators**
  - Basic Hourly Rates: 15.50
- **Cable Splicers**
  - Basic Hourly Rates: 17.53
- **San Benito, Santa Clara, and Santa Cruz Counties Groundmen**
  - Basic Hourly Rates: 11.65
- **LINEMEN/Line Equipment Operators**
  - Basic Hourly Rates: 13.70
- **Cable Splicers**
  - Basic Hourly Rates: 15.41

#### Plasterers
- **Del Norte, Humboldt, Lassen (Northwestern half), Marin, Modoc, Napa, Shasta, Siskiyou, Solano, Sonoma, Tehama and Trinity Counties**
  - Basic Hourly Rates: 10.25

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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. CA77-5039 (Cont'd)

#### Fringe Benefits Payments

<table>
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<th>H&amp;W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
</table>

**Soft Floor Layers:**
- Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Glenn, Lassen (excluding Honey Lake Area), Merced (east of San Joaquin River), Plumas, San Joaquin, Shasta, Sacramento, Stanislaus, Sutter, Tehama, Trinity, Tuolumne, Yolo and Yuba Counties and those portions of El Dorado, Nevada, Placer and Sierra Counties (excluding Lake Tahoe Area)

- $10.73

**Terrazzo Workers:**
- Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Napa, San Francisco, San Mateo, Solano, Sonoma and Trinity Counties

- $11.42

**Tile Setters:**
- Fresno, Kings, Madera, Mariposa, Merced and Tulare Counties

- $10.35

**Monterey and Santa Cruz Counties**

- $13.41

**Laborers:**
- Group 1
- $8.77
- 1.25
- 1.70
- 1.10
- 10
- Group 1(a)
- $9.08
- 1.25
- 1.70
- 1.10
- 10
- Group 1(b)
- $9.27
- 1.25
- 1.70
- 1.10
- 10
- Group 1(c)
- $8.82
- 1.25
- 1.70
- 1.10
- 10
- Group 1(d)
- $8.72
- 1.25
- 1.70
- 1.10
- 10
- Group 1(e)
- $9.22
- 1.25
- 1.70
- 1.10
- 10
- Group 1(f)
- $8.97
- 1.25
- 1.70
- 1.10
- 10
- Group 2
- $8.62
- 1.25
- 1.70
- 1.10
- 10
- Group 3
- $8.52
- 1.25
- 1.70
- 1.10
- 10

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**NOTICES**

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Decision No. CA77-5940 - Mod. 43

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<tr>
<td></td>
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<td>Pensions</td>
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#### Changes

**Bricklayers; Stonemasons:**
- Del Norte, Humboldt, Marin, Napa, San Francisco, San Mateo, Solano and Sonoma Counties
- $11.42, $1.50, $1.10, $1.00

**Cable Splicers:**
- Anza, Sacramento, Sutter, Yolo, Yuba, and those portions of Alpine, El Dorado, Nevada, and Placer Counties west of the Main Sierra Mountain Watershed
- 14.28, 14.52, 14.67, 14.75

**Electricians:**
- Alameda County
- $12.90, $1.00, $3.41, $1.15

**Woodworkers:**
- Del Norte, Humboldt, Marin, Napa, Solano, Sonoma, and Tehama Counties
- 10.35, 10.25, .80, .80

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### Decision No. CA77-5940 (Cont'd)

<table>
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<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
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</tbody>
</table>

#### Changes

**Electricians (4 stories):**
- Del Norte, Humboldt, Marin, Napa, San Francisco, San Mateo, Solano and Sonoma Counties
- $11.90, $1.10, $3.41, .70

**Electricians:**
- 12.15, 12.67, 15.20, 15.70

**Electricians:**
- 11.25, 12.15, 13.90

**Electricians:**
- 12.07, 13.50

**Electricians:**
- 13.90, 15.53

**Electricians:**
- 15.50, 15.00

**Electricians:**
- 11.30, .80

**Electricians:**
- 10.25, .98

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**NOTICES**

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Decision No. CA77-5040 (Cont'd)

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### Decision No. FL77-1065 - Mod. #3

(42 FR 24575 - May 13, 1977)
Brevard & Volusia (Cape Kennedy, Kennedy Space Flight Center and Patrick Air Force Base only and including Maburuck Radar Site), Florida

**Changes:**

- Mod. #1 in June 3, 1977 Federal Register publication to Mod. #2

### Decision #PA-1638 - Mod. #6

(39 FR 30086 - September 27, 1974)
Statewide, Georgia

**Changes:**

- **Description of Work** to read:

  - Highway Construction (does not include airport runways and taxiways; bridges over navigable waters; tunnels; rest areas which include building structures; railroad construction; and paving associated with building construction)

### Decision #ID77-5065 - Mod. #9

(42 FR 24377 - May 13, 1977)
Statewide Idaho

**Changes:**

- Ironworkers:
  - Remaining Counties and those portions of Adams, Idaho, Valley, Washington Counties located south of the Weiser-Gibbonsville Line
### Modifications P. 13

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<th>Pensions</th>
<th>Vacation</th>
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### Modifications P. 14

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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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<th>Fringe Benefits Payments</th>
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<td><strong>Decision 61726-2128 - Mod. 86</strong>&lt;br&gt;(61 FR 46628 - October 23, 1976)&lt;br&gt;Henderson, Henry, Knox, Bureau, Rock Island, Stark &amp; Warren Counties, Illinois</td>
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<td><strong>Change</strong>&lt;br&gt;Steamfitters&lt;br&gt;Millwrights &amp; Piledrivermen&lt;br&gt;Cement Masons</td>
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| **Decision 61726-2130 - Mod. 85**<br>(61 FR 46624 - October 23, 1976)<br>Henderson, Henry, Knox, Bureau, Rock Island, Stark & Warren Counties, Illinois | **Basic Hourly Rates**<br>H & W | Pensions | Vacation | Education and/or Appr Tr |
| **Change**<br>Carpenters & Soft Floor Layers | 11.11 | 40 | 50 | .05 |
| Millwrights & Piledrivermen | 11.61 | 40 | 50 | .05 |
| Cement Masons | 11.00 | 50 | 25 | .05 |

<p>| <strong>Decision 61726-2131 - Mod. 84</strong>&lt;br&gt;(61 FR 46628 - October 23, 1976)&lt;br&gt;Sangamon County, Illinois | <strong>Basic Hourly Rates</strong>&lt;br&gt;H &amp; W | Pensions | Vacation | Education and/or Appr Tr |
| <strong>Change</strong>&lt;br&gt;Bricklayers, Stonemasons, Marble-Tile-Terrazzo&lt;br&gt;Workers-Pointers-Glulkers &amp; Cleaners | 10.10 | 50 | 1.00 | .02 |
| Plasterers | 11.46 | 65 | 1.00 | .01 |
| Plumbers &amp; Steamfitters | 11.53 | 35 | 88 | .05 |</p>
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<td>Alexander, Franklin, Gallatin, Hamilton, Hardin, Jackson, Jefferson, Johnson, Marion, Mason, Perry, Pope, Pulaski, Saline, Union, White &amp; Williamson Counties, Illinois, &amp; Tipton County, Tennessee, &amp; Hahnmann County, Illinois</td>
<td>[H &amp; W]</td>
<td>[Pensions]</td>
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<td><strong>CHANGES:</strong> Bricklayers &amp; Stonemasons:</td>
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<td>Jackson &amp; Perry Counties: Bricklayers, Stonemasons, Terre Haute &amp; Tile Workers:</td>
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<td>Cement Masons &amp; Plasterers: Alexander, Jackson, Perry, Pulaski &amp; Union Counties: Plumbers &amp; Steamfitters: Alexander, Hardin, Harnett, Jackson, Johnson, Perry, Pope, Pulaski &amp; Union Counties:</td>
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<tr>
<th>Decision 0176-2113 - Mod. 06</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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</thead>
<tbody>
<tr>
<td>(41 FR 44651 - October 22, 1976)</td>
<td></td>
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<tr>
<td>Boone, Carroll, DeKalb, Jo Daviess, Lee, Ogle, Stephenson, Whitley &amp; Winneshiek Counties, Illinois</td>
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<tr>
<td><strong>CHANGES:</strong> Carpenters: DeKalb Coj; Otis Co; Ogle(E. of Hoy) 631 incl. Rockford City) Coj; Lee (Eastern 8 of Coj. incl. Carroll &amp; Carpenters County) Carpenters &amp; Subfloor Layers:</td>
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<tr>
<td><strong>Electricians:</strong> Boone, DeKalb, Winneshiek, Stephenson, Ogle, Lee, Jo Daviess Warren, Rush, Knox, Steuben, Worth, Grove,</td>
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<table>
<thead>
<tr>
<th>Decision 0176-2113 - Mod. 06 (Cont'd)</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tr>
<td>Electricians (Cont'd)</td>
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<td></td>
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<tr>
<td>Pleasant Valley, Barrannan Types: Coj; Whiteside(Galena) Jordan, Hopkins, Starling, Hurn, Montgomery, Tampson, Hahnmann Tampson Coj; County</td>
<td>$11.65</td>
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<tr>
<td>Sheet Metal Workers: Boone, DeKalb, Lee, Ogle, Whiteside, Winneshiek, Carroll Coj; Eastern Coj. Coj</td>
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<tr>
<td>Truck Drivers: Boone, Stephenson, Winneshiek Coj; Carroll(North of Rts 172 &amp; East of Rts 67) Coj Jo Daviess(East of Rts 678-Northern Coj. city of Canton Coj. &amp; East of Rts 678-Northern Coj. city of Canton Coj.</td>
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<td>4-Axle Trucks: 9.90</td>
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<td>5-Axle Trucks: 10.10</td>
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<td>6-Axle Trucks: 10.30</td>
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<tr>
<td>DeKalb Coj; East of Rts 031 in Lee &amp; Ogle Counties: 9.80</td>
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<td>4-Axle Trucks: 9.95</td>
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<td>5-Axle Trucks: 10.15</td>
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<td>6-Axle Trucks: 10.35</td>
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**ADD:**

**Under Counties:**
DeKalb County to Mod. 05 Vol. 42 FR 26743 dated June 3, 1977
### Modifications P. 19

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<th>Basic Hourly Rates</th>
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<td>H &amp; W</td>
<td>Pensions</td>
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**Decision #1176-2163 - Mod. 63**

(61 FR 32126 - November 12, 1996)
- Bureau, Carroll, Henry, Lee, Joliet, Ogle, Rock Island, Stephenson, Unionville & Winnebago Counties, Illinois

**Change:**
- Carpenters & Piledrivermen: Winnebago County North of Oregon in Ogle County
  - $10.22
  - .40
  - 1.25

**Decision #1176-2164 - Mod. 63**

(61 FR 32247 - November 25, 1996)
- Fulton, Hancock, Henderson, Knox, McDonough, McHenry, Ogle, Stark, Tazewell & Warren Counties, Illinois

**Change:**
- Cement Masons: Fulton, Peoria & Tazewell Counties
  - $10.20
  - .40
  - .60

- Carpenters & Piledrivermen: Knox, Henderson & Warren Counties
  - Carpenters
    - $10.11
    - .40
    - .50
    - .05

  - Piledrivermen
    - $10.61
    - .40
    - .50
    - .05

  - Stark Co; Peoria Co., excluding area south of Rte. 1016, west of US Rte. 26, & east Peoria in Tazewell County
    - Carpenters
      - $10.11
      - .40
      - .50
      - .05

    - Piledrivermen
      - $10.61
      - .40
      - .50
      - .05

    - McDonough Co; the Eastern 1/3 of Hancock County
      - Carpenters
        - $10.11
        - .40
        - .50
        - .05

    - Fulton Co., & Peoria Co., south of Rte. 1016 & west of US Rte. 26; Remainder of Tazewell Co.
      - Carpenters
        - $10.11
        - .40
        - .50
        - .05

      - Piledrivermen
        - $10.61
        - .40
        - .50
        - .05

---

### Modifications P. 20

**Decision #1180-2165 - Mod. 63**

(61 FR 31253 - December 3, 1996)
- Champaign, Clark, Coles, Cumberland, DeWitt, Douglas, Edgar, Mason, Ogle, Putnam, Peoria, Pike, Shelby & Vermilion Counties, Illinois

**Change:**
- Laborers

<table>
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<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
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<td>H &amp; W</td>
<td>Pensions</td>
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- Unskilled
  - 10.20
  - .30
  - 30

- Semi-Skilled
  - 10.40
  - 30
  - 30

- Skilled
  - 10.55
  - 30
  - 30

- Colfax & Cumberland Counties
  - Unskilled
    - 9.05
    - 55
    - 40
    - 035

  - Semi-Skilled
    - 9.05
    - 45
    - 60
    - 035

  - Skilled
    - 10.20
    - 55
    - 40
    - 035

- Douglas Co; S. 1/2 of Platt Co.
  - Unskilled
    - 9.75
    - 45
    - 60
    - 035

  - Semi-Skilled
    - 9.75
    - 45
    - 60
    - 035

  - Skilled
    - 10.10
    - 45
    - 60
    - 035

- Clark & Edgar Counties
  - Unskilled
    - 9.75
    - 45
    - 60
    - 035

  - Semi-Skilled
    - 9.95
    - 45
    - 60
    - 035

  - Skilled
    - 10.10
    - 45
    - 60
    - 035

- Eastern 1/3 of Illinois
  - Unskilled
    - 10.05
    - 35
    - 40
    - 035

  - Semi-Skilled
    - 10.25
    - 35
    - 40
    - 035

  - Skilled
    - 10.60
    - 35
    - 40
    - 035

- Eastern 2/3 of Illinois
  - Unskilled
    - 9.75
    - 45
    - 60
    - 035

  - Semi-Skilled
    - 9.95
    - 45
    - 60
    - 035

  - Skilled
    - 10.10
    - 45
    - 60
    - 035

- Northern 1/4 of Platt County
  - Unskilled
    - 10.20
    - 30
    - 30
    - 035

  - Semi-Skilled
    - 10.40
    - 30
    - 30
    - 035

  - Skilled
    - 10.55
    - 30
    - 30
    - 035

---

*Federal Register, Vol. 42, No. 131—Friday, July 8, 1977*
## DECISION #1176-2165 - Mod. #5 (CONT'D)

<table>
<thead>
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### DECISION #1176-2165 - Mod. #6

(AR 84429 - December 15, 1976)

### CHANGE:

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<th>Laborers (Cont’d)</th>
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<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tr>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### NOTICES

**MODIFICATIONS P 23**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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</tr>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

**DECISION 0127-2039 - Mod 61**

- **Fulton, Hancock, McDonough & Schuyler Counties, Illinois**

**CHANGES:**

- **Bricklayers:**
  - Hancock & McDonough Counties
  - Bricklayers, Stonemasons, Cement Blocklayers, Marble Tile-Terrazzo Workers
  - $11.65

- **Carpenters:**
  - McDonough Co. & Eastern 1/4 of Hancock County
  - Carpenter & STL
  - $11.11

- **Painters:**
  - Reminders of Counties
    - Brush
    - $9.35
    - Structural Steel & Spray
    - 10.30

- **Cement Masons & Plasterers:**
  - Hancock, McDonough & Schuyler Counties
    - Cement Masons
    - $11.65
    - Hancock & McDonough Co.
    - Plasterers
    - $11.40

---

### MODIFICATIONS P 24

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
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<td>Pensions</td>
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</tbody>
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**DECISION 0127-2068 - Mod 61**

- **DuPage, Grundy, Kane, Kendall, Lake, McHenry & Will Counties, Illinois**

**CHANGES:**

- **Carpenters:**
  - Carpenters, STL, Millwrights & Pile Drivers:
    - Will County:
    - Building
    - $11.18

- **Cement Masons:**
  - Kane, Kendall & McHenry Counties
    - Will County:
    - $11.05

- **Plasterers:**
  - Kane, Kendall & McHenry Counties
    - $11.05

- **Plumbers & Pipefitters & Steamfitters:**
  - Will (City Limits of Joliet) County:
    - Grundy Co. of Will Co. #47 County
    - Plumbers & Pipefitters
    - $11.90

- **Roofers:**
  - DuPage & Lake Counties:
    - Composition & Waterproof Shingles
    - $11.50

- **Truck Drivers:**
  - 2-3 Axle Trucks
    - $9.80
  - 4-Axle Trucks
    - $9.95
  - 5-Axle Trucks
    - $10.00
  - 6-Axle Trucks
    - $10.40

- **Cement Masons - Lake County**
  - Roofers:
    - Will & Grundy Counties
    - $11.85

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*FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977*
<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<td>Zone 2</td>
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<td>Cable splicers</td>
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<td>Groundman, over 1 year</td>
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<td>Groundman, 1st year</td>
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<td>6.37</td>
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<td>2nd year</td>
<td>7.62</td>
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<td>Over 2 years’ experience</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
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<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
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<td>Clinton &amp; Ingham (except</td>
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<td>Onondaga, Leslie, Stock-</td>
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<tr>
<td>bridge &amp; Rumsey Hill Twp. &amp;</td>
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<td>Remainder of Eaton Co.</td>
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<td>Jackson Co &amp; Remainder of</td>
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<td><strong>Ironworkers:</strong></td>
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<td>Remaining Counties</td>
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<td><strong>Painters:</strong></td>
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<td>Brush</td>
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<td>Paperhanging, Taping, &amp;</td>
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<td>Steamcleaning, Sandblasting &amp;</td>
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<td><strong>Plumbers:</strong></td>
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<td>(42 FR 22304 - May 6, 1977)</td>
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<td>Bay, Genesee, Huron, Iosco,</td>
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<td>Lapeer, Saginaw, St. Clair,</td>
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<td>Sanilac, Shiawassee &amp; Tuscola</td>
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<td>Counties, Michigan</td>
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<td><strong>Changes:</strong></td>
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<td>.02</td>
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<td><strong>Marble-Tile-Terrazzo Workers:</strong></td>
<td>11.47</td>
<td>1.00</td>
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<td>10.12</td>
<td>.6</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### NOTICES

#### MODIFICATIONS P. 31

<table>
<thead>
<tr>
<th>DECISION DUN77-2071 - Mod. 01</th>
<th>Fringe Benefits Payments</th>
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<tr>
<td>Basic Hourly Rates</td>
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#### DECISION DUN77-2047 - Mod. 02

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#### DECISION DUN77-2047 - Mod. 02

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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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<td>(42 F 2 5261 - March 25, 1977)</td>
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<td>Electricians:</td>
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<td>Cable Splicers</td>
<td>9.50</td>
<td>35</td>
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<tr>
<td>Ironworkers</td>
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<td>Others</td>
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<td>Plasterers</td>
<td>7.60</td>
<td>25</td>
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<td>35</td>
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<td>(42 F 2 5269 - June 3, 1977)</td>
<td>Fringe Benefits Payments</td>
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<td>Cascades, Deer Lodge, Gallatin,</td>
<td>H &amp; W</td>
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<td>Glacier, Hill, Missoula, Silver</td>
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<tr>
<td>Bow and Valley Counties, Montana</td>
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</tr>
<tr>
<td>Changes:</td>
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<td>ELECTRICIANS:</td>
<td></td>
</tr>
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<td>Electricians:</td>
<td></td>
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<td>0.00</td>
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<tr>
<td>Cable Splicers</td>
<td>11.00</td>
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<tr>
<td>Deer Lodge and Silver Bow Cas</td>
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<tr>
<td>Electricians:</td>
<td></td>
</tr>
<tr>
<td>Gallatin County:</td>
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<td>PAINTERS:</td>
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<td>Missoula County:</td>
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<td>Yeilders:</td>
<td></td>
</tr>
<tr>
<td>Castos, Gallatin, Hill and</td>
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<td>Valley Counties:</td>
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<td>Roofers:</td>
<td></td>
</tr>
<tr>
<td>Castos, Gallatin, Hill and</td>
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<td>Valley Counties:</td>
<td></td>
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<td>Yeilders:</td>
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<tr>
<td>Direct Total Workers</td>
<td>10.23</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>Change (Cont'd)</th>
<th>Fringe Benefits Payments</th>
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<tbody>
<tr>
<td>Laborers (Cont'd):</td>
<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>Zone 2: Area over 20 and not more than 40 road miles from the above communities:</td>
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<tr>
<td>Group 1</td>
<td>$9.00</td>
</tr>
<tr>
<td>Group 2</td>
<td>9.10</td>
</tr>
<tr>
<td>Group 3</td>
<td>9.25</td>
</tr>
<tr>
<td>Group 4</td>
<td>9.50</td>
</tr>
<tr>
<td>Group 5</td>
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<td>Group 6A</td>
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<td>Group 6B</td>
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<tr>
<td>Group 6C</td>
<td>9.15</td>
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<tr>
<td>Zone 3: Area over 40 road miles from the above communities:</td>
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<td>Group 1</td>
<td>9.70</td>
</tr>
<tr>
<td>Group 2</td>
<td>9.80</td>
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<td>Group 3</td>
<td>9.95</td>
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<td>Group 4</td>
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<td>Group 5</td>
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<td>Group 6C</td>
<td>9.85</td>
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<td>Sheet Metal Workers</td>
<td>10.34</td>
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**DECISION NOV-75-5061 (Mod. #1)**

(42 FR 31076 - June 17, 1977)

Clark County (does not include the Nevada Test Site), Nevada

<table>
<thead>
<tr>
<th>Change</th>
<th>Fringe Benefits Payments</th>
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</thead>
<tbody>
<tr>
<td>Carpenters:</td>
<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>Zone 1: Area within the City limits of Henderson, Nevada; Boulder City, Nevada; and Boulder City, Nevada; area within a 10 mile radius of Las Vegas, Nevada; In Clark County, the present fenced area of Nellis Air Force Base, as well as that area adjacent to Nellis Air Force Base bounded on the north by the Nellis Spar track and on the west by the train line of the Union Pacific Railroad:</td>
<td></td>
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<tr>
<td>Carpenters</td>
<td>$11.36</td>
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<tr>
<td>Floor layers; Patent scaffold erectors; Power saw operators</td>
<td>11.51</td>
</tr>
<tr>
<td>Pile drivers</td>
<td>11.56</td>
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<tr>
<td>Millwrights</td>
<td>12.06</td>
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<tr>
<td>Zone 2: Area outside of Zone 1 and not more than 20 miles from the communities described above:</td>
<td></td>
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<tr>
<td>Carpenters</td>
<td>11.86</td>
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<tr>
<td>Floor layers; Patent scaffold erectors; Power saw operators</td>
<td>12.01</td>
</tr>
<tr>
<td>Pile drivers</td>
<td>12.06</td>
</tr>
<tr>
<td>Millwrights</td>
<td>12.56</td>
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<tr>
<td>Zone 3: Area over 20 miles and not more than 40 miles from the communities described in Zone 1: Carpenters</td>
<td>12.11</td>
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<tr>
<td>Floor layers; Patent scaffold erectors; Power saw operators</td>
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<tr>
<td>Pile drivers</td>
<td>12.31</td>
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<td>Millwrights</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION No. 147751 (Cont'd)

**Change (Cont'd):**

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<td><strong>Carpenters</strong></td>
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<td>Zone 1: Area over 40 miles from the communities described in Zone 1:</td>
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<tr>
<td></td>
<td>$13.36</td>
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<tr>
<td><strong>Floor layers; painters and decorators; power saw operators</strong></td>
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<td></td>
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<tr>
<td></td>
<td>13.51</td>
<td>.65</td>
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<tr>
<td><strong>Pilots and plokers</strong></td>
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<tr>
<td></td>
<td>13.36</td>
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<td><strong>Glaziers</strong></td>
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<td></td>
<td>13.50</td>
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<tr>
<td><strong>Soft floor layers</strong></td>
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<td></td>
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### DECISION No. 147746 - Mod. 42 (42 FR 31095 - June 17, 1977)

**Stateswide, New Mexico**

**Change:**

**Carpenters:**

- General building and heavy construction
- Engineering and residential construction (dwelling houses and apartments over two stories in height)

**Bricklayers:**

- General building and heavy construction and residential construction (dwelling houses and apartments over two stories in height)

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
</tr>
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<tbody>
<tr>
<td>Zone A</td>
<td>9.20</td>
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<td>Zone B</td>
<td>10.65</td>
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<tr>
<td>Zone C</td>
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<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
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<td>Zone VIII</td>
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<td>Zone IX</td>
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<tr>
<td>Zone XI</td>
<td>8.79</td>
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</tbody>
</table>

**Bricklayers & Stonemasons:**

- Electricians:
- Remodeling of County buildings

**Ironworkers:**

- Structural, ornamental & bridge reinforcing
- Reinforcing
- Laborers:
- General laborers
- Operators of jackhammers, paving breakers and other pneumatic, electrical and mechanical tools, coming under the jurisdiction of laborers, laying of all clay, terra cotta, ironstone, vitrified concrete or non-metallic pipe and the making of joints for same, wagon drill operators and concrete power buggies, precast slab placers, signalmen, brick, stone, plasterers and cement masons tapers, machine mixers, stockers, scaffold building, plaster pump and conveyors, blaster, casing workers, wagon air track and diamond point drill operators, burning torches, green cutting machines, steam lanyard and blasting

**Lime Construction:**

- Cable splinters & laborers
- Groundmen
- Winch truck operator

### DECISION 87751-0209 - Mod. 94

(42 FR 10263 - February 19, 1977)

**Berke County, Pennsylvania**

**Change:**

- Bricklayers & Stonemasons:
- Electricians:
- Remodeling of County buildings

**Ironworkers:**

- Structural, ornamental & bridge reinforcing
- Reinforcing
- Laborers:

**General laborers**

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 9, 1977
### MODIFICATIONS P 39

<table>
<thead>
<tr>
<th>Decision No.</th>
<th>PA77-3029 - Mod. 04</th>
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<td><strong>Cont'd.</strong></td>
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<tr>
<td><strong>Painters:</strong></td>
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<tr>
<td><strong>Brush:</strong></td>
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<tr>
<td><strong>Spray &amp; steel:</strong></td>
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<td><strong>Plumbers &amp; Steamfitters:</strong></td>
<td>11.76</td>
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<tr>
<td><strong>DECISION 3PA77-3029 - Mod. 04</strong></td>
<td>(62 FR 10268 - April 13, 1977)</td>
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<td><strong>Cumberland, Dauphin, Perry, Juniata, New Cumberland, Army Depot in York County, Pa.</strong></td>
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<td></td>
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<tr>
<td><strong>Change:</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Ironworkers:</strong></td>
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<tr>
<td><strong>Lineners:</strong></td>
<td>10.81 56 30 3/8%</td>
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<tr>
<td><strong>Cable splicer:</strong></td>
<td>10.81 56 30 3/8%</td>
<td></td>
</tr>
<tr>
<td><strong>Groundmen:</strong></td>
<td>8.45 60 30 3/8%</td>
<td></td>
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<tr>
<td><strong>Winch truck operators:</strong></td>
<td>7.56 60 30 3/8%</td>
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<tr>
<td><strong>Pile drivermen:</strong></td>
<td>10.77 60 1.50 f 1.02</td>
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### MODIFICATIONS P 40

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<td><strong>Lebanon County, Pennsylvania</strong></td>
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<td><strong>Change:</strong></td>
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<td><strong>Electricians:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lawn, East Hanover &amp; Indiantown:</strong></td>
<td>11.28 84 1.36 0.03</td>
</tr>
<tr>
<td><strong>Ironworkers:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lubricators:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>General Laborers:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Operators of jackhammer, paving breaking and other pneumatic, electrical and mechanical tools coming under the jurisdiction of laborer, laying of all clay, terra cotta, ironstone, vitrified concrete or non-metallic pipe and the making of joints for same, wagon drill operators and concrete power buggies, pre-cast slab placers, sign men, brick, stone, plasterers and cement masons tenders, machine mixers, stockers, scaffold building, plaster pump and conveyors, blaster cutters, caisson workers, wagon air track and diamond point drill operators, burning torches, green cutting machine, steam tony and Plexiglas, coffee, (below 10') tunnel free air and suckers, handling and using cutting or burning torches in the wrecking of buildings, plasterers tenders, scaffold building and removal for plasterers:</strong></td>
<td>6.80 .40 .25</td>
</tr>
</tbody>
</table>

---

**Federal Register, Vol. 42, No. 131—Friday, July 8, 1977**
### DECISION NO. PA-77-3031 - Mod. #4

<table>
<thead>
<tr>
<th>Line Construction:</th>
<th>Fringe Benefits Payments</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linemen &amp; cable splicer</td>
<td>$11.51</td>
<td>.40</td>
<td>3%</td>
<td>3/4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Groundmen</td>
<td>6.87</td>
<td>.40</td>
<td>3%</td>
<td>3/4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Winch truck operator</td>
<td>8.03</td>
<td>.40</td>
<td>3%</td>
<td>3/4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pile drivers</td>
<td>10.77</td>
<td>1.13</td>
<td>1.30</td>
<td>8</td>
<td>3/12</td>
<td></td>
</tr>
</tbody>
</table>

**Add:**

- Asbestos Workers: $10.70, .65, 60, .01
- Bricklayers & Stonemasons: Zone 1, 9.55, .60, .80, .03
- Zone 4, 10.35, .60, .80, .03
- Carpenters & Soft Floor Layers: Zone 1, 10.35, .60, .80, 6, 60 off/1%
- Cement Masons: Zone 3, 10.05, .55, .40
- Electricians: Zone 2, 10.36, .65, 3%, 31, 3/4 of 1%
- Ironworkers: Zone 2, 11.28, .65, 1.26, .03
- Zone 3, 9.48, .50, 3%, 50, 60, .02
- Lineman: Zone 1, 12.04, .40, 3% 3/6%
- Groundman | 7.20 | .40 | 3% | 3/6%
- Winch truck operator | 8.41 | .40 | 3% | 3/6%
- Zone 3 | Line operator | 10.81 | .40 | 3% | 3/6%
- Winch truck operator | 7.55 | .40 | 3% | 3/6%
- Groundman | 6.45 | .40 | 3% | 3/6%
- Plumbers & Steamfitters: Zone 1, 10.56, .69, .50, .20, .05

---

**NOTICES**

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>Decision #177-3049 - Mod. # 2</th>
<th>Decision #177-3053 - Mod. # 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northumberland County, Pennsylvania</td>
<td>Elk, Forest, McKean &amp; Warren Counties, Pennsylvania</td>
</tr>
<tr>
<td><strong>Changes:</strong></td>
<td><strong>Changes:</strong></td>
</tr>
<tr>
<td>Asbestos workers</td>
<td>Electricians</td>
</tr>
<tr>
<td>Basic Hourly Rates</td>
<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td><strong>Asbestos workers</strong></td>
<td><strong>Zone 2</strong></td>
</tr>
<tr>
<td>$10 70</td>
<td>$10.90</td>
</tr>
<tr>
<td>65</td>
<td>32%</td>
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<tr>
<td><strong>Cement masons</strong></td>
<td><strong>Bricklayers, cement masons &amp; stonemasons</strong></td>
</tr>
<tr>
<td>10 10</td>
<td><strong>Zone 2</strong></td>
</tr>
<tr>
<td>65</td>
<td>32%</td>
</tr>
<tr>
<td><strong>Electricians:</strong></td>
<td><strong>Ironworkers:</strong></td>
</tr>
<tr>
<td>Delaware, Louis &amp; Trubut</td>
<td><strong>Structural &amp; ornamental</strong></td>
</tr>
<tr>
<td>9.48</td>
<td>32%</td>
</tr>
<tr>
<td>3.05</td>
<td>32%</td>
</tr>
<tr>
<td>Remainder of County</td>
<td><strong>Steel Workers:</strong></td>
</tr>
<tr>
<td>10.95</td>
<td>32%</td>
</tr>
<tr>
<td>11.28</td>
<td>32%</td>
</tr>
<tr>
<td><strong>Ironworkers:</strong></td>
<td><strong>Painters:</strong></td>
</tr>
<tr>
<td>64</td>
<td>32%</td>
</tr>
<tr>
<td>11.28</td>
<td>32%</td>
</tr>
<tr>
<td>8.40</td>
<td>32%</td>
</tr>
<tr>
<td><strong>Steel Workers:</strong></td>
<td><strong>Steel</strong></td>
</tr>
<tr>
<td>9.20</td>
<td>32%</td>
</tr>
<tr>
<td>9 90</td>
<td>32%</td>
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</tbody>
</table>

**Notes:**

FEDERAL REGISTER, VOL. 42, NO 131—FRIDAY, JULY 8, 1977
### Notices

**DEPARTMENT OF LABOR, WAGE AND HOURS DIVISION**

**DECISION 0A47-3055 - Mod. 91**

**Basis:**

- Hourly Rates: H & W, Pensions, Vacation, and Eduction and/or Appr Tr

**Chang:**

<table>
<thead>
<tr>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.00</td>
<td>.55</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Zone 3**

- Electricians: 9.48, .50, .50, 60, .02
- Lineman: 12.04, .40, 3%, 3/8%
- Groundman: 7.20, .40, 3%, 3/8%
- Winch truck operators: 8.41, .40, 3%, 3/8%
- Painters: Zone 1
  - Commercial: 8.35, .65, .35, .05
  - Brush: 9.47, .65, .35, .05
  - Industrial: 8.55, .65, .35, .05
  - Spray: 9.97, .65, .35, .05
- Plumbers & Steamfitters: Zone II, III
  - Zone II: 11.94, .65, 1.16, .02
  - Zone III: 11.05, .65, 1.05, .02

**Zone 4**

- Electricians: 10.55, .65, .60, .01
- Bricklayers: 9.25, .55, .70, .01
- Electricians: Western part of County
  - Glassers: 9.65, .60, .70, .02
  - Painters: 10.20, .70, .02
- Loft floor layers: 8.68, .40, .03
- Plumbers & steamfitters: 10.56, .69, .50, .03
- Stoneasons: 9.25, .55, .70, .01

---

**MODIFICATIONS P. 46**

**DEPARTMENT OF LABOR, WAGE AND HOURS DIVISION**

**DECISION 0A47-3055 - Mod. 92**

**Basis:**

- Hourly Rates: H & W, Pensions, Vacation, and Eduction and/or Appr Tr

**Chang:**

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<thead>
<tr>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.00</td>
<td>.55</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Zone 3**

- Electricians: 9.48, .50, .50, 60, .02
- Lineman: 12.04, .40, 3%, 3/8%
- Groundman: 7.20, .40, 3%, 3/8%
- Winch truck operators: 8.41, .40, 3%, 3/8%
- Painters: Zone 1
  - Commercial: 8.35, .65, .35, .05
  - Brush: 9.47, .65, .35, .05
  - Industrial: 8.55, .65, .35, .05
  - Spray: 9.97, .65, .35, .05
- Plumbers & Steamfitters: Zone II, III
  - Zone II: 11.94, .65, 1.16, .02
  - Zone III: 11.05, .65, 1.05, .02

**Zone 4**

- Electricians: 10.55, .65, .60, .01
- Bricklayers: 9.25, .55, .70, .01
- Electricians: Western part of County
  - Glassers: 9.65, .60, .70, .02
  - Painters: 10.20, .70, .02
- Loft floor layers: 8.68, .40, .03
- Plumbers & steamfitters: 10.56, .69, .50, .03
- Stoneasons: 9.25, .55, .70, .01

---

**MODIFICATIONS P. 46**

**DEPARTMENT OF LABOR, WAGE AND HOURS DIVISION**

**DECISION 0A47-3057 - Mod. 91**

**Basis:**

- Hourly Rates: H & W, Pensions, Vacation, and Eduction and/or Appr Tr

**Chang:**

<table>
<thead>
<tr>
<th>Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.00</td>
<td>.55</td>
<td>.50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Zone 3**

- Electricians: 9.48, .50, .50, 60, .02
- Lineman: 12.04, .40, 3%, 3/8%
- Groundman: 7.20, .40, 3%, 3/8%
- Winch truck operators: 8.41, .40, 3%, 3/8%
- Painters: Zone 1
  - Commercial: 8.35, .65, .35, .05
  - Brush: 9.47, .65, .35, .05
  - Industrial: 8.55, .65, .35, .05
  - Spray: 9.97, .65, .35, .05
- Plumbers & Steamfitters: Zone II, III
  - Zone II: 11.94, .65, 1.16, .02
  - Zone III: 11.05, .65, 1.05, .02

**Zone 4**

- Electricians: 10.55, .65, .60, .01
- Bricklayers: 9.25, .55, .70, .01
- Electricians: Western part of County
  - Glassers: 9.65, .60, .70, .02
  - Painters: 10.20, .70, .02
- Loft floor layers: 8.68, .40, .03
- Plumbers & steamfitters: 10.56, .69, .50, .03
- Stoneasons: 9.25, .55, .70, .01

---

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### DECISION SD77-5063 - Mod. #1

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 3</td>
<td>$12.125</td>
<td>.65</td>
<td>.60</td>
<td></td>
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<tr>
<td>Zone 2</td>
<td>11.60</td>
<td>.60</td>
<td>1.00</td>
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<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>12.35</td>
<td>.40</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Zone 2</td>
<td>6.65</td>
<td>.60</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
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<tr>
<td>Zone 1</td>
<td>7.00</td>
<td>.60</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Zone 1</td>
<td>12.04</td>
<td>.40</td>
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<td>3%</td>
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</tr>
<tr>
<td>Zone 1</td>
<td>5.61</td>
<td>.40</td>
<td>3%</td>
<td>3%</td>
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<tr>
<td>Zone 1</td>
<td>7.20</td>
<td>.40</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
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<tr>
<td>Zone 1</td>
<td>12.125</td>
<td>.65</td>
<td>.60</td>
<td></td>
<td></td>
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<tr>
<td>Zone 2</td>
<td>9.00</td>
<td>.65</td>
<td>.35</td>
<td>.60</td>
<td></td>
</tr>
<tr>
<td>Zone 2</td>
<td>9.56</td>
<td>.65</td>
<td>.35</td>
<td>.60</td>
<td></td>
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<tr>
<td>Zone 3</td>
<td>8.50</td>
<td>.40</td>
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<td>3%</td>
<td>3%</td>
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<tr>
<td>Zone 4</td>
<td>10.75</td>
<td>.65</td>
<td>.35</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Zone 4</td>
<td>8.00</td>
<td>.65</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Zone 4</td>
<td>9.50</td>
<td>.65</td>
<td>.35</td>
<td>3%</td>
<td>3%</td>
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<tr>
<td>Zone 4</td>
<td>10.75</td>
<td>.65</td>
<td>.35</td>
<td>3%</td>
<td>3%</td>
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<tr>
<td>Zone 4</td>
<td>11.71</td>
<td>.60</td>
<td>.35</td>
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<td>3%</td>
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<tr>
<td>Zone 4</td>
<td>11.71</td>
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<td>.35</td>
<td>3%</td>
<td>3%</td>
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<td>Zone 4</td>
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<td>.65</td>
<td>.60</td>
<td></td>
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<tr>
<td>Zone 1</td>
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<td>.65</td>
<td>.60</td>
<td></td>
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<tr>
<td>Zone 1</td>
<td>12.125</td>
<td>.65</td>
<td>.60</td>
<td></td>
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</tr>
</tbody>
</table>

**Changes:**
- **Electricians:**
  - Within a 35-mile radius of Rapid City Post Office
  - Cable Splicers
    - Within a 15- to 35-mile radius of Rapid City Post Office
    - Electricians
      - $9.00
      - .40
      - 3%
      - 3%
      - 1/2%
    - Cable Splicers
      - 10.00
      - .40
      - 3%
      - 3%
      - 1/2%
    - Outside a 35-mile radius of Rapid City Post Office
      - Electricians
        - 10.00
        - .40
        - 3%
        - 3%
        - 1/2%
      - Cable Splicers
        - 11.45
        - .40
        - 3%
        - 3%
        - 1/2%

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### MODIFICATIONS P. 49

<table>
<thead>
<tr>
<th>DECISION 07277-6007 - Mod, 01</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(62 FR 25425 - May 6, 1977)</td>
<td></td>
</tr>
<tr>
<td>Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant &amp; Walker Cos., Texas</td>
<td></td>
</tr>
<tr>
<td>Changes:</td>
<td></td>
</tr>
<tr>
<td>Carpenters:</td>
<td></td>
</tr>
<tr>
<td>Zone 1:</td>
<td></td>
</tr>
<tr>
<td>Carpenters</td>
<td>9,725</td>
</tr>
<tr>
<td>Millwrights</td>
<td>10,115</td>
</tr>
<tr>
<td>Fitted workers</td>
<td>10,225</td>
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<tr>
<td>Electricians:</td>
<td></td>
</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Cos.:</td>
<td></td>
</tr>
<tr>
<td>Area A - All work performed in Dallas &amp; Grayson Cos.:</td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10,43</td>
</tr>
<tr>
<td>Cable splicers</td>
<td>11,47</td>
</tr>
<tr>
<td>Area B - All work performed outside of Dallas Co., up to a radius of 40 road miles from the City Hall in the City of Dallas:</td>
<td></td>
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<tr>
<td>Electricians</td>
<td>10,68</td>
</tr>
<tr>
<td>Cable splicers</td>
<td>11,75</td>
</tr>
<tr>
<td>Area C - All work performed outside of Area A &amp; B:</td>
<td></td>
</tr>
<tr>
<td>Electricians</td>
<td>10,93</td>
</tr>
<tr>
<td>Cable splicers</td>
<td>12,02</td>
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<tr>
<td>A.M. Electricians:</td>
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</tr>
<tr>
<td>Zone 2 - Collin, Dallas, Ellis, Grayson, Hunt, Kaufman &amp; Rockwall Cos.:</td>
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</tr>
<tr>
<td>Electricians</td>
<td>10,63</td>
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<tr>
<td>Cable splicers</td>
<td>11,47</td>
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</table>

### MODIFICATIONS P. 50

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<thead>
<tr>
<th>DECISION 07277-6008 - Mod, 02</th>
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<tbody>
<tr>
<td>(62 FR 25933 - May 6, 1977)</td>
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<tr>
<td>Jefferson &amp; Orange Cos., Texas</td>
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</tr>
<tr>
<td>Changes:</td>
<td></td>
</tr>
<tr>
<td>Laborers:</td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>6.91</td>
</tr>
<tr>
<td>Group 2</td>
<td>6.96</td>
</tr>
<tr>
<td>Group 3</td>
<td>7.01</td>
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<tr>
<td>Group 4</td>
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<td>Group 5</td>
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<tr>
<td>Group 6</td>
<td>7.285</td>
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<tbody>
<tr>
<td>(62 FR 24705 - May 13, 1977)</td>
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<tr>
<td>Bexar County, Texas</td>
<td></td>
</tr>
<tr>
<td>Changes:</td>
<td></td>
</tr>
<tr>
<td>Painters:</td>
<td></td>
</tr>
<tr>
<td>Brush, paperhanger, Taper &amp; flosser</td>
<td>8.30</td>
</tr>
<tr>
<td>Spray, structural steel</td>
<td>8.55</td>
</tr>
<tr>
<td>Spray on structural steel: sandblasting</td>
<td>8.80</td>
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<table>
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<tr>
<th>DECISION 07277-6102 - Mod, 04</th>
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<tbody>
<tr>
<td>(62 FR 20810 - June 3, 1977)</td>
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<tr>
<td>Tom Green County, Texas</td>
<td></td>
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<td>Changes:</td>
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<td>8.25</td>
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<tr>
<td>Electricians:</td>
<td></td>
</tr>
<tr>
<td>Zone 1</td>
<td>8.20</td>
</tr>
<tr>
<td>Zone 2</td>
<td>8.55</td>
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<tr>
<td>Zone</td>
<td>Local Area</td>
</tr>
<tr>
<td>------</td>
<td>------------</td>
</tr>
<tr>
<td>Zone A</td>
<td>8 0.99</td>
</tr>
<tr>
<td>Zone B</td>
<td>8 0.69</td>
</tr>
<tr>
<td>Zone C</td>
<td>8 0.04</td>
</tr>
<tr>
<td>Zone D</td>
<td>8 0.29</td>
</tr>
<tr>
<td>Zone E</td>
<td>8 0.29</td>
</tr>
<tr>
<td>Zone F</td>
<td>8 0.29</td>
</tr>
</tbody>
</table>

| Group 2: |
| Zone A | 8 0.64 | 90 | 1 10 | 65 | 10 |
| Zone B | 8 0.04 | 90 | 1 10 | 65 | 10 |
| Zone C | 8 0.04 | 90 | 1 10 | 65 | 10 |
| Zone D | 8 0.04 | 90 | 1 10 | 65 | 10 |
| Zone E | 8 0.04 | 90 | 1 10 | 65 | 10 |
| Zone F | 8 0.04 | 90 | 1 10 | 65 | 10 |

| Group 3: |
| Zone A | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone B | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone C | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone D | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone E | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone F | 8 0.94 | 90 | 1 10 | 65 | 10 |

| Group 4: |
| Zone A | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone B | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone C | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone D | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone E | 8 0.94 | 90 | 1 10 | 65 | 10 |
| Zone F | 8 0.94 | 90 | 1 10 | 65 | 10 |
SUPERSEDES DECISION

STATE: Alabama  COUNTRIES: *See below
DECISION NUMBER: AL77-1009  DATE: Date of Publication
Supersedes Decision No. AL76-1009 dated January 15, 1976, in 41 FR 2540
DESCRIPTION OF WORK: Residential construction consisting of single family
homes and garden type apartments up to and including 4 stories

*Counties: Baldwin, Mobile, Clarke, Conecuh, Monroe and
Washington

<table>
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<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or</th>
<th>Approx.</th>
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A page of a document with text about construction and labor rates. The text is not clearly transcribed due to the image quality.
### OPERATING ENGINEERS (CONT'D)

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<th>H &amp; W</th>
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<th>Vacation</th>
<th>Education and/or Appt Tr</th>
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### Supersedes Decision

**State:** Illinois  
**County:** Cook  
**Decision Number:** IL77-2100  
**Date of Publication:** Supersedes Decision No. IL76-2122, dated October 1, 1976, in 41 FR 43576  
**Description of Work:** Building (including Residential), Heavy and Highway, Construction

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>Rate/Hour</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
</table>

| **Asbestos Workers**     | 105.50    | 65   | 1.00     | 72       | 5%                       |
| **Boilermakers**         | 10.55     | 65   | 1.00     | 72       | 5%                       |
| **Bricklayers & Stonemasons** | 11.21     | 65   | 1.00     | 72       | 5%                       |
| **Carpenters:** Building, Heavy & Highway | 10.55 | 70 | 80 | 90 | 80 |
| **Cement Masons:** Building | 10.55 | 70 | 80 | 90 | 80 |
| **Carpenters & Soft Floor Layers** | 10.55 | 70 | 80 | 90 | 80 |
| **Electricians:**        | 11.75     | 65   | 1.00     | 80       | 5%                       |
| **Elevator Constructors:** | 11.91     | 65   | 1.00     | 80       | 5%                       |
| **Helpers:**             | 70.35     | 65   | 1.00     | 80       | 5%                       |
| ** Helpers (Prob) :**    | 50.35     | 65   | 1.00     | 80       | 5%                       |
| **Glaziers**             | 11.23     | 65   | 1.00     | 80       | 5%                       |

### Additional Information

**Paid Holidays:** (Where applicable)
- New Year's Day  
- Memorial Day  
- Independence Day  
- Labor Day  
- Thanksgiving Day  
- Christmas Day

**Footnotes:**

- a) Six paid holidays A through F  
- b) Employer contributes 4% of regular hourly rate to vacation pay credit for employees who have worked in business more than 5 years. Employer contributes 2% of regular hourly rate to vacation pay credit for employees who have worked in business less than 5 years.
- c) Nine paid holidays: A through F plus Washington's Birthday, Good Friday, 4 calendar days prior to the holiday and the regular scheduled work days immediately preceding and following the holiday.
- d) Per week per employee  
- e) Per Day

_Federal Register, Vol. 42, No. 131—Friday, July 8, 1977_
### NOTICE

**DECESSION NO. JLI7-2100**

**TILL-5-240-1-2-3**

<table>
<thead>
<tr>
<th>Labor</th>
<th>Daily Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr.</th>
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</thead>
</table>
| **CLASS I**
Contra Laborers, Planter Laborers, Pumps for Dolabrating & Other Unclassified Laborers | 7 80 | .57 | 1.10 | | |
| **CLASS II**
Concrete Gun Laborers | 7 875 | .57 | 1.10 | | |
| **CLASS III**
Scaffold Laborers & Chimney Laborers over 40' | 7 90 | .57 | 1.10 | | |
| **CLASS IV**
Handcuff & Concrete Dress Laborers - Gunite | 7 95 | .57 | 1.10 | | |
| **CLASS V**
George Handler & Derrickmen | 8 00 | .57 | 1.10 | | |
| **CLASS VI**
Jackhammer | 8 05 | .57 | 1.10 | | |
| **CLASS VII**
Concrete Vibrator, Pumps, Laborer & Chain Saw Operator | 8 05 | .57 | 1.10 | | |
| **CLASS VIII**
Firebrick & Boiler Setters Laborers | 8 125 | .57 | 1.10 | | |
| **CLASS IX**
Chainsaw Laborers & Firebrick, Chain Diggers & Well Point System | 0.15 | .57 | 1.10 | | |
| **CLASS X**
Boiler Setter Plastic Laborers | 0.25 | .57 | 1.10 | | |
| **CLASS XI**
Jackhammer & Firebrick Only | 0.375 | .57 | 1.10 | | |

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### NOTICE

**DECESSION NO. JLI7-2100**

**TILL-12-FED-1**

<table>
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<th>Labor</th>
<th>Daily Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr.</th>
</tr>
</thead>
</table>
| **CLASS I**
Air compressor - small 150 & under (1) to 5 not to exceed a total of 300 ft.), Air compressor - large over 150, Combination - small equipment cranes, generators under & over 50 kW hoist, mechanical pumps, etc. | 11 95 | 75 | 85 | 40 | 05 |
| **CLASS II**
Air compressor - large over 150, Combination - small equipment cranes, generators under & over 50 kW hoist, mechanical pumps, etc. | 10 55 | 75 | 85 | 40 | 05 |
| **CLASS III**
Air compressor - large over 150, Combination - small equipment cranes, generators under & over 50 kW hoist, mechanical pumps, etc. | 9 40 | 75 | 85 | 40 | 05 |
| **CLASS IV**
Air compressor - large over 150, Combination - small equipment cranes, generators under & over 50 kW hoist, mechanical pumps, etc. | 8 15 | .75 | 85 | 40 | 05 |

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**NOTICES**

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### Notices

#### Decision No. IL77-2100

**Pump Equipment Operators: Sewer, Heavy & Highway Construction**

<table>
<thead>
<tr>
<th>Class</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tr>
<td></td>
<td>H &amp; W</td>
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<tr>
<td>Class I</td>
<td>11 50</td>
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<tr>
<td>Class II</td>
<td>10 95</td>
<td>75</td>
</tr>
<tr>
<td>Class III</td>
<td>10 70</td>
<td>75</td>
</tr>
<tr>
<td>Class IV</td>
<td>8 10</td>
<td>75</td>
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</tbody>
</table>

**Class I** - Asphalt plant, asphalt heater & planer combination, asphalt spreader, autograde, belt loader, cotton rigid, central reclaimer, concrete paver over 27E cu ft, concrete placer, concrete tube float, cranes, all attachments, cranes, Linder, Peco 6 machines of like nature, derricks, traveling, dreggers, spreader, elevating type gradall, & mechanisms of a like nature, derricks, all derrick boats, derricks, traveling, dreggers, cement loader, elevating type gradall, and machines of a like nature, 1 cu yd & over, muckers, machine, under 1 cu yd, piling drivers & slide rig, pre-stress machine, pump erectors dual ram (requiring frequent lubrication & water), rock drill crane type, slip form power, straddle buggies, tracto w/boom tractors w/attachment, trenching machine, underground boring 4/8, mining machine under 5 ft, wheel excavator widener (ApSCO)

**Class II** - Mechanic-welder, batch plant, bituminous mixer, bulldozer, combination backhoe front end loader machine, concrete breaker or hydro-hammer, concrete grinding machine, concrete mixer or paver 75 Series to 8 including 27 cu ft., concrete spreader, concrete curing machine, bull rope machine, bolting machine & sealant machine, finishing machine, concrete grader, motor grader, auto grader, form grader, pull grader, sub grader, high lift shovels or front end loader, hydraulic boom trucks (all attachments), locomotives, dinky, pump erectors; squeeze erectors; saw type pumps Cypress bulkers & pump, rock drill (self-propelled), roto-tiller, seaman, etc; self-propelled scoops; tractor drawn, self-propelled compactors, spreader, chipstogs, etc; scraper, tank, car heater, tractor, push, pulling sheaves for; disc, compactor, etc tug boats

#### Decision No. IL77-2108

**Power Equipment Operators (Cont'd)**

**Class III** - Boilers, boiler & throttle valve, brooms, all power propelled, cement supply tender, compressor throttle valve, concrete mixer (2 bags & over) conveyor, portable, firearm on boiler, forklift trucks, groser engineer, grouting machine hoists, automatic, hoists, all elevators, hoists, tugger, single drum, jeep diggers, pipe power saw, concrete, power-driven, pug mills, rollers, all steam generators, stone crushers, dump machine, winch truck with 'A' frame, work boats, tamper, form motor driven

**Class IV** - Air Compressors, all, generators, heaters, mechanical, light plants, all (1 through 5), pumps, all, pumps well points, tracto, welding machines (2 through 6)

**Class V** - Oilers
**SUPERSEDES DECISION**

**STATE:** Kansas  
**COUNTIES:** Douglas, Jefferson, Leavenworth, Miami & Shawnee  
**DECISION NO.:** R377-4161  
**Supersedes Decision No. S377-4084 dated April 15, 1977 in 42 FR. 30099**  
**DESCRIPTION OF WORK:** Highway Construction  

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<table>
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<th>AREAS COVERED BY CARPENTERS AND PILE DRIVERS ZONES</th>
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<td>Zone 1 - Douglas and Shawnee Counties (includes Forts Air Force  &amp; within the City of Topeka &amp; the City of Lawrence &amp; with 3 miles of the city limits of these cities)</td>
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<td>Zone 2 - Remainder of Douglas &amp; Shawnee Counties</td>
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<tr>
<td>Zone 3 - Leavenworth County</td>
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<td>Zone 4 - Miami County</td>
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<td>Zone 5 - Jefferson County</td>
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<tr>
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**CLASSIFICATION DEFINITIONS**

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**EQUIPMENT MACHINES**

| EQUIPMENT MACHINES | Fringe Benefits Payments |
|                    | Basic Hourly Rates      |
|                    | H & W       | Pens. | Vac. | Education and/or Appr Tr |
| Group 1            | 6.25        | .40   | .35  | 05                          |
| Group 2            | 6.75        | .40   | .35  | 05                          |
| Group 3            | 7.25        | .40   | .35  | 05                          |
| Group 4            | 5.025       | .40   | .35  | 05                          |
| Group 5            | 6.50        | .40   | .35  | 05                          |
| Group 6            | 7.35        | .40   | .35  | 05                          |
| Group 7            | 5.275       | .35   | .35  | 05                          |

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
# DECISION NO 2577-5161

## CLASSIFICATION DEFINITIONS

### POWER EQUIPMENT OPERATORS:

- **Group 1** - Asphalt paver and spreader, asphalt plant console operator, auto grader, back hoe, blade operator, all types, bagger, 2nd level:ayspreader: operator; concrete plant operator—central mix, concrete mixer paver, crane operator; derrick or derrick truck; ditching machine, dragline operator, dredge engine man, dredge operator, drill with compressor mounted on lift; drilling or bore hole, rotary, self-propelled, high loader fork lift; locomotive operator, standard gauge, mechanics and welders, maintenance operator, mockup machine, pile driver operator, pitman crane operator, pump-2; quad-truck; scoop operator— all types; scoop in tandom, self-propelled rotary drill (leery or equal—net air track); shovel operator, side discharge spreader; sideboom crane, skimmer, spreader, skip form paver (CFE, AEH, or equal); throttle man, truck crane, welding machine maintenance operator—2; hoist or crane—2 active drums

- **Group 2** - "A" frame truck, asphalt hot mix silo, asphalt plant fireman, drum or boiler, asphalt plant mixer operator, asphalt plant man, asphalt roller backfiller operator; chip spreader, concrete batch plant, dry-powder operated, concrete mixer operator, skip loader, concrete pump operator, crusher operator; elevating grader operator, grease, hoist engine—1 drum, Letonreade rooster, multiple compactor, pavement breaker, self-propelled of the hydro-hammer or similar type, power shield, tug mill operator, stump cutting machine, towboat operator, tractor operator—over 50 HP

- **Group 3** - Boilers—1; chip spreader (front man) drum drill operator, compressor maintenance operator—1; concrete cones, self-propelled, conveyer ope, distributor operator, finishing machine operator, fireman, rig, float operator, form grader operator, pump; pump maintenance operator, other than dredge; roller operator, other than high type asphalt; screening and washing plant operator; self-propelled street broom or sweeper; siphon and jet; sub grading machine operator; tank car heater operator—combination boiler and booster; tractor—50 HP or less without attachments; vibrating machine operator, hot hand; welding machine maintenence operator—1

- **Group 4** - Mechanic's helper; oiler

- **Group 5** - Clamshells, 3 yd capacity or over; crane or rig, 80 ft of boom or over (including jib); draglines, 3 yd capacity or over; pile drivers, 80 ft of boom or over (including jib); shovels, 3 yd capacity or over

- **Group 6** - Crane or rig, over 200 ft of boom (including jib)

- **Group 7** - Hoists (each additional drum over 1 drum)

- **Group 8** - Oilier drivers, all types

*Men working in tunnels or shafts (not air shafts or cofers) doing of twenty-five (25) feet or more in length or depth will be paid fifty (50) cents per hour above the regular classification*
POWER EQUIPMENT OPERATORS:

Group 1 - Master mechanic

Group 2 - Asphalt pavier and spreader, backhoe, boring machine, blower, all types, clamshell, concrete mixer, power operator, concrete central plant operator (automatic), crane, truck crane, pitron crane, hydro crane or any machine with power swing, derrick or derrick trucks, derrick line operator, dredge operator, dozer, ditching machine, duclit loader, hoist - 2 active drums; loader, all types, mechanic or welder, motorhome, multi-unit scraper, pickoff operator, power shovel operator, quad track scoop operators, all types; sideboom cut-cherry picker; skiffer scoop operator

Group 3 - Asphalt plant operator, elevating grader operator; pushcart operator

Group 4 - A-frame truck, asphalt roller operator; asphalt plant roller, fireman, backhoe operator, banner green loaders, loader - other than asphalt, bull float operator, churn drill operator, compactor operator (1); concrete central plant operator, concrete mixer operator, chipper, concrete pump operator, crusher operator, distributor operator, flusher machine operator - concrete; fireman other than asphalt, flat top operator, fork lift, form grinder operator; grader loader - 1 drum jeep ditching machine, power, small, self-propelled (of the hydraulic or spiral type); pump operator, over 100, over, 20 pump operators, other than dredge; screening and wash plant operator, small machine operator; spreader box operator, self-propelled tractor operator over 50 hp.; self-propelled roller operator, other than asphalt; siphon and jet; subgrading machine operator, tank car heater operator, combination loaders and loaders, tank operator, vibrating, machine operator, not fixed

Group 5 - Concrete pumps, self-propelled (con-cut); conveyor operators; harrow, disc, spreader; oiler, tractor operator, 50 hp. or less without attachments

Group 6 - Oiler, rotor crane

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
<th>Zone 2 - Douglas and Shawnee Cos</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
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<tr>
<td>Group 1</td>
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<td>Group 3</td>
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<table>
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<tr>
<th>Zone 3 - Miami County</th>
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**CLASSIFICATION DEFINITIONS**

**TRUCK DRIVERS:**

Group 1 - Pickups, panel trucks, station wagons, flat beds, dump and batch trucks single axle

Group 2 - Tandem trucks, warehousemen or partmen, mechanic helpers and servemen

Group 3 - Lowboys; semi-trailers, all transit mixer trucks, (single or tandem axle); a-frame and winch trucks when used as such; euclid, end and bottom dump; tournoateckers; atheys, dumpsters and similar off-road equipment and mechanics on such equipment.

Group 4 - Lowboys, semi-trailers, all transit mixer trucks (single or tandem axle); A-frame and winch trucks when used as such.

Group 5 - Euclid, end and bottom dump; tournoateckers; atheys; dumpsters and similar off-road equipment and mechanics on such equipment.

Group 6 - Watchmen or partmen; mechanic helpers; servemen.

**NOTICES**

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Decision No. M077-4150

#### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Occupation</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
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**Electicians (Up to and Including 3 Stories):**

- **Zone 1 - Johnson County, Kansas:**
  - Johnson County west of Auburn, Oxford, and Shawnee Townships
  - Basic Hourly Rate: 6.60
  - Pensions: 0.45
  - Vacation: 0.34
  - Education and/or Apprenticeship: 0.05

- **Zone 2 - Cass, Clay, Jackson, Platte, and Ray Counties, Missouri:**
  - Basic Hourly Rate: 8.31
  - Pensions: 0.39
  - Vacation: 0.34
  - Education and/or Apprenticeship: 0.06

- **Electicians (4 Stories):**
  - **Zone 1 - Western half of Clay and Jackson Counties, Missouri:**
    - Not including Blue Springs: 11.22
    - Basic Hourly Rate: 0.39
    - Pensions: 0.34
    - Vacation: 0.05
  - **Zone 2 - Eastern half of Clay and Jackson Counties, Missouri:**
    - Not including Northeastern portion of Case County, Missouri, not including Pleasant Hill
    - Basic Hourly Rate: 11.22
    - Pensions: 0.39
    - Vacation: 0.05
  - **Electicians (Contracts $6,000 and over):**
    - Basic Hourly Rate: 10.47
    - Pensions: 0.39
    - Vacation: 0.05

---

### Decision No. M077-4160

#### Basic Hourly Rates

<table>
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<tr>
<th>Occupation</th>
<th>H &amp; W</th>
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<th>Education and/or Apprenticeship</th>
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</table>

**Footnote:**
- a Employer contributes 4% basic hourly rate for over 5 years of service, and 2% of basic hourly rate for 3 years, 2 years, and 1 year of service, plus any Vacation Pay Credit.
- b Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day.

<table>
<thead>
<tr>
<th>Occupation</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
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<td><strong>Lamplighters</strong></td>
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</table>

**Building Construction:**

- **Zone 1 - Cass, Clay, Jackson, and Platte Counties, Missouri:**
  - Basic Hourly Rate: 8.10
  - Pensions: 0.45
  - Vacation: 0.40
  - Education and/or Apprenticeship: 0.50

- **Zone 2 - Ray County, Missouri:**
  - Basic Hourly Rate: 7.60
  - Pensions: 0.45
  - Vacation: 0.40
  - Education and/or Apprenticeship: 0.50

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### LABORERS:

**Group 1** - General labor; Wire mesh handlers or setters; Carpenter tender; Track men; Flagmen; Signalmen; Salamander tenders; Window cleaners; Floor cleaners; Landscape men; Bed layers; Wrecker (for alterations or entire projects)

**Group 2** - Plumber laborers (conduit pipe, sewer work, drain tile and duck lines, digging and back filling), power tool operators; Pier hole diggers (over 10 ft); Vibrator, jackhammer, and chipping hammer operators; Chain saw operators; Concrete saw operators; Bush operators; on pulverizers; Reinforcing steel handlers; Air tank operators; Ditch witch operators; Bolting scaffolds

**Group 3** - Cutting torch or burner men; Georgia huggers (self-propelled); Fork lift; Hoistmen; Insulation men

**Group 4** - Fork lift (masonry); Brick tenders; Plasterer Tenders; Stonemasons tender (includes all hod carriers; classifications previously shown as mortar men and scaffolding)

**Group 5** - Barco, Jackson or similar tamp operators; Asphalt takers; Powder men; Mastic hot bottle men; Sandblasting and gunite nozzlemen; Wagon and churn drill operators

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<thead>
<tr>
<th></th>
<th>Basic Hourly Rates (in $)</th>
<th>fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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### LABORERS (Cont'd)

**Site Preparation and Grading**

**ZONE 3** - Johnson and Wyandotte Counties, Kansas; Site Preparation, Incidental Paving and Utilities Clay, Jackson, Platte, and Ray Counties, Missouri

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### CLASSIFICATION DEFINITIONS

**LABORERS:**

**Group 1** - Carpenter tenders; Salamander tenders; Dump man and ticket takers on stock piles; Flagmen; Loading trucks under bins, hoppers and conveyors; Track men and all other general laborers

**Group 2** - Air tool operators; Cement handler (bulk or sack); Chain or concrete saw; Ditch operators; Dump man on earth fills; Grade checkers on cuts and fills; Georgia huggers; Material batch hopper man; Scale man; Material mixer man (except on manholes, coffee shop, abutments and pier hole men working below ground); Riprap pavers rock, block, or brick; Signalmen; Scaffolds over 10 ft, not self-supported from ground up; Shipman on concrete paving; Vibrator men; Wire mesh setters on concrete paving; All work in connection with sewer, water, gas, gasoline, oil, drainage pipes, conduit pipe, tile and duct lines and all other pipe lines; Power tool operators; All work in connection with hydroelectric or general dredging operations; Form setter helpers; Pudlers (paving only)

**Group 3** - Crusher feeders; Men handling creosote ties or creosote materials; Men working with and handling epoxy material or materials (where special protection is required); Head pipe layer on sewer work; Topper of standing trees; Battery man on pipe and ditch work; Feeder man on wood pulverizers; Board and wilow mat wrappers and cable tiers on river work; All laborers working on underground tunnels where compressed air is not used

**Group 4** - Spreader or second man on asphalt machine; Asphalt spreaders; Laser beam man; Barco tampers; Jackson or any other similar tamp; Wagon drillers; Churn drillers; Air track drills and all other similar drills; Form setters; Gutters and etc.; Hot mastic ketil men; Hot tar applicators; Hand blende operators; Manhole builders helpers and mortar men on brick or block manholes; Sandblasting and gunite nozzle men; Rabing concrete; Air tool operators in tunnels

**Group 5** - Manhole builder (brick or block); Dynamite and powder men
NOTICES

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POWER EQUIPMENT OPERATORS:

Building Construction (Zone 1)

Group 1
- 10.10
- 1.00
- .75
- .10

Group 2
- 9.85
- 50
- 1.00
- .75
- .10

Group 3
- 8.60
- 50
- 1.00
- .75
- .10

Group 4
- 9.10
- 50
- 1.00
- .75
- .10

Group 5
- 9.10
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- 1.00
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Group 6
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Group 7
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- .75
- .10

Group 8
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- 1.00
- .75
- .10

Group 9
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- 1.00
- .75
- .10

Group 10
- 11.10
- 50
- 1.00
- .75
- .10

Group 11
- 10.60
- 50
- 1.00
- .75
- .10

Group 12:
- (a) 9.85
- (b) 9.60
- (c) 9.60
- (d) 8.85

- .50
- 1.00
- .75
- .10

Group 13: Oiler

Group 14: Forklift-masonry

Group 15: Oiler driver all types

Group 16: Tractors (except when hauling material less than 50 h.p.

Group 17: Graders, 80 ft. of beam or over; (including jib); crane or rig, 60 ft. of beam or over; (including jib); draglines, 60 ft. of beam or over; (including jib); feller; 80 ft. of beam or over (including jib)

Group 18: Crane or rig, over 200 ft. of beam

Group 19: Hoists each additional drum over 1 drum

Group 20: Master Mechanic

Group 21: Crane - tower or climbing

Group 22: Ready Mix Concrete Plants:
- (a) Crane operators
- (b) Loader operators
- (c) Plant mix
- (d) Conveyor operators

Zone 1:
- Asphalt paver and spreader
- Asphalt plant mixer operators
- Asphalt plant operators: Back fillers; Backhoe; all types; Barrow-grease loader (similar type); Blade-powder, all types; Boat-powder; Rollers (2); Boring machines (all types); Cableways; Cherry pickers (all types); Chip spreader; Cmashichella: Combination concrete hoist and mixer such as mixer-mobilized (with tower, 220 ft. per hour additional); Compressors (1) 105 ft. or over not more than 200 h.p.; Compressors tandem (any sizes); Compressors, single, truck mounted; Concrete ready-mixed plant, portable (job site); Concrete mixer paver; Crane-oversized; Crusher, rock; Derricks and derrick cars (power operated); Ditching machines; Dredges; Draglines; Dredges-any type power; Grade-allsimilar type; Hoists, endless chain - power operated with power travel; Loaders, all types; Locomotives all types; Mechanic and welder; Mechanic, crane; Orange peelers; Pile drivers - all types; Pumps - material all types; Push cars; Scopes all types; Self-propelled rotary drill; Shovel, power; Side boom, skipper; Trenchers; Throttle man

Group 2:
- A-frame trucks; Rollers (1);
- Broom-power operated; (all types); Chip spreader (front end); Cleat plow, or planer; Concrete saws, self-propelled; Conveyor operators; Crane-power operated; Curb finishing machine; Firemen on rigs; Flex plans; Floating machine; Form grader; Fork lift-all types and sizes (except mast); Graders; Hoist: Crane, endless chain - power operated; Hopper - power operated; Hydro hammer (all types); Lad-a-dan - similar type; Mixers with side loader; Pumps (with roll points); Pump; Rollers - all types; Stokers, janes and jetties; Sub-grader; Tractors over 50 h.p.

Group 3:

Group 4:

Group 5:

Group 6:

Group 7:

Group 8:

Group 9:

Group 10:

Group 11:

Group 12:

Group 13:

Group 14:

Group 15:

Group 16:

Group 17:

Group 18:

Group 19:

Group 20:

Group 21:

Group 22:

NOTICES

DECISION NO. M77-6160

POWER EQUIPMENT OPERATORS (Cont'd)

CLASSIFICATION DEFINITIONS

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
POWER EQUIPMENT OPERATORS (Cont'd)

Site Preparation and Grading
Johnson and Wyandotte Counties, Kansas; Site Preparation, Incidental Paving and Utilities
Clay, Jackson, Platte, and Ray Counties, Missouri

ZONE 2

<table>
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<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
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</table>

Group 1: Asphalt paver and spreader; Asphalt plant console operator; Auto grader; Backhoe; Blade operator, all types; Bollorz-2: Bore- fleet hancos; Bore fleet crane mounted; Bulldozer operator; Camelback operator; Compressor maintenance operator-1; Concrete plant operator, central mix; Concrete mixer operator; Crane operator; Drill rig; Derrick truck; Ditching machine; Dragline operator; Dragline equipment; Drill cat with compressor mounted; Boxer; Drilling or boring machine, rotary; self-propelled; high loader, fork lift; Hoisting engine; Active drum; Locomotive, standard gauge; Mechanics and welders, field or shop; Maintenance operator; Masking machine, pile driver operator; Pitman crane operator; Pump-2; Quad-truck; Scoop operator-1, all types; Scoops in tandem; Self-propelled rotary drill (troy or equal); not air track; Shovel operator; Side discharge spreader; Sidewalk cutter; Skimmer, scoop operator; Slip-form paver (Cir, REX, or equal); Shoveling machine operator-1

Group 2: A-frame truck: Asphalt hot mix, mill; Asphalt plant fireman, drum or boiler; Asphalt plant mixer operator; Asphalt roller operator; Backfiller operator; Chip spreader; Concrete batch plant, dry-pour operator; Concrete mixer operator, skip loader; Concrete pump operator; Crusher operator; Elevating grader operator; Greaser; Hoisting engine; Luteurneau, rousset; Multiple compressor; Pavement breaker, self-propelled, of the hydra-hammer or similar type; Power shield; Pug mill operator; Stump cutting machine; Towboat operator; Tractor operator, over 50 h.p

Group 3: Boilers-1; Chip spreader (front man); Chute drill operator; Compressor maintenance operator-1; Concrete saws, self-propelled; Conveyor operator; Distributor operator; Felling machine operator; Fireman; FOB; Float operator; Form grader operator; Pump; Pump maintenance operator, other than dredge; Roller operator, other than high type asphalt; Screening and washing plant operator; Self-propelled street broom or scraper; Siphons and jets; Sub-grading machine operator; Tank car hoist operator-combination boiler and booster; Tractor, 50 h.p or less with attachments; Vibrating machine operator; not hand; Welding machine maintenance operator-1

Group 4: Mechanics, Helper's; Oilers

Group 5: Oilers, diesel, all types

Group 6: Clamshells, 3 yd. capacity or over; Crane or rig, 80 ft. of boom or over (including jib); Dragline, 3 yd. capacity or over; Pile drivers, 80 ft. of boom or over (including jib); Shovels, 3 yd. capacity or over
### Truck Drivers:

#### Classification Definitions

**Zone 1**
- **Group 1:** Warehousemen and stockmen
- **Group 2:** Flatbed truck drivers; bank truck drivers, under 10 yd.
- **Group 3:** Flatbed truck drivers, 10 yd. and over; all truck drivers; sheet-metal and trimmen
- **Group 4:** Steel drivers; signalmen (signmen); switchmen; trackmen; hybrid drivers (yard, yarding, switching, and switching trucks); tank truck drivers; excavator operators; fuel tank drivers; and similar occupations
- **Group 5:** Distributor truck drivers and operators; oilers; mechanics and related workers
- **Group 6:** Mechanics

#### Truck Drivers:

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<tr>
<th>Group</th>
<th>Warehousemen and stockmen</th>
<th>Flatbed truck drivers, 10 yd. and over; all truck drivers; sheet-metal and trimmen</th>
<th>Steel drivers; signalmen (signmen); switchmen; trackmen; hybrid drivers (yard, yarding, switching, and switching trucks); tank truck drivers; excavator operators; fuel tank drivers; and similar occupations</th>
<th>Distributor truck drivers and operators; oilers; mechanics and related workers</th>
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#### Basic Hourly Rates

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<td>Education and/or Appr Tr</td>
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**Zone 2**
- **Group 1:** Tank wagon drivers, single axle
- **Group 2:** Tank wagon drivers, tandem axle; semi-trailers; semi-tractor
- **Group 3:** Tank wagon drivers, tandem axle; semi-trailer; tank wagon drivers, single axle; tank wagon drivers (tank, semi-tractor, and semi-trailer); half-trailers; speeders; and other similar occupations

**Classification Definitions**

**Zone 2**
- **Group 1:** One ton; station wagons; pickup trucks; all trucks, single axle
- **Group 2:** Material trucks, tandem axle; tandem axle; semi-trailers; semi-tractor
- **Group 3:** Tank wagon drivers, single axle; tank wagon drivers, tandem axle; semi-trailer; tank wagon drivers, single axle; tank wagon drivers, tandem axle; semi-trailer; half-trailers; speeders; and other similar occupations

**WINCHER:** Receive rate prescribed for craft performing operation to which worker is assigned.
NOTICES

SUPERSEDES DECISION

STATE: Montana
COUNTIES: Statewide
DECISION NUMBER: MT77-5074
dated March 11, 1977,
in 42 FR 13765
DESCRIPTION OF WORK: Heavy and Highway Construction

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<th>Basic Hourly Rates</th>
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<th>Pensions</th>
<th>Vacation</th>
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DECISION NO MT77-5074

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<th>Basic Hourly Rates</th>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
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<tr>
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<td>H &amp; W</td>
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Flathead, Granite (northern area north limits of Phillipsburg), Lake (northern area including the City of Ronan), Lincoln, Mineral, Hinsdale, Powell (northern area through south limits of Melville), Ravalli and Sanders Counties

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### **Sheet Metal Workers:**

Broadwater, Jefferson (including north half of the City of Boulder), Lewis and Clark and Meagher Counties

Flathead, Lake, Lincoln, Mineral, Hinsdale, Ravalli and Sanders Counties

Big Horn, Carbon, Carter, Custer, Daniels, Dawson, Fallon, Garfield, Golden Valley, Musselshell, Petroleum, Powder River, Prairie, Richland, Rosebud, Sheridan, Stillwater, Treasure, Wheatland, Wibaux and Yellowstone Counties

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<td>Assman</td>
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<td>Burning Bar</td>
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<td>Car and Truck Tenders, Scarfman</td>
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<td>Colocn Workmen (free air)</td>
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<td>Carpenter Tender</td>
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<td>Dril, Air-tract, self-propelled, Hasting type or similar</td>
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<td>Fence Erector and Installor (including Installation and Erection of fences, guard rails, median rails, reference posts, guideposts and right-of-way markers)</td>
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<tr>
<td>Torn Striper</td>
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<tr>
<td>Torn Cutter</td>
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<tr>
<td>Grid Cutter</td>
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<tr>
<td>General Laborion</td>
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### LABORERS (Cont'd)

<table>
<thead>
<tr>
<th>Laborer Description</th>
<th>Base Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Hand Puller</td>
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<td>Hand Scaler</td>
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<td>High Pressure Machine Hoseman</td>
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<tr>
<td>Hoeor Tender</td>
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<tr>
<td>Jackhammer, Pavement Breaker, Hagen Drills, Concrete Vibrator, Mechanic Tamper, Vibrating</td>
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<tr>
<td>Rollor, hand steered and other</td>
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<tr>
<td>Power Tools</td>
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<tr>
<td>Landscape Laborion</td>
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<tr>
<td>Hoseman-Air and Water, Gunite and Plass Machine</td>
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<tr>
<td>Pipe Layer (all types)</td>
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<td>Pipe Tapper</td>
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<tr>
<td>Post Hole Digger (power auger)</td>
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<tr>
<td>Power Saw, bucking</td>
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<tr>
<td>Power Saw, cutting</td>
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<td>Nipprop Hoper</td>
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<td>Calsion</td>
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<td>Sandblaster</td>
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<td>Sandblaster Tail Hoseman, Pot Tender</td>
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<td>Endcutter-hand operated</td>
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<tr>
<td>Cyclone Driver, single or dual or hand</td>
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<td>Cyclone Driver for Equipment</td>
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<td>Cyclone Driver</td>
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<tr>
<td>Tawr</td>
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<td>Tawr, Chacker, Tawr, Mower, Culler</td>
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<td>Tawr, Chacker, Tawr, Mower, Culler</td>
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### POWER EQUIPMENT OPERATORS (Cont'd)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
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<tr>
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<tr>
<td>Concrete Power Saw, self-propelled</td>
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<td>Concrete Travel Hatcher</td>
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<tr>
<td>Concrete Conveyor under 40 ft</td>
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<tr>
<td>Concrete Conveyor over 40 ft</td>
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<td>Concrete Pump</td>
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<td>Ballast, two and including 12&quot; belt</td>
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<tr>
<td>Crane</td>
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<tr>
<td>Crane, 131' to 150' boom</td>
<td>10 37</td>
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<tr>
<td>Crane, 151' boom and over</td>
<td>10 42</td>
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<tr>
<td>Crane Oiler</td>
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<tr>
<td>crane with jib, additional $15 per hour</td>
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<tr>
<td>Crusher</td>
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<td>Crusher Oiler and Helper</td>
<td>9 50</td>
<td>55</td>
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<tr>
<td>Crusher Conveyor, when required</td>
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<td>55</td>
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<tr>
<td>Distributor</td>
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<tr>
<td>09 10, 15, or 20 Tractor pulling Roller</td>
<td>9 70</td>
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<tr>
<td>Electric Overhead Cranes</td>
<td>10 22</td>
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<tr>
<td>Elevating Grader</td>
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<td>Farm type Tractor, up to and including 50 HP engine</td>
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<tr>
<td>Farm type Tractor, over 50 HP engine</td>
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<tr>
<td>Field Equipment Serviceman</td>
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<tr>
<td>Field Equipment Serviceman Helper</td>
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<td>Fireman</td>
<td>9 60</td>
<td>55</td>
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<tr>
<td>Forklift, on construction job site</td>
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<tr>
<td>Form Grader</td>
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<tr>
<td>Gradall</td>
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<tr>
<td>Grader operator</td>
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**DECISION NO MT77-5074**

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 6, 1977**
### POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heavy Duty Drill, all types</strong></td>
<td>9 00 91</td>
<td>.55</td>
<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Heavy Duty Driller Helper</strong></td>
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<td>.55</td>
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<tr>
<td><strong>Hermon-Holman Monitors and similar types</strong></td>
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<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Hoes, two or more drums</strong></td>
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<td>.55</td>
<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Hot Plant</strong></td>
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<td>.55</td>
<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Hot Plant Fireman, when in operation</strong></td>
<td>10 01</td>
<td>.55</td>
<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Hot Plant Oiler, 1 ton per hour or over</strong></td>
<td>9 50</td>
<td>.55</td>
<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Hydraulic Lift and similar types</strong></td>
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<td>.55</td>
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<tr>
<td><strong>Industrial Locomotive all classes</strong></td>
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<tr>
<td><strong>Mechanic and/or Helper on job</strong></td>
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<tr>
<td><strong>Mechanic, Shop (Dec 1 to April 1)</strong></td>
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<tr>
<td><strong>Mechanic Helper, Shop (Dec 1 to April 1)</strong></td>
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<td><strong>Mixer tender</strong></td>
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<td><strong>Motor Tender or similar type</strong></td>
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<tr>
<td><strong>Mule Tender</strong></td>
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<tr>
<td><strong>Pier Winch, Rubber Tired Cranes</strong></td>
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<td>.35</td>
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<tr>
<td><strong>Pier, other than chow and cranes</strong></td>
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<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Tender, High Pressure</strong></td>
<td>9 91</td>
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<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Traffic and Mining Machines</strong></td>
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<td>.55</td>
<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Trolley, Large Truck or Tractor mounted and Punch</strong></td>
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<td><strong>Trolley, single or double drum</strong></td>
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<tr>
<td><strong>Trolley, multiple deck, self-propelled</strong></td>
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<tr>
<td><strong>Air Crane or Great Machine</strong></td>
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<td><strong>Air Tractor</strong></td>
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### POWER EQUIPMENT OPERATORS (Cont'd)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tbody>
<tr>
<td><strong>Quad Cat</strong></td>
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<tr>
<td><strong>Quad Loader and similar type</strong></td>
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<tr>
<td><strong>Radiator Repairman</strong></td>
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<td><strong>Ravenet</strong></td>
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<td><strong>Refrigeration Plant</strong></td>
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<td><strong>Retort</strong></td>
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<td>.55</td>
<td>.35</td>
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<tr>
<td><strong>Roller, on blade or hot mix oil paving</strong></td>
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<tr>
<td><strong>Roller, on other blade or hot mix paving</strong></td>
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<td><strong>Roller, 25 ton or over</strong></td>
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<tr>
<td><strong>Roller and similar type carriers, on construction site</strong></td>
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<tr>
<td><strong>Rubber-tired Dozer</strong></td>
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<tr>
<td><strong>Rubber-tired Front End Loader, 1 yard and under</strong></td>
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<td><strong>Rubber-tired Front End Loader, 1 yard to and including 3 yards</strong></td>
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<td>.35</td>
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<tr>
<td><strong>Rubber-tired Front End Loader, over 3 yards to and including 6 yards</strong></td>
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<tr>
<td><strong>Rubber-tired Front End Loader, over 6 yards to and including 10 yards</strong></td>
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<td>.55</td>
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<tr>
<td><strong>Rubber-tired Front End Loader, over 10 yards to and including 15 yards</strong></td>
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<tr>
<td><strong>Rubber-tired Front End Loader, over 15 yards</strong></td>
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<tr>
<td><strong>Scooper, D1, 15, 20, 21 and similar type if power unit is not used</strong></td>
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<td><strong>Scooper, single or twin engine, palling box, dump trailers</strong></td>
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<tr>
<td><strong>Scooper, single engine</strong></td>
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<tr>
<td><strong>Scooper, tandem engine or 3 engine</strong></td>
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<td><strong>Self-propelled Sheepsfoot and similar type</strong></td>
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### Power Equipment Operators (Cont'd)

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
<tbody>
<tr>
<td>Shovels, including attachments, under 1 cu yd</td>
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<td>35</td>
<td>05</td>
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<tr>
<td>Shovels, including all attachments, 1 cu yd to and including 3 cu yds</td>
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<td>35</td>
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</tr>
<tr>
<td>Shovels, including all attachments, over 3 cu yds to and including 5 cu yds</td>
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<td>55</td>
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<tr>
<td>Shovel Loader, over 5 cu yds to and including 10 cu yds</td>
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</tr>
<tr>
<td>Track-type Front End Loaders, up to and including 5 cu yds</td>
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<tr>
<td>Track-type Front End Loaders, over 5 cu yds to and including 10 cu yds</td>
<td>10 24</td>
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<tr>
<td>Track-type Front End Loaders, over 10 cu yds to and including 15 cu yds</td>
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<td>Track-type Front End Loaders, over 15 cu yds</td>
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<td>Track-type Tractor w/o attachments</td>
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<td>Track-type Tractor, on End Loaders</td>
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<tr>
<td>Trenching Machine</td>
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<tr>
<td>Turntable Conveyor, or Read Tower on Batch Plant</td>
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<td>55</td>
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<tr>
<td>Wagner Roller and similar type</td>
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<td>55</td>
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<tr>
<td>Whirley Crane</td>
<td>10 54</td>
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<tr>
<td>Whirley Crane Loader</td>
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<td>55</td>
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<td>05</td>
</tr>
<tr>
<td>Water Pull when used for Compaction</td>
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</tr>
<tr>
<td>Washing and Screening Plant</td>
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<tr>
<td>Washing and Screening Plant Oiler</td>
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<tr>
<td>Yo-Yo Cat, both ends</td>
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### Truck Drivers

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMBINATION TRUCK: Concrete Mixer and Transit Mixer:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To and including 4 cu yds</td>
<td>9 01</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 4 cu yds to and including 6 cu yds</td>
<td>9 09</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 6 cu yds to and including 8 cu yds</td>
<td>9 17</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 8 cu yds to and including 10 cu yds</td>
<td>9 25</td>
<td>65</td>
<td>50</td>
<td></td>
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</tr>
</tbody>
</table>

### Additional

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>DISTRIBUTOR DRIVER and HELPER</td>
<td>8 99</td>
<td>65</td>
<td>50</td>
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</table>

### Dry Batch Trucks

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 3 Batch to and including 5 Batch</td>
<td>8 76</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 5 Batch to and including 10 Batch</td>
<td>8 89</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 10 Batch to and including 15 Batch</td>
<td>9 05</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Over 15 Batch to and including 20 Batch</td>
<td>9 21</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per hour each additional 5 Batch increment</td>
<td></td>
<td></td>
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</tbody>
</table>

### Pickup Driver, Hauling Materials

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 86</td>
<td>65</td>
<td>50</td>
<td></td>
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<td></td>
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</tbody>
</table>

### Division, Gravel Spreader Box Operator; Pilot Car Driver, Tows and Helpers

<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warehousesmen, Partsman, Cardox Men, Warehouse Expediter</td>
<td>8 96</td>
<td>65</td>
<td>50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### TRUCK DRIVERS (Cont'd)

#### DUMP TRUCKS AND SIMILAR EQUIPMENT
- **DE 20, DE 21, or DELOID TRACTORS, Pulling P.R. 21 or similar Dump Wagons, Water Level Capes by, including Sideboards**
  - 7 cu. yds. or less: $8.76, 65, 50
  - Over 7 cu. yds. to and including 10 cu. yds.: $8.89, 65, 50
  - Over 10 cu. yds. to and including 15 cu. yds.: $9.05, 65, 50
  - Over 15 cu. yds. to and including 20 cu. yds.: $9.19, 65, 50
  - Over 20 cu. yds. to and including 25 cu. yds.: $9.25, 65, 50
  - Over 25 cu. yds. to and including 30 cu. yds.: $9.31, 65, 50
  - Over 30 cu. yds. to and including 35 cu. yds.: $9.37, 65, 50
  - Over 35 cu. yds. to and including 40 cu. yds.: $9.43, 65, 50
  - Over 40 cu. yds. to and including 45 cu. yds.: $9.45, 65, 50
  - Over 45 cu. yds. - additional: 0.10 per hour each additional 2 cu. yds. increased

#### DUMPSTERS
- Basic Rate: $8.80, 65, 50

#### SEWER CLEANERS
- Basic Rate: $9.60, 65, 50

#### POWER TRUCK DRIVER (bulk unloader type)
- Basic Rate: $9.94, 65, 50

#### FLAT TRUCKS:
- To and including 3 tons: $9.01, 65, 50
- Over 3 tons Factory rating: $9.11, 65, 50

### TRUCK DRIVERS (Cont'd)

#### SERVICE TRUCK DRIVERS; FUEL TRUCK DRIVERS; TIRE MEN
- BASIC RATE: $9.35, 65, 50

#### LOGBOYS, FOUR-WHEEL TRAILER, FLAT SHOVEL TRAILER
- LOGBOYS, FOUR-WHEEL TRAILER: $9.11, 65, 50
- FLAT SHOVEL TRAILER: $9.01, 65, 50

#### LUMBER CARRIERS, LIFT TRUCKS
- BASIC RATE: $9.05, 65, 50

#### POWER BROOM
- BASIC RATE: $8.05, 65, 50

#### WATER TANK DRIVERS, PETROLEUM PRODUCTS DRIVERS:
- Over 2,500 gallons and under: $8.76, 65, 50
- Over 2,500 gallons to and including 4,500 gallons: $9.05, 65, 50
- Over 4,500 gallons to and including 6,000 gallons: $9.25, 65, 50
- Over 6,000 gallons to and including 8,000 gallons: $9.31, 65, 50
- Over 8,000 gallons to and including 10,000 gallons: $9.39, 65, 50
- Over 10,000 gallons - additional: 0.10 per hour each additional 2,000 gallons increased

#### TRUCK WITH POWER EQUIPMENT IF GREEN TIMBERS JURISDICTION, SUCH AS:
- Winch, A-tracks, Swedish Crane, Hydra-lift, Grove-truck, and Combination raising, bedding and fertilizing: $9.01, 65, 50

#### TRUCK MECHANIC
- BASIC RATE: $9.75, 65, 50

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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### MONTANA LINE CONSTRUCTION

**LINE CONSTRUCTION**

| Flathead, Lake and Lincoln Cos |  |

All construction of "H" fixtures and steel tower transmission lines with capacity of 69 kV voltages and over, Switch yard and substation rated at 6900 kV A and all work not covered by schedule "B".

**SCHEDULE "A"**

<table>
<thead>
<tr>
<th>Title</th>
<th>H &amp; W</th>
<th>Weekly</th>
<th>Education</th>
<th>Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lineman</td>
<td>610</td>
<td>25</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Cable Splicer</td>
<td>11.44</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Line Equipment Operator</td>
<td>7.60</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Groundman</td>
<td>6.15</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Groundman (Experienced)</td>
<td>7.33</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
</tbody>
</table>

All work for power utilities except work covered under Schedule "A", all highway lighting, street lighting and motor traffic controlling.

**SCHEDULE "B"**

<table>
<thead>
<tr>
<th>Title</th>
<th>H &amp; W</th>
<th>Weekly</th>
<th>Education</th>
<th>Appr Tr</th>
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</thead>
<tbody>
<tr>
<td>Lineman</td>
<td>9.19</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Cable Splicer</td>
<td>10.22</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Line Equipment Operator</td>
<td>9.08</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
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<tr>
<td>Line Equipment Operator</td>
<td>7.97</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
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<tr>
<td>Groundman</td>
<td>6.94</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Groundman</td>
<td>6.52</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Tree Trimmer</td>
<td>9.44</td>
<td>45</td>
<td>14</td>
<td>1/24</td>
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</table>

**LINE CONSTRUCTION (Cont'd)**

**Remaining Counties**

**Jobs over 69,000 Volts**

<table>
<thead>
<tr>
<th>Title</th>
<th>H &amp; W</th>
<th>Weekly</th>
<th>Education</th>
<th>Appr Tr</th>
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<tbody>
<tr>
<td>Lineman</td>
<td>9.31</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Cable Splicer</td>
<td>9.80</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Line Equipment Operator</td>
<td>8.53</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
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<tr>
<td>Groundman</td>
<td>7.04</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
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</table>

**Jobs 69,000 Volts or less**

<table>
<thead>
<tr>
<th>Title</th>
<th>H &amp; W</th>
<th>Weekly</th>
<th>Education</th>
<th>Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lineman</td>
<td>8.65</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Cable Splicer</td>
<td>9.56</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Line Equipment Operator</td>
<td>8.47</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
</tr>
<tr>
<td>Groundman</td>
<td>5.93</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
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</table>

**Truck Drivers**

<table>
<thead>
<tr>
<th>Title</th>
<th>H &amp; W</th>
<th>Weekly</th>
<th>Education</th>
<th>Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groundman (1000 hours)</td>
<td>6.60</td>
<td>35</td>
<td>14</td>
<td>1/24</td>
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<tr>
<td>Decent (Weekly Rates)</td>
<td>fringe Benefits Payments</td>
<td>Education</td>
<td>Approx Tr</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------</td>
<td>-----------</td>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pension</td>
<td>Vacation</td>
<td></td>
</tr>
<tr>
<td>Assistant Hato (Dockhand)</td>
<td>$10.04</td>
<td>.00</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Fireman</td>
<td>10 14</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Oilor</td>
<td>10 14</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Assistant Engineer (Electric, Diesel, Steam or Booster Pump)</td>
<td>10 48</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Mate and Boatman</td>
<td>10 48</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Engineer Waldor</td>
<td>10 53</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Crane operator</td>
<td>10 53</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Assistant Engineer (Electric, Generator Operator for Primary Pump, Power Barge or Dredge)</td>
<td>10 58</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>Lumberman, Digger:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) 5 Yards and Under</td>
<td>11 29</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
</tr>
<tr>
<td>(b) Over 5 Yards</td>
<td>11 04</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
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<tr>
<td>Lumberman, Hydraulics</td>
<td>10 90</td>
<td>60</td>
<td>1.05</td>
<td>11</td>
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</table>
### Notices

**SUPERSEDING DECISION**

**STATE:** Nevada  
**COUNTIES:** Nevada Test Site  
Including Tonopah Test Range  
in Clark and Nye Counties, Nevada  
**DECISION NUMBER:** NV77-5072  
**DATE:** Date of Publication  
Supersedes Decision No NV77-5012 dated February 11, 1977, in 42 FR 8947

**DESCRIPTION OF WORK:** Building Construction (excluding single family homes and garden type apartments up to and including 4 stories), heavy and highway construction

<table>
<thead>
<tr>
<th>Labor Category</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>H &amp; W</strong></td>
<td><strong>Pensions</strong></td>
</tr>
<tr>
<td>ASBESTOS WORKERS</td>
<td>$11.92</td>
<td>$1.17</td>
</tr>
<tr>
<td>BRICKLAYERS</td>
<td>11.37</td>
<td>0.60</td>
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<tr>
<td>BRICK TENDER</td>
<td>8.47</td>
<td>0.51</td>
</tr>
<tr>
<td>CARPENTERS</td>
<td>11.19</td>
<td>0.65</td>
</tr>
<tr>
<td>Floor Layers</td>
<td>11.25</td>
<td>0.65</td>
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<tr>
<td>Hillwrights</td>
<td>11.69</td>
<td>0.65</td>
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<tr>
<td>CEMENT MASON</td>
<td>8.25</td>
<td>1.50</td>
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<tr>
<td>Cement Masons</td>
<td>8.60</td>
<td>1.00</td>
</tr>
<tr>
<td>ELECTRICIANS</td>
<td>11.07</td>
<td>7.3</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>13.40</td>
<td>7.3</td>
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<td>Groundmen</td>
<td>60.00</td>
<td>73</td>
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<tr>
<td>IRONWORKERS</td>
<td>11.00</td>
<td>1.14</td>
</tr>
<tr>
<td>Reinforcing; Ornamental; Structural Painters</td>
<td>12.00</td>
<td>75</td>
</tr>
<tr>
<td>Painters</td>
<td>9.21</td>
<td>75</td>
</tr>
<tr>
<td>Paperhangers; Spray; Steel; Sandblasters; Swing Steeple</td>
<td>9.56</td>
<td>75</td>
</tr>
<tr>
<td>Tapers; Buffing; Sand</td>
<td>11.05</td>
<td>1.05</td>
</tr>
<tr>
<td>PIPEFITTERS</td>
<td>12.75</td>
<td>65</td>
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<tr>
<td>ROOFERS</td>
<td>10.00</td>
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<tr>
<td>SHEET METAL WORKERS</td>
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</tr>
<tr>
<td>SPRINKLER FITTERS</td>
<td>15.05</td>
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</tr>
</tbody>
</table>

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
LABORERS

Group 1: Laborer - general; Laborer - demolition (cleaning of bricks, lumber, etc.); Dry packing of concrete and filling of form-bolt holes; Flagman, spotter, debris handler and dumpman; Fence Builder; Tool Attendant (jobsite only); Gas and oil pipeline laborer

Group 2: Cutting torch operator (demolition); Turner and Mortarman

Group 3: Guinea Chaser

Group 4: Fine grader; highway and street paving, airport runways and similar work; Landscape gardener, nurseryman and groundskeeper

Group 5: Laborer - packing rod steel and pans

Group 6: Undergrounder laborer including cllasson bellowers (except tunnels)

Group 7: Chucktender (except tunnels); Salar; Tank scroller and cleaner

Group 8: Ceaspool digger and installer

Group 9: Concrete curer — impervious membrane and oiler of all materials and form oiler; Riprap stonepaver; Sandblaster (pot tender); Making and caulking of all non-metallic pipe joints

Group 10: Operators and tenders of pneumatic and electric tools, vibrating machines, and similar mechanical tools not separately classified herein, including hand guided ditch witch and hand type roller; Asphalt eaker, ironer, spreader; Buggymobile man; Cement gunner (on 1 yard or larger mixers and handling bulk cement); Concrete saw man excluding tractor type; Concrete core cutter; Gas and oil pipeline wrapper — pot tender and form man; Operator of cement grinders machines; Eto-scraper; Tree climber, faller, chain saw operator; Pittsburgh chipper and similar type brush shredders

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
POWERS EQUIPMENT OPERATORS
(Except Pilking and Steel Erection)

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$8.99</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 1</td>
<td>8.22</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 2</td>
<td>8.46</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 3</td>
<td>8.57</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 4</td>
<td>8.76</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 5</td>
<td>9.76</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 6</td>
<td>9.47</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 7</td>
<td>9.36</td>
<td>$2.00</td>
<td>30</td>
</tr>
<tr>
<td>Group 7-C</td>
<td>9.12</td>
<td>$2.00</td>
<td>30</td>
</tr>
</tbody>
</table>

Group 1: Air Compressor, Pump or Generator; Engineer Oiler and Signal Man; Heavy Duty Repairman's Helper; Switchman or Brakeman

Group 2: Concrete Mixer, Skip type; Conveyor and Boltman; Fireman; Generator, Pump or Compessor (2-5 units inclusive, over 5 units, $9.10 per hour for each additional unit up to 10 units; portable units); Generator, Pump or Compressor Plant; Rotary Drill Helper (oilfield type); Sliploader, wheelltype, Ford, Ferguson, Jeep or similar type, 3/4 yard or less (w/o drag-type attachments); Temporary Heating Plant; Truck Crane Oiler; Hydrosopic Pump

Group 3: A-Frame or Winch Truck; Dinky Locomotive or Tunnel Motor; Elevator Hoist; Equipment Greaser; Ford, Ferguson or similar type (wth drag-type attachments); Hydra-hammer or similar type equipment; Power Concrete Curbing Machine; Power Concrete Sprayer; Power-driven Jumbo Form Setter; Boom Carrier; Self-propelled Tor Pipe-lining Machine; Stationary Pipe Wringing and Cleaning Machine; Trowelhane Operator

Group 4: Asphalt Plant Fireman; Boring Machine; Boom or Mixer Box (concrete or asphalt plant); Derrickman (oilfield type); Drilling Machine (including water wells); Highline Cabling Signalman; Locomotive Engineer; Power Sweeper; Roller, compacting; Screed; Trenching Machine (up to 6 feet depth)

Group 5: Asphalt or Concrete Spreading; Mechanical Tamping or Finishing Machine - Roller (all types and sizes), Soil, Cement, Asphalt - Finish, Asphalt Plant Engineer; Deck Engine; Grade Checker; Heavy Duty Welder; Machine Tool; Pavement Breaker; Pneumatic Heading Shield - Tunnel; Road Oil Mixing Machine; Forklift, under five tons; Rubber-tired, heavy duty equipment (Oakwood, Do, Buck, LeTourneau, Lovelace-Choate, or similar type equipment with any type attachments); Sliploader, wheelltype, over 3/4 yards, up to and including 15 yards; Slip Form Pump (power-driven hydraulic lifting device for concrete forms); Tractor Operator - drag-type Shovel, Bulldozer, Tamper, Scraper and Push Tractor

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
POWER EQUIPMENT OPERATORS (Cont'd)

Group 6: Combination Heavy Duty Repairman and Valver; Concrete Mixer - paving; Concrete Mobile Mixer; Concrete Pump or Pump stock; Concrete Gun; Crushing Plant Engineer; Elevating Grader; Heavy Duty Repairman; Highline Cabaneau; Hoist (Chicago Boom and Hino); Kompan Belt Loader and similar type; Lift Slope Machine; Loader Operator - Ahoy, Euclid, Hancock, Sierens or similar type; Motor Patrol (any type or size); Multiple-engine earth-moving machinery; Pneumatic Concrete placing machine - Mackley-Prewall or similar type; Rotary Drill, excluding Closion type; Skiploader, wheel type, over 1$ yards; Surface Heater and Planer; Tractor Loader - crawler type - all types and sizes; Tractor, with boom attachments; Traveling Pipe Wrapping, cleaning and bending Machine; Trenching Machine (over 6 foot depth); Universal equipment (Shovel, Backhoe, Dragline, Classifier, Derrick, Derrick Barge, Crane, Pile-driver and Hacking Machine); Forklift, over 5 ton

Group 7: Driller Operator; Fishing hook engineer

Group 7-A: Derrickman

Group 7-B: Hotoxman

Group 7-C: Drill Helper

<table>
<thead>
<tr>
<th>TRUCK DRIVERS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
</tr>
<tr>
<td>Group 2</td>
</tr>
<tr>
<td>Group 3</td>
</tr>
<tr>
<td>Group 4</td>
</tr>
<tr>
<td>Group 5</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
TRUCK DRIVERS

Group 1: Light Duty Driver

Group 2: Bootman; Truck Greaser; Light Vehicle Dispatcher

Group 3: Tireman; Warehouse Clerk

Group 4: Heavy Duty Driver; Forklift Driver; Equipment Parts Stockroom Clerk

Group 5: Extra Heavy Duty Driver
### DECISION NO N377-3093

<table>
<thead>
<tr>
<th>Area Covered by Carpenters, Etc. Zones</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1 - Bergen (east of the Hackensack River including but not limited to Cliffside, Fort Lee, Grantwood, Palisades Park, Ridgefield, Englewood, Fairview, Leonia and Coketville) and Hudson Counties</td>
</tr>
<tr>
<td>ZONE 2 - Hunterdon (starts at the south of the town of Frenchtown on the Delaware River, thence following the line in the center of the road to Baptist to Croton to the City of Flemington to Flemington Junction to Three Bridges, thence following the Somerset County Line northward, all territory south of this line including the City of Flemington and Somerset (all territory south of a line beginning at Annec on the County Line to Lion to Fairview to Dutfan to Plainsville to Belle Mead to Griggstown to the Delaware and Hartran Canal) Counties</td>
</tr>
<tr>
<td>ZONE 3 - Hunterdon (remainder of county), Middlesex, Morris, Passaic, Somerset (remainder of county), Sussex, Union and Warren Counties</td>
</tr>
<tr>
<td>ZONE 4 - Essex County</td>
</tr>
<tr>
<td>ZONE 5 - Bergen (remainder of county)</td>
</tr>
</tbody>
</table>

### DECISION NO N377-3093

<table>
<thead>
<tr>
<th>Dock Builders &amp; Pile Drivers, Riggers</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1</td>
</tr>
<tr>
<td>ZONE 2</td>
</tr>
<tr>
<td>ZONE 3</td>
</tr>
<tr>
<td>ZONE 4</td>
</tr>
<tr>
<td>ZONE 5</td>
</tr>
</tbody>
</table>

### DECISION NO N377-3093

<table>
<thead>
<tr>
<th>Electricians &amp; Cable Splicers</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1 - Essex County</td>
</tr>
<tr>
<td>ZONE 2 - Union (that portion east and north of a line running in a southerly direction from Harris Avenue along Baltsur Road, across Baltsur Road Club to Baltsur Road and Summit Lane in Mountainside, to and along Hamilton Road, to and along the Mountain Road, to and along Hamilton Road, to and along Park Avenue in Scotch Plains, and continuing along Martine Avenue, to and northeast along the Raritan Road, to and easterly along the Westfield-Scotch Plains Line, to the Lehigh Valley Railroad and southeast on the railroad to the County Line) County</td>
</tr>
<tr>
<td>ZONE 3 - Union (that portion south and west of a line running east from Somerset County on Mountain Avenue, in New Providence Borough, to the Diamond Hill Road, south on that road to and along Park Avenue in Scotch Plains and continuing along Martine Avenue, to and northeast along the Raritan Road, to and easterly along the Westfield-Scotch Plains Line to the Lehigh Valley Railroad and southeast on the railroad to Middlesex County Line) County</td>
</tr>
<tr>
<td>ZONE 4 - Union (remainder of county) County</td>
</tr>
<tr>
<td>ZONE 5 - Bergen and Hudson Counties</td>
</tr>
</tbody>
</table>

**FEDERAL REGISTER, VOL. 42, NO 131—FRIDAY, JULY 8, 1977**
NOTICES

June 30, 1977

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

AREA COVERED BY ELECTRICIANS & CABLE SPLICERS ZONE (CONT'D)

ZONE 6 - Passaic County

ZONE 7 - Morris and Sussex Counties

ZONE 8 - Hunterdon (except Towamensing Township and Callicoon Boro) and Somerset (that portion south of a line following Mountain Ave. from the Union County Line west to Hillcrest Ave. in Union Village, north on Hillcrest Ave. to and west on the Passaic River, west on the Dead River, west on Allen Rd., north on Somerville Rd., west on Howell Rd., southeast on Mount Prospect Rd., west on Martinsville Pluckemin Rd., west on Kinns Hill Rd. North on John Hane Rd., west on Whitney Rd., west on Stillwell Rd., and west on Hall's Bridge Rd. to Hunterdon County Line, and also that portion of Montgomery Township east and south of a line following U.S. Highway 206 north from Morris County to the Harlingen Rd. and west along that road the Dutchtown - Zion Rd. to Hillsboro Township Line) County.

ZONE 9 - Hunterdon (Towamensing Township and Callicoon Boro) and Somerset (that portion north of a line following Mountain Ave. from the Union County Line west to Hillcrest Ave. in Union Village north on Hillcrest Ave. to and west on the Passaic River, west on the Dead River, west on Allen Rd., north on Somerville Rd., west on Howell Rd., southeast on Mount Prospect Rd., west on Martinsville Pluckemin Rd., west on Kinns Hill Rd., North on John Hane Rd., west on Whitney Rd., west on Stillwell Rd., and west on Hall's Bridge Rd. to the Hunterdon County Line) County.

ZONE 10 - Somerset (remainder of county) County.

ZONE 11 - Middlesex (that portion south of a line extending east from the Harlan River along the Philadelphia and Reading Railroad to Staton Road, south on Staton Rd. to Lincoln Highway, along Lincoln Highway to Vinyard Road to Old Post Rd., along Old Post Rd. to Hill Rd., along Hill Road to the Harlan River along the Harlan River to the South River, along the North River to the southern boundary of the Borough of South River, along this boundary to the Cranbury South River Turnpike, along this road and continuing on the Washington Boro and Maplewood Avenue in Cranbury to South Ave., along South Ave. to Main Street, on Main Street and the Turnpike to the Millstone River) County.

ZONE 12 - Middlesex (that portion north of a line following the Philadelphia and Reading Railroad east from the Harlan River to Dical Rd., northeast on Dical Rd. to Park Ave., north on Park Ave. to the Lehigh Valley Railroad, and northeast along that railroad to the Union County Line) County.
### DECISION NO. H77-3093

<table>
<thead>
<tr>
<th>IRONWORKERS - Structural, Reinforcing &amp; Ornamental</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr. Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warren County</td>
<td>12 10</td>
<td>84</td>
<td>1.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bergen, Essex, Hudson, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex &amp; Union Counties</td>
<td>10 82</td>
<td>76</td>
<td>238</td>
<td>101</td>
<td>18</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>LABORERS, BUILDING CONSTRUCTION:</th>
<th>Fringe Benefits Payments</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 1</td>
<td>Laborers, Air Tool Ops (jackhammers, vibrators), Mason Tenders, Mortar Mixers, Plasterers</td>
<td>7 80</td>
</tr>
</tbody>
</table>

| ZONE 2                           | Laborers, Air Tool Ops (jackhammers, vibrators), Mason Tenders, Mortar Mixers, Plasterers, Wrecking & Excavation | 7.70 | 1 00 | 70 | 02 |

| ZONE 3                           | Laborers, Mason Mixers, Scaffolding & Pneumatic Hammer Ops | 8 55 | 60 | 40 | 02 |

| ZONE 4                           | Common Laborers | 8 35 | 55 | 40 | 02 |

| ZONE 5                           | Common Laborers | 7 80 | .75 | .85 | 02 |

| ZONE 6                           | Common Laborers, Air Tool Ops, Mason Tenders, Mortar Mixers & Pipelayers (concrete & clay) | 8 00 | 70 | 70 | 02 |

| ZONE 7                           | Common Laborers | 7 05 | .75 | 75 | 90 | 02 |

| ZONE 8                           | Common Laborers | 8 50 | 50 | 50 | 02 |

| ZONE 9                           | Common Laborers | 8 50 | 50 | 50 | 02 |

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### DECISION NO. H77-3093

<table>
<thead>
<tr>
<th>LABORERS, BUILDING CONSTRUCTION CONT'D:</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZONE 10</td>
<td>Laborers, Wrecking, Demolition, Concrete Mixers, H/o Hoppers, Drill Runners, Jackhammers, Mason Tenders, Mortar Mixers, Excavation &amp; Foundations, Scaffold Builders, Carpenter Tenders &amp; Grading for Concrete</td>
</tr>
</tbody>
</table>

| ZONE 11                               | Laborers, Air Tool Ops (jackhammers, vibrators), Mason Tenders, Mortar Mixers, Plasterer Tenders, Pipelayers, Wreckers & Excavation | 8.25 | 65 | 50 | 02 |

| ZONE 12                               | Laborers, Tenders, Scaffolding, Excavation, Bituminous Concrete & Aggregates, Pipelayers, Underpinning, Lagging, Braiding & Wrecking | 8.25 | 60 | 55 | 02 |

| ZONE 13                               | Laborers, Tenders, Scaffolding, Excavating & Site Preparation & Cleancare, Bituminous Concrete & Aggregates, Trenches, Manholes, Handling & Distribution of Pipes, Underpinning, Lagging, Bracing, Propping & Shoring | 7 80 | 75 | .85 | 02 |

| ZONE 14                               | Common Laborers | 7 95 | 70 | 60 | 02 |

| ZONE 15                               | Common Laborers | 8 00 | 70 | 70 | 02 |

| ZONE 16                               | Common Laborers, Air Tool Ops, Mason Tenders, Plasterer Tenders & Mortar Mixers | 7 80 | 75 | .85 | 02 |

| ZONE 17                               | Common Laborers, Weld Carriers, Power Tool Ops & Plasterer Tenders | 8 25 | .50 | 35 | 02 |
NOTICES

AREA COVERED BY LABORERS, BUILDING CONSTRUCTION ZONES

ZONE 1 - Bergen (Garfield, Passaic and Wallington Townships, Lodi, Lodi Boro and East Patterson) and Passaic County
ZONE 2 - Bergen (remainder of County) County
ZONE 3 - Essex (City of East Orange, Townships of South Orange and Maplewood) County
ZONE 4 - Essex (Orange and Montclair) County
ZONE 5 - Essex (Millburn) and Union (Springfield and Union Townships) Counties
ZONE 6 - Essex (remainder of county) and Hudson ( Kearny, East Newark and Harrison) Counties
ZONE 7 - Hudson (remainder of county) Counties
ZONE 8 - Middlesex (Perth Amboy, Carteret, Woodbridge and Metuchen Townships) County
ZONE 9 - Middlesex (remainder of County) and Somerset (East Millstone and Franklin Townships) Counties
ZONE 10 - Morris (Boonton, Boonton Township, Montville, Lincoln Park Boro, Butler, Kinnelon Boro, Pin Brook, Towaco, Danville, Mountain Lakes, Pequannock, Pompton Plains and Riverdale Boro) County
ZONE 11 - Morris (Jefferson, Rockaway, Mt. Arlington, Rockaway Boro, Wharton, Mine Hill, Dover, Hackett, Roxbury, Mt. Olive and Randolph Townships) and Sussex Counties
ZONE 12 - Morris (Morristown, Morristown Township, Morristown Plains, Mendham, Randolph, Chester, Brookside, Flanders, Ironia, Mt. Freedom, Mt. Tabor, Parsippany, Troy Hills, Pine Brook, Cedar Knolls, Wharton, Hanover Township and Long Valley) County
ZONE 13 - Morris (remainder of County) County
ZONE 14 - Somerset (Townships of Bernardsville, Peapack, Gladstone, Fan Hills, Bernards and Bedminster) County

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
CLASSIFICATION DEFINITIONS

LABORERS, HEAVY AND HIGHWAY CONSTRUCTION

GROUP 1 - Blasters

GROUP 2 - Finishers, Rasmers, Pavers, Gunite Nozzle Men and Stonecutters

GROUP 3 - Linemen

GROUP 4 - Formmoters

GROUP 5 - Wagon Drill Operators, Drill Masters, Jackhammers, Chipping Hammers, Pavement Breakers, Power Buggies, Concrete Cutters, Asphalt Cutters, Sheet Hamar and Torch Cutter Operators, Sandblasting, Cutting, Burning, and such other power tools used to perform work usually done manually by Laborers

GROUP 6 - Sewer Pipe, Laser Men, Conduit and Duct Line Layers

GROUP 7 - Wagon Drill Operator Helpers, Drill Master Helpers, Powder Carriers and Magazine Tenders

GROUP 8 - Wrapping and Coating of all pipe

GROUP 9 - Common Laborers, Landscape Laborers, Railroad Track Laborers, Flagmen, Traffic Directors, Pitsmen and Dungmen, Waterproofing, Rakers and Tumppers on cold Patch Hock

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. 8177-3033

#### LABORERS, ASPHALT CONSTRUCTION

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ZONE 1</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Head Laborers</td>
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<tr>
<td>Laborers</td>
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<td><strong>ZONE 2</strong></td>
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<tr>
<td>Laborers</td>
<td>13.33</td>
<td>.6%</td>
<td>.8%</td>
<td>1/4 of 14</td>
</tr>
<tr>
<td>Groundcrew</td>
<td>9.33</td>
<td>.6%</td>
<td>.8%</td>
<td>1/4 of 14</td>
</tr>
</tbody>
</table>

#### LINE CONSTRUCTION

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tbody>
<tr>
<td><strong>ZONE 3</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Linemen, Cable Splicers, Line Equipment Operators and Groundcrew</td>
<td>12.00</td>
<td>5%</td>
<td>8% + .5%</td>
<td>1/4 of 14</td>
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<tr>
<td><strong>ZONE 4</strong></td>
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<tr>
<td>Linemen, Cable Splicers, Line Equipment Operators and Groundcrew</td>
<td>12.00</td>
<td>6%</td>
<td>8% + .54</td>
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</tr>
<tr>
<td><strong>ZONE 5</strong></td>
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<tr>
<td>Linemen, Cable Splicers, Line Equipment Operators and Groundcrew</td>
<td>12.05</td>
<td>4%</td>
<td>3% + .42</td>
<td></td>
</tr>
<tr>
<td><strong>ZONE 6</strong></td>
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<tr>
<td>Linemen, Cable Splicers, Line Equipment Operators and Groundcrew</td>
<td>12.05</td>
<td>6%</td>
<td>3% + .60</td>
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<tr>
<td><strong>ZONE 7</strong></td>
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<tr>
<td>Linemen and Equipment Operators</td>
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<td>3% + .60</td>
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<tr>
<td>Groundcrew and Line Truck Operators</td>
<td>11.00</td>
<td>6%</td>
<td>3% + .60</td>
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<tr>
<td><strong>ZONE 8</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Linemen and Equipment Operators</td>
<td>11.05</td>
<td>4%</td>
<td>3% + .42</td>
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<tr>
<td>Groundcrew and Line Truck Operators</td>
<td>10.09</td>
<td>4%</td>
<td>3% + .42</td>
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<tr>
<td><strong>ZONE 9</strong></td>
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<tr>
<td>Linemen and Equipment Operators</td>
<td>11.95</td>
<td>6%</td>
<td>3% + .60</td>
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<td>6%</td>
<td>3% + .60</td>
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<tr>
<td><strong>ZONE 10</strong></td>
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<tr>
<td>Linemen and Equipment Operators</td>
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<td>6%</td>
<td>3% + .29</td>
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<td>Groundcrew and Line Truck Operators</td>
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<td>6%</td>
<td>3% + .29</td>
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<tr>
<td><strong>ZONE 11</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Linemen and Equipment Operators</td>
<td>12.05</td>
<td>4%</td>
<td>3% + .42</td>
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<tr>
<td>Groundcrew and Line Truck Operators</td>
<td>12.00</td>
<td>4%</td>
<td>3% + .42</td>
<td></td>
</tr>
</tbody>
</table>

#### AREA COVERED BY LABORERS, ASPHALT CONSTRUCTION ZONES

- **ZONE 1**: Bergen, Essex, Hudson, Hunterdon, Middlesex (northern half of County), Morris, Passaic, Somerset, Sussex, Union and Warren Counties
- **ZONE 2**: Middlesex (remainder of County) County

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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. 04122-3067

**LINE CONSTRUCTION: (Cont'd)**

<table>
<thead>
<tr>
<th>Zone</th>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
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<tbody>
<tr>
<td>Zone 12</td>
<td>Lineman and Equipment Operators</td>
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<tr>
<td>Zone 13</td>
<td>Lineman, Line Truck Operators, Equipment Operators and Cable Splicers</td>
<td>11.20</td>
<td>6%</td>
<td>3% + .50</td>
</tr>
<tr>
<td>Zone 14</td>
<td>Lineman, Line Truck Operators, Equipment Operators and Cable Splicers</td>
<td>11.20</td>
<td>6%</td>
<td>3% + .50</td>
</tr>
</tbody>
</table>

**AREA COVERED BY LINE CONSTRUCTION ZONES**

**ZONE 1** - Essex County

**ZONE 2** - Passaic County

**ZONE 3** - Bergen and Hudson Counties

**ZONE 4** - Union (that portion east and north of a line running in a southerly direction from Morris Ave. along Baisutro Rd., across Baisutro Country Club to Baisutro Rd., along Baisutro Rd. and Summit Ln. in Mountainside to and along New Providence Rd., to and along the Mountainside Line, to and along Washington Valley Rd., to and along Diamond Hill Rd., to and along Park Ave. in Scotch Plains, and continuing along Arline Ave., to and northeast along the Rahway Rd., to and easterly along the Westfield-Scotch Plains Line, to the Westfield-Scotch Plains Railroad and southwest on the railroad to the County Line) County

**ZONE 5** - Union (that portion south and west of a line running east from Somerset County on Mountain Ave in New Providence Boro to the Diamond Hill Rd. south on that road to and along Park Ave. in Scotch Plains and continuing along Arline Ave., to and northeast along the Rahway Rd., to and easterly along the Westfield-Scotch Plains Line to the Westfield-Scotch Plains Railroad and southwest on the railroad to the Middlesex County Line) County

**ZONE 6** - Union (remainder of County) County

**ZONE 7** - Morris and Sussex Counties

**ZONE 8** - Hunterdon (except Townsborough Township and Callicoon Boro.) and Somerset (that portion south of a line following Mountain Ave. in Union County, north on Hillcrest Ave. to and west on the Passaic River, west on the Dead River, west on Allan Rd., north on Somerville Rd., west on Hail Rd., southeast on Mount Prospect Rd., west on Martinsville-Plankemn Rd., west on Kline Hill Rd., north on John Kane Road to Hunterdon County Line, and also that portion of Montgomery Township west and south of a line following US. Highway 266 north from Mercer County to the Roselle Rd., West along that road the Dutchtown - Line Rd. to Hillsboro Township Line) County

**ZONE 9** - Hunterdon (remainder of county) and Somerset (remainder of County) Counties

**ZONE 10** - Middlesex (that portion south and west of a line, extending east from the Rahway River along the Philadelphia and Reading Railroad to Stelton Road, south on Stelton Rd. to Lincoln Hwy., along Lincoln Hwy. to Visby Rd. to Old Post Rd., along Old Post Rd. to Hill Rd., along Hill Rd. to the Rahway River, along the Rahway River to the South River, along the South River to the southern boundary of the Borough of South River, along this boundary to the Cranbury South River Turnpike, along this road and continuing onto the Washington Rd. and Maplewood Ave. in Cranbury to Scott Ave., along Scott Ave. to Main St., on Main St. and the Turnpike to the Hilltop River) County

**ZONE 11** - Middlesex (that portion north and west of a line following the Philadelphia and Reading Railroad east from the Rahway River to Dismal Rd., northeast on Dismal Rd. to Park Ave., north on Park Ave. to the Lehigh Valley Railroad, and northeast along that railroad to the Union County Line) County

**ZONE 12** - Middlesex (remainder of county) County

**ZONE 13** - Warren (from Palisades, Blairtown, Knowlton, Hope, Liberty, White, Oxford, Washington, Harmony, Franklin, Lopatcong, Greenwich, Hopatcong Twp. and that portion of Mansfield Twp. west of line following the Point Mt. Pleasant Rd. to Independence Tp. County

**ZONE 14** - Warren (remainder of County) County

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**FEDERAL REGISTER, VOL. 42, NO 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

### Marble Setters, Terrazzo Workers

#### ZONE 1
- Marble Setters: 11.19
- Terrazzo Workers: 10.73
- Tile Setters: 9.15

#### ZONE 2
- Marble Setters: 10.00
- Terrazzo Workers: 10.73
- Tile Setters: 9.15

### Area Covered by Marble Setters, Terrazzo Workers & Tile Setters Zones

#### ZONE 1 - Hunterdon (remainder of county), Morris (Rockaway, O'connell, Grover, Middle Valley and Parker Twp.), Sussex (Branchville, Flatbrookville, Swartswood, Millstone, Newton and Stillwater Twp.) and Warren County

#### ZONE 2 - Bergen, Essex, Hudson, Hunterdon (Hackettstown, Newark, Flatbrookville, Swartswood, Hanapepe, Newton and Stillwater Twp.) and Union County

### Terrazzo Finishers

#### ZONE 1
- Marble Setters Finishers: 8.28
- Terrazzo Workers Finishers: 9.14
- Tile Setters Finishers: 9.00

#### ZONE 2
- Marble Setters Finishers: 8.28
- Terrazzo Workers Finishers: 9.14
- Tile Setters Finishers: 9.00

### Area Covered by Terrazzo Finishers, Etc. Zones

#### ZONE 1 - Bergen, Essex, Hudson, Hunterdon (Hackettstown, Newark, Foreman and Cities east thereof to the County Line), Middlesex, Morris, Passaic, Sussex (Collingswood, River Vale, Mt. Pleasant, Swartswood, Hanapepe and all cities exclusive to the Morris and Passaic County Line) and Union County

#### ZONE 2 - Bergen, Essex, Hudson, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex and Union County.

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**NOTICES**

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### DECISION NO. M77-3093

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Repaint work as described above</td>
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</tr>
<tr>
<td>On bridges, televisions and radio towers, steel and tanks above 3 stories in height (30' or over), smoke stacks, water towers, sandblasting, steam-cleaning, spraying or application of hazardous materials</td>
<td>10 00</td>
</tr>
<tr>
<td>ZONE 4</td>
<td>Commercial &amp; Industrial Painters</td>
</tr>
<tr>
<td>Painters, Sprayers, Coverers, &amp; Spacklers</td>
<td>9 80</td>
</tr>
<tr>
<td>Paperhangers</td>
<td>10 00</td>
</tr>
<tr>
<td>All extension ladder work, 3 stories in height (30' or over), scaffold work, structural steel, tanks, bridges, towers, smoke stacks, radio towers, television towers, flag poles (steel or wood), fire escapes from roof to bottom, cable work &amp; hazardous work</td>
<td>10 46</td>
</tr>
<tr>
<td>Sandblasting &amp; Spraying</td>
<td>10 50</td>
</tr>
</tbody>
</table>

**AREA COVERED BY PAINTERS ZONES**

**ZONE 1** - Bergen, Passaic and Sussex Counties

**ZONE 2** - Middlesex (Edison Twp, South of Metuchen, Highland Twp, New Brunswick, North Brunswick, East Brunswick and South Brunswick Twp's, and Monroe Twp) and Somerset (Franklin Twp) Counties

**ZONE 3** - Essex, Hudson (west half of county), Hunterdon, Middlesex (remainder of county), Morris, Somerset (remainder of county) Union and Warren Counties

**ZONE 4** - Hudson (remainder of county),

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### DECISION NO. M77-3093

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tr>
<td></td>
<td>H &amp; W</td>
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<tr>
<td>PIPE FITTERS:</td>
<td>11 00</td>
</tr>
<tr>
<td>Bergen &amp; Hudson Counties</td>
<td>11 55</td>
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<tr>
<td>ZONE 1</td>
<td>11 50</td>
</tr>
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<tr>
<td>ZONE 4</td>
<td>10 60</td>
</tr>
<tr>
<td>ZONE 5</td>
<td>11 35</td>
</tr>
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</table>

**AREA COVERED BY Plumbers ZONES**


**ZONE 2** - Bergen (Cliffside Park Englewater, Fairview, Fort Lee, Hackensack and Ridgewood) and Hudson (Cullenberg, North Bergen, Secaucus, Weehawken and West New York) Counties

**ZONE 3** - Hudson (Citibank Hoboken, Bayonne and Jersey City) County

**ZONE 4** - Union (Fanwood, Fanwood, Plainfield and Plainfield Twp) County

**ZONE 5** - Union (Barnes, Cranford, Cranford Twp, Garwood, Hillside, Hillside Twp, Kenilworth, Linden, Lorrain, Lyons Farms, Mountainside, Picton, Rahway, Roselle, Roselle Park, Scotch Plains, Scotch Plains Twp, South Elizabeth, Township, Union Township, West Elizabeth, Westfield, Westfield Twp and Winfield) County

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### DECISION NO. 4777-1975

#### PLUMBERS & GAS FITTERS:

<table>
<thead>
<tr>
<th>Zone</th>
<th>Base Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
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<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
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<td>Zone 1</td>
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<td>Zone 2</td>
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<td>Zone 3</td>
<td>65</td>
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<td>25</td>
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<tr>
<td>Zone 4</td>
<td>65</td>
<td>1.00</td>
<td>30</td>
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</table>

**NOTICE:** The above rates are applicable to plumbers and gas fitters employed in the Essex County area.

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### DECISION NO. 4777-1975

#### PLUMBERS & STEAMFITTERS:

**Zones Covered:**

- **Zone 1:** Essex (East Orange, West Orange, South Orange, Maplewood and Livingston) County
- **Zone 2:** Middlesex (Mountainside to Old Bridge to the County Line and North thereof) County
- **Zone 3:** Middlesex (Adana, Berdina Corners, Dayton, Hanover, Hightstown, Highland Park, Kingston, Livingston Park, Joppa, Hillside, Ensema Town, New Brunswick, New Durham, North Brunswick Twp., North bergen, Old Bridge, Piscataway, Monmouth, South Brunswick Twp., South River, Spotswood and St. Peter'sville) and Centereach (Clyde, Middletown, South Bound Brook, Bounds Branch, Voorhees, Warren Twp. and West New Brunswick) Counties.

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**AREA COVERED BY PLUMBERS AND STEAMFITTERS ZONES:**

**Zone 1:** Bergen (Lodi, Garfield and Wallington and Passaic (Paterson) County.

**Zone 2:** Essex (West Orange, East Orange, South Orange, Maplewood and Livingston) County.

**Zone 3:** Middlesex (Mountainside to Old Bridge to the County Line and North thereof) County.

**Zone 4:** Middlesex (Adana, Berdina Corners, Dayton, Hanover, Hightstown, Highland Park, Kingston, Livingston Park, Joppa, Hillside, Ensema Twp., New Brunswick, New Durham, North Brunswick Twp., North bergen, Old Bridge, Piscataway, Monmouth, South Brunswick Twp., South River, Spotswood and St. Peter’sville) and Centereach (Clyde, Middletown, South Bound Brook, Bounds Branch, Voorhees, Warren Twp. and West New Brunswick) Counties.

---

**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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</thead>
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<tr>
<td>Group 1</td>
<td>15.31</td>
<td>7%</td>
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<tr>
<td>Group 2</td>
<td>13.69</td>
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<tr>
<td>Group 9</td>
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<tr>
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<tr>
<td>Group 14</td>
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50c per hour on machines where "Cat Head" or "Sheave Point" is at least 100 feet above ground level and less than 140 feet; 75c per hour on machines where "Cat Head" or "Sheave Point" is 140 feet or over above ground level.

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**CLASSIFICATION DEFINITIONS - POWER EQUIPMENT OPERATORS**

**GROUP 1 - Helicopters pilot/engineer**

**GROUP 2 - Autograde-combination subgrader, base WTL spreader & base trimmer (GTS & similar type); autograde placer-trimmer-spreader-combination (GTS & similar type); autograde slip form paver (GTS & similar type); back hoe (all types, including all combination hoe loaders); central power plants (all types); concrete paving machines; cranes (all types including overhead & straddle travelling type); cranes, gantry; dozers - land or floating (building & heavy construction rate only); drillmaster, quarry master (down the hole drill); draglines; elevator grader; engines, large diesel (1625 HP) and ataging pumps; front end loaders (5 yds & over); gradalls; grader, rager; helicopters co-pilot and communication engineer; jack, screw air hydraulic power operated unit or console type (not hand jack or pile load test type); locomotive (large); mucking machines; pavers (21E and over); paver, resilient, Brohill; pavement and concrete breaker (a superhammer); pavement breaker truck mounted; piloderiver; scoop (loader and shovel) Koshring; shovels; treechop; with boom; trench machine.

**GROUP 3 - Pump, staging**

**GROUP 4 - A-frame boom attachment on loaders; boring & drilling machines; brush chopper, chipper & shredder; cableways; carryalls; cherry picker - 6 tons & under (over 6 tons - crane rate applied); concrete pump; concrete pump system pumpscrete; squeezecrete & similar types; conveyors, 125' & over; excavator type (hilo, lull, hystrac similar type equipment); forklifts; front end loaders (2 yds but less than 5 yds); groove cutting machines (ride or type); heater plans; hoist (Chicago Boom); Pans, Letourneau, 726's, Ukes, pumpscrete-unit type; pumpscrete machines, squeezecrete & concrete pumping; scrapers-LeTourneau, 306's Ukes; side booms; squeezecrete; straddle carrier, hose and similar types; winch trucks (hoisting).

**GROUP 5 - Aerial platform (used as hoist); hoists all types except Chicago Boom type (building & heavy construction rate only); elevator or house cars (building and heavy construction rate only); roof hoists.

**GROUP 6 - Asphalt spreaders; bridge deck finisher; grader, finish only; roller-blacktop.
CLASSIFICATION DEFINITIONS
POWDER EQUIPMENT Operators (Cont'd)

GROUP 7 - Asphalt curbing machines; asphalt plant engineer; autograder tube finisher & texturing machine; autograder concrete machine; (CHU & similar types); autograder curb machine; (CHU & similar types); autograder curb (inner & sidewalk shoulder, slipform (CHU & similar types)); bender machine; (power); batcher, batching plant & crusher on site; beton convey or system; boilers and steam jennies (building & heavy construction rate only); borrow type skimmer machines (building & heavy construction rate only); car dumpers (carrload); compressor and blower type units; concrete breaking machines; concrete finishing machines; concrete mes & cutters (ride on type); concrete spreaders; hotels, reomatic & similar types; concrete vibrators (highway, road, street & sewer construction rate only); conveyors, under 125 ft; crushing machines; ditches machines, small (ditch winch or similar); drill doctor (duties include dust collector); dope pots (mechanical with or without pump); dumpers; fine grade machine (large type); front end loaders (1 yd & over but less than 2 yd) - highway, road, street & sewer construction rate only; front end loaders (under 2 yd) - building and heavy construction rates only; generators; giraffes grinders; grinders and corder patrol; grunicie machines (excluding nozzle); hammer vibratory (in conjunction with generator); hoppers; hopper doors (power operated); hoppers (power operated); ladders (rotated) - building & heavy construction rate only; ladcravory lights, portable generating light plants; locomotive (dinky type); machinery, mechnics (excluding paving machines); motor patrol and grader's, paving (under 21 st); pavement breakers - small, self-propelled ride on type (also maintain compressor or hydraulic unit); pike bending machine (power); pitch pumps; plater pump (regardless of size) - building & heavy construction rate only; post hole digger; rod bending machines (power); ceses, corder, recaen vulcanizing nicker; ciler, skinner machine (boon type); highway, road, street & sewer construction rate only; steam jennies and boilers; steel cutting machines, services & maintance; vibrating plants (used in conjunction with unloading); wielder and repair mechanic.

GROUP 8 - Compresor (2 or 3 within a total distance of 100' constitutes a battery) - building & heavy construction rate only; welding system, multiple (rectifier transformer type) - building & heavy construction rate only.
NOTICES

DECISION NO M177-1093

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------</td>
</tr>
<tr>
<td>GOVERNMENT ENGINER</td>
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<td>GROUP 8</td>
<td>12.00</td>
</tr>
<tr>
<td>GROUP 9</td>
<td>12.00</td>
</tr>
</tbody>
</table>

CLASSIFICATIONS DEFINITIONS

POWER EQUIPMENT OPERATORS

GROUP 1 - Helicopters' pilot/enginner

GROUP 2 - Cranes (all cranes - land or floating with beams - including jib, 140 feet and over above the ground); derricks (land or floating with beams including jib, 140 feet and over above the ground); helicopters co-pilot and communications engineer

GROUP 3 - Cranes (all cranes - land or floating with beams - including jib, less than 140 feet above the ground); derricks (land or floating, with beams including jib, less than 140 feet above the ground)

GROUP 4 - Aerial platform used as hoist; A-frame; cherry pickers - 6 tons and under (over 6 tons - crane rate applied); fork lifts; hoists (all types except Chicago Boom type); jacks (screw air hydraulic power operated unit or console type, not hand jack or pile load test type); side booms

GROUP 5 - Compressors (2 or 3 in battery); generators; welding machines (gas or electric converters of any type except battery multiple welders); welding system multiple (rectifier transformer type)

GROUP 6 - Maintenance engineer

GROUP 7 - Fireman

GROUP 8 - Compressor (single); rod bending machines (power); welding machines (gas or electric converters of any type - single)

GROUP 9 - Assistant engineer/oiler; straddle carrier.

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

DECISION NO M177-1093

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
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AREA COVERED BY ROOFERS ZONES

ZONE 1 - Bergen and Passaic Counties
ZONE 2 - Hunterdon and Somerset (Rocky Hill, Harlingen, Belle Haven, Mendham, Clover Hill, Montgomery 10, Skillman, Stoutsburg, Blauvelt, Centerville and Kingston) Counties
ZONE 3 - Essex, Hudson (west of the Hackensack River), Morris, Somerset (Potterville, Peapack, Gladstone, Bernardsville, Basking Ridge, Bedminster, Far Hills, Mine Brook, Lyons, Liberty Corner, Pluckemin, M. Bethel and Watchung), Sussex, Union (remainder of county) and Warren Counties
ZONE 4 - Bergen, Passaic and Sussex Counties
ZONE 5 - Essex, Hudson, Morris, Somerset (Potterville, Peapack, Gladstone, Bernardsville, Basking Ridge, Bedminster, Far Hills, Mine Brook, Lyons, Liberty Corner, Pluckemin, M. Bethel and Watchung), Sussex, Union (remainder of county) and Warren Counties
ZONE 6 - Middlesex, Somerset (remainder of county) and Union (Scotch Plains, Plainfield, Clark and Rahway) Counties
ZONE 7 - Hudson (remainder of county) County.
### Decisions

**Decision No. 3177-3093**

**Notices**

**Page 29**

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**Classification Definitions**

**Truck Drivers, etc.**

**GROUP 1 - Mechanic Helper**

**GROUP 2 - Drivers on the following type vehicles:** Straight Dumps, Flat, Floats, Pickups, Container Trailers, Fuel, Water Sprinkler, Road Oil, Stringer, Road, Hot Pano, Dan, Dumpers, Transit Mixers, Hauling Mixers, Bulk Trucks, Haul Truck, Bile-0-Static, Dynamic, Powder, X-Ray, Welding, Skid, Jeep, Station Wagon, Stringer, X-Truck, All Purpose Trailers, Trucks with mechanical tail gates, Asphalt Distributor, Batch Trucks, Seeding, Mucking, Fertilizer, Air Compressor Trucks (Intransit), Parts Changer, Escort, Schneider, Hi-life. Tokoman, Concrete Breaker, Gin Pole, Steam, Bob, Asphalt Distributor and Sprinkler, Hipper, Fuel Trucks (drivers on Fuel Trucks including handling of hose and nozzle-entire unit), Road Driven, Vacuum or Vac-all Trucks (entire unit), Skid Truck (drivanie container - entire unit), Concrete Mobilo Trucks (entire unit), Expediter (parts changer), Belteder Trucks, Pumpcrete Trucks, Line Truck, Roll-Truck, Western, Utility Trucks, Truck-Drives, Warehousemen, Warehouse Parts-men, Yardmen, Lift Truck in Warehouse, Helper when required on Lift Truck in Warehouse, Warehouse Clerk, Parts Man, Material Checker, Receive-tr, Shippers, Binning Men (Materials), Cardex Man, Helper when required on Bulkhip Coal Tar Epoxy Truck and Asphalt and Bituminous Distributor Truck, Drivers on the following type vehicles: Asphalt, Coal Tar Epoxy Truck, Little Ford Bituminous Distributor, Shurry Seal Truck or Vehicle, Thermo Track Hauler Pickup (Dump Cot Pickup), Bucket Loader Pump Truck and any Faster Tired Truck used in pulling and towing Farm Wagon and Trailers of any description, similar type vehicles, Off-site and On-site Repair Shop

**GROUP 3 - Drivers on straight 3-axle Trailers, Trucks and Floaters**

**GROUP 4 - Drivers on all Euclid Type Vehicles:** Euclid, International Harvester, Ward, Caterpillar, Hotlel, Treaders and Wagons, Pumpers, Straight, Easton, Rear and Side Dumps, Endville and Gogers (not self loading-loading over the top), Water Sprinkler Trailers, Water Pulls and similar type of Vehicles; Drivers on Tractors and Trailer type Vehicles: Float, Floats, &-Xc-c, Box Beds, Water Sprinkler, Bituminous Transit Mix, Road Oil, Float, Boatec Dumps, Rear Dumps, Offices, Shanty, Epoxy, Asphalt, Agitator Mixers, Hauling, Stringer, Seed- ing, Fertilizing Past, Sprod, Bituminous Distributor, Water Pulls (entire unit) (Tractor Trailer, Fuel Traler, and similar type of Vehicles)

**GROUP 5 - Mack Tractor Drivers**

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**

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### SHEET METAL WORKERS:

<table>
<thead>
<tr>
<th>Area</th>
<th>Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Eligibility Period</th>
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<td>54%</td>
<td>8%</td>
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<tr>
<td>Morris, Passaic, and Union Counties</td>
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<td>54%</td>
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### SOFT FLOOR LAYERS:

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### Truck Drivers:

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<th>Hours</th>
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<td>.96</td>
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</tbody>
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NOTICES

DEFINITIONS

4) a 'a

4) a 'a

Footnotes (cont'd)

g) Holiday: A half day's pay for Labor Day

h) Holidays: A through F, plus Washington's Birthday, Presidential Election Day and Veterans' Day providing the employee works any of the 3 days in the 5 days preceding the holiday and the first work day after the recognized holiday

i) Employer contribution of 3% based on the basic hourly rate plus Health and Welfare plus Pension and Vacation Fringes

j) Holidays: A through P, plus Lincoln's Birthday, Washington's Birthday, Good Friday, Memorial Day, Columbus Day and Veterans' Day, provided the employer has been able to work or 'shape' one day of the extended week during which the holiday falls

k) Employers working or receiving pay for 80 days within a year receive one week's vacation (40 hours); 126 days receive two weeks vacation (96 hours); 145 days receive 15 days (120 hours); 15 years seniority and 145 days receive 4 weeks vacation (160 hours)

l) Employer contribution of $1.60 per month per employee to Health and Welfare Funds

m) Holidays: A through P, plus Armistice Day and Washington's Birthday

ZONES

ZONE 1 - Bergen, Hudson, Hunterdon, Middlesex, Passaic, Somerect, Union (up to Woods Avenue south of Cranford) and Warren Counties

ZONE 2 - Essex, Morris, Sussex and Union (remainder of county) Counties

WELDERS - Receive rate prescribed for craft performing operation to which welding is incidental

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

Footnotes:

a) Employer contributes $8.00 per day per employee to an Annuity Fund

b) Holidays: A through F, plus Lincoln's Birthday, Washington's Birthday, Columbus Day, Election Day and Armistice Day

c) Employees with 6 months of service but less than 5 years of service receive 2 weeks vacation; 5 or more years of service receive 3 weeks vacation

d) Employees with 6 months of service but less than 5 years of service receive 2 weeks vacation; 5 years but less than 15 years of service receive 3 weeks; 15 or more years of service receive 4 weeks vacation

e) Holidays: A through F, plus Washington's Birthday, Veteran's Day and Presidential Election Day providing the employee works on 3 days for the same employer during a period of 10 working days, consisting of 5 working days before and 5 working days after the day upon which the holiday falls or is observed as such

f) Holidays: A through F, plus Washington's Birthday, Good Friday and Christmas Eve, providing the employer has worked 30 full days for the employer during the 90 calendar days immediately prior to the holiday, and the employee works his regularly scheduled work days immediately preceding and following the holiday.
### SUPREME DECISION

SYRACUSE, NEW YORK

COUNTY: ONONDAGA

Decision No. NY77-3087 Dated February 11, 1977 in 42 FR 8973

Description of Work: Building Construction (Excluding single family homes and garden type apartments up to and including 4 stories), heavy and highway construction.

<table>
<thead>
<tr>
<th>ASBESTOS WORKERS</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>10.00</td>
<td>.00</td>
<td>.00</td>
<td>.00</td>
</tr>
</tbody>
</table>

| BOILERMAKERS     |                    |       |          |          |                   |
|                  |                    |       |          |          |                   |
| 12.00            | .00                | .00   | .00      | .00      | .00                |

| BRICKLAYERS       |                    |       |          |          |                   |
| Bricklayers & stone masons | 12.40 | .00 | .00 | .00 | .00 |
| Torrazo workers & tile setters | 12.00 | .00 | .00 | .00 | .00 |
| Mason workers | 12.00 | .00 | .00 | .00 | .00 |

| CARPENTERS, BUILDING |          |       |          |          |                   |
| Grand Island north of White Haven Road | 12.00 | .00 | .00 | .00 | .00 |
| Carpenter | 12.00 | .00 | .00 | .00 | .00 |
| Millwright | 12.00 | .00 | .00 | .00 | .00 |

| Remainder of County, Building, Heavy and Highways |          |       |          |          |                   |
| Carpenter, dock carpenters, drivers, tenders, millwrights, and pliedrivermen | 12.00 | .00 | .00 | .00 | .00 |

| RIVERS |                    |       |          |          |                   |
|        |                    |       |          |          |                   |
| 12.00  | .00                | .00   | .00      | .00      | .00                |

| CEMENT MIXERS |                    |       |          |          |                   |
|                |                    |       |          |          |                   |
| 12.00  | .00                | .00   | .00      | .00      | .00                |

| ELEVATOR CONSTRUCTORS |          |       |          |          |                   |
|                      | 12.00 | .00 | .00 | .00 | .00 |

| ELEVATOR CONSTRUCTORS' HEADS & HELPER |          |       |          |          |                   |
|                                    | 12.00 | .00 | .00 | .00 | .00 |

| GLASSIERS |                    |       |          |          |                   |
|           | 12.00  | .00   | .00      | .00      | .00                |

| GRINDERS, STRUCTURAL, |          |       |          |          |                   |
| OSMANTILES & REINFORCING | 12.00 | .00 | .00 | .00 | .00 |

| Grand Island to White Haven Road | 12.00 | .00 | .00 | .00 | .00 |
| Remainder of County | 12.00 | .00 | .00 | .00 | .00 |

| LAYERS |                    |       |          |          |                   |
|        |                    |       |          |          |                   |
| 12.00  | .00                | .00   | .00      | .00      | .00                |

| Lumber |                    |       |          |          |                   |
|        |                    |       |          |          |                   |
| 12.00  | .00                | .00   | .00      | .00      | .00                |

| LINE CONSTRUCTION |          |       |          |          |                   |
| Line | 12.00  | .00   | .00      | .00      | .00                |

| Linemen |                    |       |          |          |                   |
|         | 12.00  | .00   | .00      | .00      | .00                |

| Cable Splicer |                    |       |          |          |                   |

| Grounds-ten digging machine operator | 12.00 | .00 | .00 | .00 | .00 |
| Grounds-ten mobile equipment | 12.00 | .00 | .00 | .00 | .00 |
| Grounds-ten truck driver and r. chml & eng. | 12.00 | .00 | .00 | .00 | .00 |
| Grounds-ten dynamo man | 12.00 | .00 | .00 | .00 | .00 |

### FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FOOTNOTES:
a Holidays: A through F
b Employer contributes 4% of basic hourly rate for 5 years or more of service or 24 basic hourly rate for 6 months to 5 years of service on Vacation Pay Credit
c Holidays: A through F; Washington's Birthday, Good Friday and Christmas Eve, providing employee has worked 30 full days during the 90 calendar days prior to the holiday and the regular scheduled work day immediately preceding and following the holiday
d Holidays: A through F; Washington's Birthday; Election Day for President of the United States and election of Governor of New York State, provided employee works the day before
e After one year, one week vacation; 2 years, 6 days vacation; 3 years, 7 days vacation; up to 2 weeks maximum vacation after completion of the 5th year, full vacation is earned by a driver who works 1040 hours or more in the calendar year, if an employee works less than 1040 hours in any calendar year, vacation will be prorated for either 1 or 2 weeks of vacation on the basis of using the number of hours worked as the numerator and 1040 as the denominator
f Holidays: A through F except where the employee is laid off 2 or more weeks prior to the holiday
g Employees shall be given time off with pay on election day in accordance with the New York State Election Laws

DECISION NO NY77-3087

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Bottom man, blaster; plumbing laborer, wagon drill operator; swing scaffold; pneumatic-gas-electric tool operator; tool operator (over 8 ft deep); mortar mixer; foundation laborer (over 8 ft deep); Rod carriers; plasterers; tender; plasterers, scaffolds; builders; pneumatic-gas-electric tool operator</td>
<td>8 555</td>
</tr>
<tr>
<td>Wagon drill operator; pneumatic-gas-electric tool operators; steel burners</td>
<td>8 405</td>
</tr>
<tr>
<td>Wrecking &amp; topper</td>
<td>8 305</td>
</tr>
<tr>
<td>Blaster: wagon drill operator; pneumatic-gas-electric tool operator; laborer: Top man</td>
<td>8 555</td>
</tr>
<tr>
<td>CUTTER</td>
<td>8 405</td>
</tr>
<tr>
<td>Bottom man; wagon drill operator; pneumatic-gas-electric tool operator; Top man</td>
<td>8 305</td>
</tr>
<tr>
<td>SOFT GROUND TUNNEL OR JACKING</td>
<td>8 905</td>
</tr>
<tr>
<td>Rodman (reinforced); welder</td>
<td>8 705</td>
</tr>
<tr>
<td>Concrete form mowers; monky hole man; side miner</td>
<td>8 655</td>
</tr>
<tr>
<td>Bottom shaft men</td>
<td>8 505</td>
</tr>
<tr>
<td>Tunnel-shaft muckers; shaft miner</td>
<td>8 555</td>
</tr>
<tr>
<td>Car pusher; concrete placing crew; bull gangs &amp; track gang</td>
<td>8 455</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO NY77-3087

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appt Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td><strong>ROCK TUNNEL</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodman (reinforcer) welder</td>
<td>8.905</td>
<td>1.55</td>
<td>1.40</td>
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<tr>
<td>Load heading rock drillers</td>
<td>8.705</td>
<td>1.55</td>
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<tr>
<td>Concrete form mice; side</td>
<td>8.655</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>heading rock drillers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plug hole and roof bolt</td>
<td>6.555</td>
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<tr>
<td>drillers; Hacking machine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>tender; tunnel &amp; shaft muck;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>shaft; sinking drillers</td>
<td>6.505</td>
<td>1.55</td>
<td>1.40</td>
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<tr>
<td>Bottom shaft man</td>
<td>6.455</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>Car pusher; ball &amp; track gang</td>
<td>6.305</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>concrete placing crew</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Top man</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MACHINE WORKERS AND CUST SEEKERS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt plant men, blacksmith</td>
<td>8.155</td>
<td>1.55</td>
<td>1.40</td>
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<tr>
<td>Dummers, gutterman, painters, &amp; smoothers</td>
<td>8.48</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>Rakers, screed men</td>
<td>8.59</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>Stone, wood &amp; brick pavers</td>
<td>8.50</td>
<td>1.55</td>
<td>1.40</td>
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<tr>
<td>Shovelers</td>
<td>8.45</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>Curb cutter helper</td>
<td>8.45</td>
<td>1.55</td>
<td>1.40</td>
</tr>
<tr>
<td>Curb cutter &amp; flag layer</td>
<td>9.24</td>
<td>1.55</td>
<td>1.40</td>
</tr>
</tbody>
</table>

### DECISION NO NY77-3087

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Basic Hourly Rates</th>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td><strong>LABORERS: HEAVY AND HIGHWAY CONSTRUCTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CLASS A</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborers, drill helper, flagmen, outboard and hand boats</td>
<td>8.055</td>
<td>1.50</td>
<td>1.45</td>
</tr>
<tr>
<td><strong>CLASS B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborers, drill operator, excavators, crane operators and generics</td>
<td>8.255</td>
<td>1.50</td>
<td>1.45</td>
</tr>
<tr>
<td><strong>CLASS C</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborers, crane operators and generics</td>
<td>8.455</td>
<td>1.50</td>
<td>1.45</td>
</tr>
<tr>
<td><strong>CLASS D</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laborers, crane operators and generics</td>
<td>8.655</td>
<td>1.50</td>
<td>1.45</td>
</tr>
</tbody>
</table>

#### Notes:
- Laborers: All rock or drilling machine operators (except quarry operator and similar type), acetylene torch op., asphalt raker, paver raker.
- **CLASS B**: Laborers; form cutters, stone or concrete curb cutters.
- **PAID HOLIDAYS**: A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

Federal Holiday:
- Paid holidays A through F, provided the employee has worked the day before and after the holiday.

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*Federal Register, Vol. 42, No. 131—Friday, July 8, 1977*
<table>
<thead>
<tr>
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<th>NY77-3087</th>
</tr>
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</table>

### POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Basic Hourly Rate</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP I</td>
<td>12 735</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP II</td>
<td>12 235</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP III</td>
<td>12 00</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP IV</td>
<td>12.04</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP V</td>
<td>11 955</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP VI</td>
<td>9 15</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP VII</td>
<td>11 235</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP VIII</td>
<td>8 835</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP IX</td>
<td>6 68</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP X</td>
<td>12 185</td>
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<tr>
<td>GROUP XI</td>
<td>11 90</td>
<td>1.00</td>
<td>75</td>
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<tr>
<td>GROUP XII</td>
<td>9 305</td>
<td>1.00</td>
<td>75</td>
</tr>
<tr>
<td>GROUP XIII</td>
<td>12 645</td>
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<td>75</td>
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<tr>
<td>GROUP XIV</td>
<td>8 335</td>
<td>1.00</td>
<td>75</td>
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<tr>
<td>GROUP XV</td>
<td>12 735</td>
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<td>75</td>
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<tr>
<td>GROUP XVI</td>
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</tr>
<tr>
<td>GROUP XVII</td>
<td>13 735</td>
<td>1.00</td>
<td>75</td>
</tr>
</tbody>
</table>

### BUILDING - POWER EQUIPMENT OPERATORS

**GROUP I:** Master Mechanic

**GROUP II:** All boom type equipment (100 ft or less), all jam and carry-all operators, archer hoist, back and pull hoe operator, blast or rotary drill, track or cat mounted, hoists used for power, boom trucks, cableway operator, concrete paver machine, crane operator, derrick operator, drilling operator, elevating grader (self-propelled), hand trench operator, hot roller (finishing course), hydraulic booms, hoist crane, maintenance engineer, machine operator, multiple drum hoist, (more than 1 drum in use), Pneumatic crane, pile driving machine operator, power grader machine operator, scrapper, shovel operator, skimmer operator, tractor shovel operator, vertical/hammer auger drill, well drilling machine

**GROUP III:** Back filling machine operator, clamshell loader, roller machine operator, snatch and pusher cat, stone cutter, trowel or self-propelled rollers, trenching machine operator

**GROUP IV:** Air hoist operator, cage hoist operator, conveyor operator, conveyor system, (belt-conveyor or similar), hoisting engine operator, house elevator, (when used for hoisting), industrial tractor, locomotive operator, (irrespective of power), push button hoist operator, straddle tower, tractor (when using winch power)

**GROUP V:** Concrete mixer operator, (1/2 c h p or over), gasoline driven boring machine, hydraulic system pumps, hoist hoist operator, finishing machine operator

**GROUP VI:** Air compressor operator, (under 150 C.F.M.), air compressor operator, (over 150 C.F.M.) generator mechanical heater, (when 3 are in a battery), power plant (in excess of 100K), welding machine operator, (to and including 3 machines)

**GROUP VII:** Bulldozer & tractor, (50 h p, drawbar or under), motorail

**GROUP VIII:** Fireman

**GROUP IX:** Truck crane driver

*FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977*
Notices

Decision No. NY77-3087

Building - Power Equipment Operators Cont'd

Group XI: Aggregate bin op, cement bin op, concrete mixer op, (under 40 y.), tractor machine

Group XII: Grout machine operator, heating boiler operator (used for temporary heat), lubrication unit on truck, pneumatic mixer operator

Group XIII: Pump operator (4" or over); pump operator 2-3 in a battery

Group XIV: Bulldozer & Tractor (50 hp. drawbar and under), jeep trench, muckers, power brooms 7 taken, feeders

Group XV: Apprenticeship engine or oiler, mechanical heaters (when 1 or 2 are used), pump operators (one inch), pump operators (2 inches), pump operators (3 inches)

Group XVI: Crane with boom over 100 feet

Group XVII: Crane with boom over 200 feet

Paid Holidays: A-New Year's Day; B-President's Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

Footnote:
A Holidays: A through F: Election Day

Decision No. NY77-3087

Power Equipment Operators: Heavy and Highway

Class 1

All boom type equipment all pan and carry-all operators, archer hoist (finish course), asphalt roller (finish course), asphalt spreader or paver, automatic fine grade machine (C H I and similar type), back filling machine operators, back and roll hoe operator, bolt place (C H I and similar type), black top plants, blast or rotary drill, truck or cat mounted, boiler (when used for power), boom trucks, boring machine operators, bulldozers (all sizes), cableway operator, calmer operator, cableway operator, central mix plant (and all concrete batching plants), cherry picker, concrete paver machine concrete pump, crane operator, derrick operator, dragline operator, dredge, elevating grader (self-propelled), excavator (all purposed hydraulically operated), forklift, front end loader, gradall, grader, head tower operator, hydro crane, hydraulic hoists, lubrication unit on truck, maintenance engineer, mucking machine operator, multiple drum hoist (more than 1 drum in use), overhead crane, pole crane or similar type, pile driving machine operator, pump control, push or snatch hook, quarry operator or equivalent, ready mix concrete plant, road winders, rock bit sharpeners (all types), screw auger, shovel, side boom, skimder operator, slip form paver (C H I and similar type), tire truck and repair, tractor drawn bolt type graders, trenching machine, tractor shovel operator, truck crane, tunnel shovel machine, well drilling machine winch, winch truck with a frame.

Federal Register, Vol. 42, No. 131—Friday, July 8, 1977
POWER EQUIPMENT OPERATORS: HEAVY AND HIGHWAY CONT'D

CLASS 2
Air hoist operator, automatic fine grade machine (C M I and similar type), belt placer (C M I and similar type), bonding machine (pipe), boring machine operator, bituminous spreader and mixer, cago hoist operator, concrete finishing machine, concrete mixer operator \( \frac{1}{4} \) cu. yd. or more, concrete saw—self-propelled, concrete spreader, conveyor operator, conveyor systems (belt or crete or similar), hoisting engine operator, house elevator (when used for hoisting), hydraulic pipe jack machine or similar type machines, hydro hammer or similar types, industrial tractor, kiln loader or similar type machines, locomotive operator, mixer for stabilized base self-propelled, monorail, plant engineer, push button hoist operator, roller machine operator, slip form paver (C M I and similar type), snorkel, stone crushers, strato-tower, towed or self-propelled, rollers, tractors (when used winch power), tractors (with towed accessories) tube finisher (C M I and similar type)

CLASS 3
Air compressors (under 160 cu. ft.), air compressors (over 160 cu. ft.), mechanics, heating systems, self-propelled, monorail, plant engineer, push button hoist operator, roller machine operator, slip form paver (C M I and similar type), snorkel, stone crushers, strato-tower, towed or self-propelled, rollers, tractors (when used winch power), tractors (with towed accessories) tube finisher (C M I and similar type)

CLASS 4
Fironmen, jeep trencher, motorized hydraulic seeders, plowing machine power broom and rakes

CLASS 5-A
Aggregate bid operator, apprentice engineer or olier, C M I and similar type, concrete spreader, cement bid operators, concrete mixer operator (under \( \frac{1}{4} \) cu. mechanical heaters (when one or two are used), pump operator (one inch), pump operator (two inch), pump operator (three inch), revirius widener, steam cleaner, tractor machines

CLASS 5-B
Truck crane driver

CLASS 5-C
Oiler


FOOTNOTE:
a Paid holidays: A through F, provided employee works the day before and after the paid holiday
NOTICES

SUPERSEDES DECISION

STATE: Ohio
COUNTY: Statewide
DECISION NO: OH77-2108
DATE: Date of Publication
 supersede Decision No OH77-2063, dated April 15, 1977 in 42 FR 20085
DESCRIPTION OF WORK: Heavy and Highway Construction

<table>
<thead>
<tr>
<th>BRICKLAYERS &amp; STONE MASON'S</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>ADAMS &amp; SCIOTO Cos</td>
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<td>&amp; VON HEUER Cos</td>
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<td>HARRIS, HANCOCK, HICKMAN,</td>
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<tr>
<td>HUMMEL, &amp; HAMPTON Cos &amp;</td>
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<tr>
<td>NARROW Co (except Townships</td>
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<td></td>
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<tr>
<td>of Crawford, Richland,</td>
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<td></td>
</tr>
<tr>
<td>Richland &amp; Tuscarawas)</td>
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<td></td>
</tr>
<tr>
<td>Bricklayers</td>
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<td>0.60</td>
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<td>Sewer Bricklayers</td>
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<td>DEWITT &amp; HICKMAN County &amp;</td>
<td>11.24</td>
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<tr>
<td>HAMILTON Cos (except</td>
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<tr>
<td>Townships of Dixon, Grant,</td>
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<tr>
<td>Leetonia, &amp; Leetonia)</td>
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<td>BUTLER &amp; WARREN Co &amp; PETERS</td>
<td>10.43</td>
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<td>Co (Townships of Dixon, Grant,</td>
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<td>Leetonia, &amp; Leetonia)</td>
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<td>CARROLL, CRAND &amp; TUSCARAWAS</td>
<td>10.79</td>
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<td>Cos &amp; FISKIN Co (Township</td>
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<tr>
<td>of Eureka, COWELL, LENNOX</td>
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<tr>
<td>Cos (Townships of Butler,</td>
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<tr>
<td>Hanover, Knox &amp; Union)</td>
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<td>CHAMPION, CLARK &amp; LOOMIS Cos</td>
<td>10.60</td>
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<tr>
<td>CLAYTON &amp; HIGHLAND Cos</td>
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<tr>
<td>COLUMBIA Co (Townships of</td>
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<tr>
<td>Center, Etna, Fairfield,</td>
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<tr>
<td>Halden, New Waterford,</td>
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<td>Perry, Salem &amp; Unity,</td>
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<tr>
<td>MASONING Co (except Union</td>
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<tr>
<td>Twp.)</td>
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DECISION NO: OH77-2108

<table>
<thead>
<tr>
<th>BRICKLAYER &amp; STONE MASON (CON'T)</th>
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<td>COLUMBIA County (Township of</td>
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<td>E LIVERPOOL, Franklin, Madison,</td>
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<td>St. Clair, Washington, Wayne &amp;</td>
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<td>YELLOW CREEK, JEFFERSON Co.</td>
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<td>COHOMON, CHERRY, HICK,</td>
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<td>LICKING, NORWAY &amp; MARION County</td>
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<tr>
<td>COWAN &amp; Co &amp; MEDINA Co (except</td>
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<tr>
<td>the Town of Benton,</td>
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<tr>
<td>WIGHTON, Homer, Richland &amp;</td>
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<tr>
<td>SPRINGFIELD)</td>
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<tr>
<td>DARKE, MIAMI, &amp; SHELBY Co</td>
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<td>HEGELMANN, PAULING, FULTON &amp;</td>
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<tr>
<td>WILLIAM Co &amp; FULTON Co (except</td>
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<tr>
<td>Twp. of Anson, Bolton &amp;</td>
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<tr>
<td>SAW CREEK, HICKORY Co (except</td>
</tr>
<tr>
<td>Town of Arcola, Liberty, Marion,</td>
</tr>
<tr>
<td>Monroe, Richfield, Washington &amp;</td>
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<tr>
<td>SE Side of Hurricane outside</td>
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<tr>
<td>City Limits of Napoleon)</td>
</tr>
<tr>
<td>HELMANN, FRANKLIN &amp; GIBBONS,</td>
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<tr>
<td>PICKWAR &amp; ENGLISH Co</td>
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<tr>
<td>BRICKLAYER</td>
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<tr>
<td>ERIC, HICKMAN &amp; HEBER, OTTAWA,</td>
</tr>
<tr>
<td>CAINSBURG, GENTRY,</td>
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<tr>
<td>WOOD (Peru &amp; BPA Twp.)</td>
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<tr>
<td>WINGARD (Tuscarawas, Crawford,</td>
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<td>Richland Twp.) &amp; ISLAND OF</td>
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<tr>
<td>LAKE ERIE NORTH OF CAINSBURG)</td>
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<tr>
<td>FAIRFIELD, HOOKS &amp; PERKINS Co</td>
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<td>FAYETTE, EAGLE &amp; PIKE Co</td>
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<td>GALENA &amp; HICKS Co.</td>
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<td>GLENDON &amp; LANE Co</td>
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<tr>
<td>GRIFFIN &amp; MONTGOMERY Co &amp; the</td>
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<tr>
<td>remainder of FAIETTE Co</td>
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</tbody>
</table>

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. OR77-2108

#### bricklayers & Stonemasons (Cont'd)

| NOBLE Co (Tops of Beaver, Buffalo, Marion, Seneca & Wayne) | 9 68 | 45 | 50 | 02 |
| HARRISON Co & the remainder of JEFFERSON Co | 10 53 | 50 | 50 | 02 |
| JACKSON & VINTON Cos | 10 50 | 50 | 50 | 02 |
| LAWRENCE County | 9 00 | 40 | 40 | 01 |
| LOUIS Co & the remainder of MEDINA Co | 12 10 | 40 | 50 | 01 |
| LUCAS Co & the remainder of FULTON Co & WOOD Co (Tops of Lake, Perryburg & Ross) | 11 65 | 73 | 80 | 01 |
| PORTAGE & SUMMIT Cos | 10 97 | 57 | 50 | 02 |
| TRUMBULL County | 11 84 | 40 | 50 | 02 |
| WASHINGTON Co & the remainder of NOBLE Co | 10 10 | 50 | 50 | 04 |
| The remainder of WOOD & HENRY Cos | 11 86 | 65 | 45 | 01 |

#### Carpenters & Piledrivermen

| ADAMS, FAYETTE, GALIA, HIGHLAND, JACKSON, LAURENCE, MEIGS, PLE, RUS, & SCITU COS | 10 41 | .50 | 75 | 03 |
| Carpenters | 10 70 | 50 | 75 | 03 |
| Piledrivermen | 10 47 | .40 | 70 | 02 |
| ALLEN, AUGLAIZE, CHAMPAIGN, CLARK, COHESCTON, DELAWARE, FAIRFIELD, FRANKLIN, GUERNSEY, HAMSIN, HOLLIS, KNOX, LICKING, LOGAN, MADISON, MARION, MERCER, MORGAN, MORRISTOWN, NOBLE, PERRY, PICKAWAY, PUTNAM, UNION, VAN WERT, & WYANDOT Cos | 9 87 | .40 | 70 | 02 |
| Carpenters | 10 76 | 50 | 50 | 02 |
| Piledrivermen | 9.52 | .40 | .50 | 01 |

### DECISION NO. OH77-2108

#### Carpenters & Piledrivermen (Cont'd)

| ASHLAND, CRAGFORD, HUNION, LOBAIN and RICHLAND Counties | 10 66 | 70 | 1.00 | a | 04 |
| Carpenters Piledrivermen | 10 66 | 70 | 1.00 | a | 04 |
| ERIE (East of B & O Rail Road Tracks) | 10 66 | 70 | 1.00 | a | 04 |
| Carpenters Piledrivermen | 12 10 | 77 | 1.25 | a | 03 |
| ERIE (East of B & O Rail Road Tracks), CANTON, SANDUSKY and SENECA Counties and City of Portsmouth in Wood and HANOCK Counties | 10.66 | 70 | 1.00 | a | 04 |
| Carpenters Piledrivermen | 11 97 | 73 | 50 | 05 |
| ASHTABULA, CUYAHOGA, CUYUGA and LAKE Counties | 10.66 | 70 | 1.00 | a | 04 |
| Carpenters Piledrivermen | 11 97 | 73 | 50 | 05 |
| ATHENS HOCKING, VINTON and WASHINGTON Counties | 10.66 | 70 | 1.00 | a | 04 |
| Carpenters Piledrivermen | 11 97 | 73 | 50 | 05 |

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**FEDERAL REGISTER, VOL. 42, NO 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>Carpenters &amp; Piledrivermen (Cont'd)</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apr Tr</th>
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<tr>
<td>for Workers in Certain Counties</td>
<td>H &amp; W Pensions</td>
<td>Vacation</td>
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<tr>
<td>Cuyahoga, Hamilton, Jefferson, Lucas, Mahoning and Trumbull Counties</td>
<td>10 35 65 1.00 .05</td>
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<tr>
<td>Cuyahoga, Lucas, Mahoning, and Trumbull Counties</td>
<td>11 35 70 1.00 .05</td>
<td></td>
<td></td>
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<tr>
<td>Mahoning and Trumbull Counties</td>
<td>11 50 70 1.00 .05</td>
<td></td>
<td></td>
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<tr>
<td>Medina, Portage, and Summit Counties</td>
<td>10 60 70 1.00 .05</td>
<td></td>
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<tr>
<td>OHIO: 2 Paid Holidays: Memorial Day and Independence Day</td>
<td>10 60 70 1.00 .05</td>
<td></td>
<td></td>
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<tr>
<td>Electricians:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Adams and Scioto Counties</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adams and Scioto Counties, Jackson County (all but Coal, Jackson, Liberty, Nelson and Washington Towns), Pike County (Tope of Cape Creek, Harrison, Nelson, Scioto, Sunfish and Union)</td>
<td>10 75 70 1.02 .04</td>
<td></td>
<td></td>
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</tbody>
</table>
### DECISION NO. GM77-2108

#### ELECTRICIANS (CONT'D)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

- **CLINTON, DARKE, GREENE, MIAMI, HAMILTON, MONTGOMERY, & Preble Cos.**
  - Within 11 Mi radius of 3rd & Main Streets, Dayton:
    - $11.43
  - Beyond 11 Mi radius:
    - $11.66
- **COLUMBIANA Co.** (except Tp of Butler, Fairfield, Knox, Perry, Salem, & Unity):
  - $10.26
- **COSHOCTON Co., Knox (Jackson, Clay, Morgan, Muskingum, Hartford, Hilliard, Butler, Harrison, Pleasant, & College Tp).**
- **LUCAS Co.**
- **TUSCARARA Co.** ($1 incl Tps of Auburn, Clay, Rush, York, Salem, Jefferson, Oxford, Washington, Perry, & Bucks)
- **Cuyahoga Co., Lorain Co.** (Tps of Cleveland, Akron, & Geauga Co. Tps of Bainbridge, Chester & Russell).
- **Defiance Co., Fulton, Hancock, Henry, Lucas, Ottawa, Paulding, Putnam, Sandusky, Seneca, Williams & Wood Co.**
- **DUPMERS, Fairfield, Franklin, & Union Co.**
  - Madison (Rem of Co.), Pickaway Co. (Excl Deer Creek, Perry, Pickaway, Salt Creek & Wayne Tps)
- **ERIE Co., Huron Co.** (Rem of Co.)
  - $11.48
- **FAYETTE, Knoxland, Rocking, & Ross Cos. & Jackson Co.** (Rem of Co.), Pickaway, Pike & Vinton Co.
  - $10.95
- **GALLIA Co.**
  - $11.47

### DECISION NO. GM77-2108

#### ELECTRICIANS (CONT'D)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

- **Guernsey, Muskingum and Perry Cos.**
  - Harrison and Jefferson Counties and Carroll County (south of I-71, Harrison, Rose and Washington Tps)
  - $12.00
- **Hones and Stark Counties, the remainder of Carroll and Tuscarara Co., Columbus County (Knox Tp), Hocking County (Smith Tp), and Wayne County (south of Alum Creek, Chester, Green and Wayne Tps)
  - $11.75
- **Lake County and Geauga County (all but Aurora, Bainbridge, Chester, Middlefield, Parkman, Russell and Troy Tps)
  - $11.48
- **Lawrence County**
- **Lorain County (remainder of Co.)**
  - Medina County (Tps of Kirtland and Liverpool) & Mansfield County (excluding Hilt and Smith Tps)
  - $11.60
  - $12.55
- **Summit County, the remainder of Medina and Wayne Counties and Portage County (excluding Tps of Cleveland, Beachwood, and Richfield)
  - $12.33
- **Morgan County**
  - $9.40
- **Ashtabula (remainder of County), remainder of Portage and Trumbull Counties, Geauga County (Tps of Aurora, Middlefield, Parkman, and Troy), and Hocking County (Twp of Jackson)
  - $12.59

### DECISION NO. D77-2108

#### IRONWORKS:

<table>
<thead>
<tr>
<th>ADAMS (Part), BROWN, CLEMONST and HAMILTON Counties and the South half of BUTLER and WARREN Cos. Structural and Ornamental Reinforcing</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADAMS, ALLEN, ASHTAN, CLINTON, DARKS, GREENE, MCKINZ, MIAMI, MONROE-MEDINA, WRIGHT, &amp; SUMMIT Cos., the North 5/8 of BUTLER &amp; WARREN Cos., the West 3/4 of CAMP HAMILTON &amp; BOARD Cos., the West 1/4 of HIGHLAND Cos.</td>
<td>11.88</td>
<td>1.05</td>
</tr>
<tr>
<td>Outside Dayton Metro Area</td>
<td>10.96</td>
<td>1.25</td>
</tr>
<tr>
<td>ASHLAND, CARROLL, COSHOCTON, FREMONT, HARDIN, HARRISON, MARION, MOHICK, &amp; WAYNE Cos.</td>
<td>11.88</td>
<td>1.05</td>
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<tr>
<td>Outside Dayton Metro Area</td>
<td>11.88</td>
<td>1.25</td>
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<tr>
<td>ASHLAND, CRAWFORD, CLINTON, HAMILTON, HANCOCK, WARREN &amp; WAYNE Cos.</td>
<td>11.88</td>
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<tr>
<td>Outside Dayton Metro Area</td>
<td>12.22</td>
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<tr>
<td>ASHTABULA (Remaider of Co.)</td>
<td>11.88</td>
<td>1.05</td>
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<td>ATHENS, HARRIS, HOLLAND, HURON, &amp; WAYNE Cos.</td>
<td>11.88</td>
<td>1.25</td>
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<td>ASHTABULA CO.</td>
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<td>COLUMBIA, HARRISH &amp; TRUMBULL Cos.</td>
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<td>1.25</td>
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<td>CRAWFORD, FAVER, HARDIN, HARRAP, HARRIS, HARRIS, HARRIS, HARRIS, HARRIS, HERMAN, HICKS, HICKS, HICKS, &amp; SUMMIT Cos.</td>
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<td>1.05</td>
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<tr>
<td>DELAWARE, FAIRFIELD, LEWIS, HAMILTON, HANCOCK, HARRISON, &amp; HARRISON Cos.</td>
<td>11.88</td>
<td>1.25</td>
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<tr>
<td>DAUPHIN, FAYETTE, JEFFERSON, &amp; HUNTINGTON Cos.</td>
<td>11.88</td>
<td>1.25</td>
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<tr>
<td>FULTON, HURON, HURON, HUDSON, LUCAS, MONTGOMERY, &amp; SUMMIT Cos.</td>
<td>11.88</td>
<td>1.25</td>
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<tr>
<td>WAGNER, WAGNER, &amp; WAGNER Cos.</td>
<td>11.88</td>
<td>1.25</td>
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<tr>
<td>WASHINGTON CO.</td>
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<tr>
<td>WASHINGTON CO.</td>
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#### DECISION NO. D77-2108

#### LINESHIPS:

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<th>ADAMS, ATHENS, GALLIA, LAMARCHE, MERRI, &amp; SCIOTO</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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</thead>
<tbody>
<tr>
<td>ADAMS, ALLEN, ASHTAN, CLINTON, DARKS, GREENE, MCKINZ, MIAMI, MONROE-MEDINA, WRIGHT, &amp; SUMMIT Cos., the North 5/8 of BUTLER &amp; WARREN Cos., the West 3/4 of CAMP HAMILTON &amp; BOARD Cos., the West 1/4 of HIGHLAND Cos.</td>
<td>11.88</td>
<td>1.05</td>
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<tr>
<td>Outside Dayton Metro Area</td>
<td>10.96</td>
<td>1.25</td>
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<td>7.75</td>
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<tr>
<td>Outside Dayton Metro Area</td>
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<td>ASHTABULA (Remaider of Co.)</td>
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<td>ATHENS, HARRIS, HOLLAND, HURON, &amp; WAYNE Cos.</td>
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<td>1.05</td>
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<td>1.25</td>
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<td>FULTON, HURON, HURON, HUDSON, LUCAS, MONTGOMERY, &amp; SUMMIT Cos.</td>
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<td>WAGNER, WAGNER, &amp; WAGNER Cos.</td>
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<td>WASHINGTON CO.</td>
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<td>WASHINGTON CO.</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
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<tbody>
<tr>
<td><strong>LINEHAN</strong> (CONT'D)</td>
<td><strong>Fringe Benefits Payments</strong></td>
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<tr>
<td><strong>Basic Hourly Rates</strong></td>
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<tr>
<td>CHAPAIG, &amp; CLARK COS</td>
<td>9 11</td>
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<td>CLINTON, DARKE, GREENS, HAM, MONTGOMERY, &amp; HEBBLE COS</td>
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<td>WARREN CO (Rem. of Co)</td>
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<td>COLUMBIA Co except the Tups of Butler, Knox, Fairfield, Perry, Salem &amp; Unity</td>
<td>10 43</td>
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<td>COSHOCTON &amp; TUSCARAAS Co</td>
<td>11 72</td>
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<tr>
<td>CUYAHOGA Co &amp; GEEGA Co (Tups of Bainbridge, Chester, &amp; Russell), LORAIN Co (Columbia Tups)</td>
<td>12 76</td>
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<tr>
<td>DEPTNIGS, FULTON, HANCOCK, HENRY, JACOK, OTAWA, PAULDING, PUTMAN, SANDUSKY, SENECA, WILLIAMS &amp; WOOD Co.</td>
<td>12 41</td>
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<td>DELAWARE, HADDON, PICKIV &amp; UNION Co.</td>
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<td>ERIE Co &amp; HUNIC Co (Remainder of Co)</td>
<td>11 73</td>
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<td>FAIRFIELD &amp; LICKING Co &amp; KNOX Co (Remainder of Co)</td>
<td>10 95</td>
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<td>FAYETTE, HIGHLAND, HOCKING &amp; ROSE Co &amp; the remainder of JACKSON, PIKE &amp; VINTON Co</td>
<td>9 88</td>
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**FOOTNOTES:**
- 9 paid holidays: New Year’s Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day; New Year’s Eve & Day after Thanksgiving Day.

**PAYMENTS:**
- Brush
- Spray

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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977

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<table>
<thead>
<tr>
<th>PAINTERS (CONT'D)</th>
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<td>ALLEN, ADAMS, DEFANCE, HARDIN, MARION, MONROE, and RICHLAND Counties</td>
<td>$ 8.90</td>
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<tr>
<td>Brush</td>
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<td>Spray</td>
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<tr>
<td>ATHENS and HOPKINS Counties: Brush</td>
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<tr>
<td>BERNARD, CLARK, and HAMILTON Cos</td>
<td>Brush</td>
</tr>
<tr>
<td>Spray</td>
<td>10.80</td>
</tr>
<tr>
<td>BUTLER and WARREN Counties: Brush</td>
<td>10.23</td>
</tr>
<tr>
<td>Spray</td>
<td>10.73</td>
</tr>
<tr>
<td>CRAWFORD, HOLLIDAY, STARK, TUSCARAWAS and WAYNE Counties</td>
<td>Brush</td>
</tr>
<tr>
<td>Structural Steel</td>
<td>9.97</td>
</tr>
<tr>
<td>CUMBERLAND, CLARK and LOGAN Cos</td>
<td>Brush</td>
</tr>
<tr>
<td>Structural Steel</td>
<td>8.35</td>
</tr>
<tr>
<td>Spray</td>
<td>8.50</td>
</tr>
<tr>
<td>CLINTON, DAVE, GREENE, HANIA, MONTGOMERY and FREHSE Counties</td>
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</tr>
<tr>
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<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>CUYAHOGA, GENOA, and LAKE Cos, LOYIN, and SUMMIT Counties</td>
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</tr>
<tr>
<td>North of the Ohio Turnpike</td>
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</tr>
<tr>
<td>Closed steel above 55'</td>
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</tr>
<tr>
<td>DARLINGTON, FAIRFIELD, FAYETTE, FRANKLIN, MADISON, PICKAWAY and UNION Counties</td>
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</tr>
<tr>
<td>Structural Steel</td>
<td>9.75</td>
</tr>
<tr>
<td>Spray</td>
<td>9.95</td>
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<tr>
<td>ERIE, HAMMOND, HUDSON, SANDUSKY, SERIES, and WYANDOTT Counties</td>
<td>Brush</td>
</tr>
<tr>
<td>Structural Steel and Bridges</td>
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</tr>
<tr>
<td>FULTON, HENRY, LUCAS, and OWEN Counties</td>
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</tr>
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<td>Structural Steel</td>
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<tr>
<td>GALNASA, LAKESIDE, MENSIE, and WINTON Counties</td>
<td>Brush</td>
</tr>
<tr>
<td>Spray</td>
<td>9.75</td>
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<tr>
<td>GUERIN County</td>
<td>Brush</td>
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<td>Structural Steel</td>
<td>7.50</td>
</tr>
<tr>
<td>Tank and Bridges</td>
<td>8.75</td>
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<tr>
<td>HARRISON and JEFFERSON Counties: Brush</td>
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<td>Spray</td>
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<tr>
<td>Hot Slacks</td>
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<td>KNOX, LICKING, MEKING, and VERNON Counties: Brush</td>
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### DECISION NO. CH77-2108

#### PAINTERs (CONT'D)

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<th>Co. Name</th>
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<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Appr Tr</th>
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<td>MONROE &amp; SUMMIT Cos.</td>
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<td>60</td>
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<tr>
<td>MEDINA Co. &amp; PORTAGE Co.</td>
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<tr>
<td>HARRISBURG &amp; YORK Co.</td>
<td>9 40</td>
<td>62</td>
<td>60</td>
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<tr>
<td>WASHINGTON Co.</td>
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<td>62</td>
<td>60</td>
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<tr>
<td>ROSS Co.</td>
<td>10 00</td>
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<tr>
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#### PLUMBERS & STEAMFITTERS (CONT'D)

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<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Appr Tr</th>
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<tr>
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<tr>
<td>CARROLL Co. (South Half)</td>
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<td>65</td>
<td>1 10</td>
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<tr>
<td>CARROLL Co. (except Cos. of Ross, Monroe, Union, Lee, Orange, Perry &amp; London)</td>
<td>11 82</td>
<td>65</td>
<td>1 10</td>
<td></td>
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<tr>
<td>CARROLL (Cos. of Ross, Monroe, Union, Lee, Orange, Perry Co. line, HARRISBURG, NOBLE, &amp; TUSCARAWAS Cos.)</td>
<td>11 42</td>
<td>45</td>
<td>55</td>
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<tr>
<td>CHAMPAIGN, CLARE &amp; ROY Co.</td>
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<tr>
<td>GREENE Co.</td>
<td>11 32</td>
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<td>MADISON Co.</td>
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<td>50</td>
<td>80</td>
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<tr>
<td>CLINTON, DARE, FAYETTE, MIAMI, MONROE, PENDLETON &amp; SHELBY Cos.</td>
<td>11 81</td>
<td>55</td>
<td>80</td>
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</tr>
<tr>
<td>COLUMBIANA &amp; WARREN Co. &amp; TRUMBULL Co.</td>
<td>12 21</td>
<td>75</td>
<td>50</td>
<td></td>
<td></td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. OH77-2108

#### PLUMBERS & STRAMFITTERS (CONTD)

<table>
<thead>
<tr>
<th>Localities</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
<tbody>
<tr>
<td>DEFIANCE, FULDA, HANNIBAL, HERNANDO, KNOXVILLE, PUTNAM, SANGER, SEQUOIA, WILLIAMS &amp; WOOD CO.</td>
<td>$12.50</td>
<td>.00</td>
<td>.00</td>
<td>.00</td>
<td>09</td>
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<tr>
<td>BISHOP, BROWN, BURLINGTON, CHAMBER, CINCINNATI, DAVISON, ELYRIA, MARION, NEWARK, PICKAPANY, ROSS &amp; UNION CO. &amp; MADISON (remainder of Co.)</td>
<td>12.32</td>
<td>.50</td>
<td>.00</td>
<td>.00</td>
<td>.05</td>
</tr>
<tr>
<td>MICHIGAN, MURRAY, NETHERLANDS (remainder of Co.), MORGAN (remainder Co.), &amp; PORTAGE &amp; WASHINGTON CO.</td>
<td>10.90</td>
<td>.55</td>
<td>.00</td>
<td>.00</td>
<td>.045</td>
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<tr>
<td>MEDINA &amp; SUMMIT CO.</td>
<td>10.61</td>
<td>.75</td>
<td>.00</td>
<td>.00</td>
<td>.04</td>
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<td>TRUMBULL CO. (remainder of Co.)</td>
<td>10.75</td>
<td>.55</td>
<td>.00</td>
<td>.00</td>
<td>.01</td>
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**FOOTNOTE:**
- One paid holiday: Labor Day. Providing the employee has worked 5 consecutive days before and after the holiday.

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### DECISION NO. OH77-2108

#### LABORERS

<table>
<thead>
<tr>
<th>ZONE 1</th>
<th>ZONE 2</th>
<th>ZONE 3</th>
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<td>Basic Hourly Rates</td>
<td>Basic Hourly Rates</td>
<td>Basic Hourly Rates</td>
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<tr>
<td>GROUP I</td>
<td>$ 9.53</td>
<td>8.70</td>
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<tr>
<td>GROUP II</td>
<td>9.652</td>
<td>8.835</td>
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<td>GROUP III</td>
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<td>8.90</td>
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<tr>
<td>GROUP IV</td>
<td>9.80</td>
<td>9.05</td>
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<tr>
<td>GROUP V</td>
<td>9.90</td>
<td>9.35</td>
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</table>

**FRINGE BENEFITS FOR ALL ZONES AND CLASSIFICATIONS**

- $ 65 - Health & Welfare
- 40 - Pension
- 10 - Education and/or Apprenticeship Training

**ZONE DEFINITIONS**

- **Zone 1** - Cuyahoga, Geauga & Lake Cos
- **Zone 2** - Ashtabula, Erie, Huron, Lorain, Lucas, Mahoning, Medina, Ottawa, Portage, Stark, Summit, Trumbull & Wood Cos
- **Zone 3** - Remainder of Counties

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
### POWER EQUIPMENT OPERATORS

**ZONE I - Columbiana, Mahoning & Trumbull Counties**

<table>
<thead>
<tr>
<th>Class</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W Pensions</th>
<th>Education and/or Appr Tr</th>
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<tbody>
<tr>
<td>Class I</td>
<td>$12.01</td>
<td>65</td>
<td>80</td>
</tr>
<tr>
<td>Class II</td>
<td>$11.32</td>
<td>65</td>
<td>80</td>
</tr>
<tr>
<td>Class III</td>
<td>10.68</td>
<td>65</td>
<td>80</td>
</tr>
<tr>
<td>Class IV</td>
<td>10.27</td>
<td>65</td>
<td>80</td>
</tr>
<tr>
<td>Class V</td>
<td>10.17</td>
<td>65</td>
<td>80</td>
</tr>
<tr>
<td>Class VI</td>
<td>10.28</td>
<td>65</td>
<td>80</td>
</tr>
</tbody>
</table>

**CLASS I** - Asphalt planer heater; Austin western & similar type; Backhoe; Batch plant-concrete mix; Batch plant-portable concrete; Bem builder; Auto; Backfiller w/drag attachment; Boat dredger; Boat-tug; Boring mach attached to tractor; Bulldozer; Bulldozers; C M I road builder & similar types; Cabo placer & layer; Carrier-straddle; Carryall scraper or scoop; Chicago boom; Conductor w/blade attached; Concrete spreader finisher comb; Crane; Crane-stationary or climbing; Crane-electric overhead; Crane-slime boom; Crane truck; Crane-tower; Derrick-boom; Derrick-car; Diggers-wheel (not trencher or road widener); Double nine; Drag line; Dredge; drill-Kenny or similar type; Electrostatic; Fork lift; Frankie pile; Gradally Grader-power; Curvy; Curvy-self-propelled; High lift; Holst-monorail; Holst-stationary & mobile tractor; Hoeist-2 or 3; Jackall; Jumbo mach; Kocak or Kuhlman land-sea-going vehicle; Loader - Elevating; Loader-Front end; Locomotive; Mechanic as welder; Metro slip harvester w/boom; Huckling mach; Favor-asphalt finishing mach; Favor-road concrete; Favor-asphalt form; Paver crete mach; Post driver; Power driven hydraulic pumps & jackets; Pump-crete machine; Regulator-ballast; Reise-drilling; Shovel; Spikerester; Stonecrusher; The pulley & loader; Tie tamper; Tractor-double boom; tractor w/attachments; Trucks-boom; Truck-tire-assigned to job; Trench mach; Tunnel machine (Mark 21); Trolley; Traylet

**CLASS II** - Asphalt plant; bonding machine; Boring mach; Chip harvester w/o boom; cleaning mach - pipeline type; Coating Mach-pipeline type; Concrete belt placer; concrete finisher; Concrete planer or asphalt; Concrete spreader; Elevator; Fork lift walk behind; form line mach; Grease truck op; Grout pump; Gunite mach; Huck bolting Mach; Hydraulic scaffold; Paving breaker; Pipe dray; Pot fireman; Power booms; Refrigeration plant; Sacramento; SCALING Mach; Self-propelled mobile vibrator compactor or roller; Holst-single drum; Soil Stabilizer (pump type); Spray cure Mach - self-propelled; Sawdust blower mach; Sub-grades; Tube finisher or boom C M I or similar type; Tugger Holist

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>ZONE</th>
<th>ZONE</th>
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<tr>
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<td>Fringe Benefits Payments</td>
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<tr>
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<td>H &amp; W</td>
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<tr>
<td>CLASS A</td>
<td>512.03</td>
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<tr>
<td>CLASS B</td>
<td>11.93</td>
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<tr>
<td>CLASS C</td>
<td>10.69</td>
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<tr>
<td>CLASS D</td>
<td>8.73</td>
</tr>
</tbody>
</table>

CLASS A - Air compressor on steel erection; Asphalt plant engineer (Cleveland District only); Boiler Op, compressor or generator when mounted on rig; Calaway; combination concrete mixer & tower; Concrete plants (over 4 yds cap.); Concrete pumps; Crane (all types incl. A-frame, boom truck, cherry picker); Derrick; Dragline; Excav (drill or suction); Excavator; generator; Floating equipment (all types); Helicopter crew (helit. & winch); Hoist (all types); Holding engine (including shaft & tunnel work); Industrial type tractor; Jet engine dryer (22 or 23) diesel tractor; Locomotive (standard gauge); Maintenance Op; Class A; Mixer (paving single or double drum); Mucking hand; Multiple scraper; Pile driving, each (all types); Power shovel; Quad 9 (double pusher); Refrigerating (fresher operation); Rotary drill on calson work; Slip form paver; Trier; Trencher; Trencher (over 24" wide), Trench. Track mounted concrete pump; Tug boat; Tunnel, and/or mining machine; Wheel excavator; Diving (over 48"), Bulldozer, Endo, Endo-Endo, Endo-Leader (production type diesel); Lead 

CLASS B - Air compressor on tunnel work (low pressure); asphalt plant engineer (in Zone 2, Portage & Summit Cos. only); Concrete mixers (24" wide & under); Concrete mixers (more than 1 bag cap.); Concrete mixers (1 bag cap. - 12" loader); Power tools (over 24" wide); Pile driving, each; Pile, each; Pump, erecting or operating well points; Pump (6" over discharge); Rollers (asphalt) Utility Op. (small equipment); WELDING EQUIPMENT OPERATORS (cont'd)

CLASS D - Dredge firing, asphalt plant; Helpers; Inboard-outboard, motor boat-launch; Oil heaters (asphalt plant); Oilers; Power driven heaters; Pump (under 25" discharge); Signalsmen; TIRE REPAIRMEN

ZONE 2 - Ashtabula, Cuyahoga, Erie, Geauga, Lake, Lorain, Medina, Portage & Summit Counties

ZONE 3 - Remainder of counties

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
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<th>TRUCK DRIVERS</th>
<th>ZONE I - CUYAHOGA, LAKE &amp; GEauga COUNTIES</th>
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<tr>
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<tr>
<td>CLASS IV</td>
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</tbody>
</table>

CLASS I - Straight & skids (including asphalt); Warehousemen; Straight fuel
CLASS II - Semi fuel; semi pole drivers (hauling steel pipe); & semi tractor drivers
CLASS III - Ready-mix; egitator or bulk concrete drivers; dry batch truck
CLASS IV - Euclid, dart; tank asphalt sprayers; low boys; carry-all
driver; tourniers; hi-lifts; fork lifts; extra long trailers & semi pole trailers except when hauling steel pipe; double hook-up tractor trailers including team track & railroad siding; semi tractor & tri-axle trailers; tandem tractor, tandem trailer & tri-axle trailer; bag along trailer, expandable trailers, loads (requiring road permits)

PAID HOLIDAYS:
A- New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F- Christmas Day

FOOTNOTES:

a For week Per employee
b One week's paid vacation for one year of service; two weeks for five years;
three weeks for ten years & four weeks for seventeen years
c Seven paid holidays: A through F plus National Election Day
<table>
<thead>
<tr>
<th>Occupation</th>
<th>Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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<td>LABORERS</td>
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<table>
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<td>PAINTERS</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
<table>
<thead>
<tr>
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<th>Fringe Benefits Payments</th>
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<td>H &amp; W</td>
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<tr>
<td>Laborers:</td>
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<tr>
<td>air tool operator (jackhammer, vibrator)</td>
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<td>asphalt raker</td>
<td>2.82</td>
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<td>pipelineyo</td>
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<td>Plumbers and Pipelayers</td>
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<td>Truck Drivers:</td>
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<tr>
<td>3/4 ton to 3 ton</td>
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<td>1.5 ton to 3 ton</td>
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<tr>
<td>3/4 ton to 3 ton</td>
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<td>Power Equipment Operators:</td>
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## SUPERSEDES DECISION

**STATE:** Tennessee  
**COUNTY:** *See below*  
**DECISION NUMBER:** TN77-1042  
**DATE:** Date of Publication  
**Supersedes Decision No:** TN77-1052 dated May 6, 1977, in 42 FR 23427, and No  
TN77-1037 dated April 1, 1977 in 42 FR 17780  
**DESCRIPTION OF WORK:** Building Construction (does not include single family homes or garden type apartments of 4 stories or less)

*Counties: All of Knox and Monroe, and those portions of Anderson & Roane which comprise the Oak Ridge Energy Research and Development Administration site.*

<table>
<thead>
<tr>
<th>Daily Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Fringe Benefits Payments</th>
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<tbody>
<tr>
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<td>H &amp; W</td>
<td>Pension</td>
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<td>Cable splicer</td>
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<td>Structural, ornamental, &amp; fence erector</td>
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<td>Reinforcing</td>
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<td>Roofers</td>
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<tr>
<td>Roofers helpers</td>
<td>7.63</td>
<td>.25</td>
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<td>Sheet metal workers;</td>
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<td>Roofers</td>
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<td></td>
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<td>Anderson &amp; Roane Counties:</td>
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<td>Roofers</td>
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<td>Roofers helpers</td>
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<td>Soft floor layers</td>
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<tr>
<td>Sprinkler fitter</td>
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### TN77-1042 - (Cont'd)

| Daily Hourly Rates | H & W | Pension | Vacation | Education & Appr Tr |
|--------------------|--------------------------|--------------------------|
| 9.92               | 5.10  | 25      | d        |
| 5.45               | 25    | d       |

**PAID HOLIDAYS:**

**FOOTNOTES:**

a) **Holidays:** A through F.

b) Employer contributes 4% of regular hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years; employer contributes 2% of regular hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

c) **9 Paid Holidays:** A through J, providing employee has worked 45 full days during the 120 calendar days prior to the holidays, and the regular scheduled work days immediately preceding and following the holidays.

d) **$14.00 per week for each employee.**

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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>LABORERS</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
<tbody>
<tr>
<td>GROUP A</td>
<td>5 14</td>
<td>15</td>
<td>15</td>
<td>01</td>
</tr>
<tr>
<td>GROUP B</td>
<td>5 29</td>
<td>15</td>
<td>15</td>
<td>01</td>
</tr>
<tr>
<td>GROUP C</td>
<td>5 32</td>
<td>15</td>
<td>15</td>
<td>01</td>
</tr>
<tr>
<td>GROUP D</td>
<td>5 44</td>
<td>15</td>
<td>15</td>
<td>01</td>
</tr>
</tbody>
</table>

GROUP A: Construction laborer
GROUP B: Mortar mixer, plasterer tender
GROUP C: Rod carriers, power buggies, yawner, potman, graderman, snake man, form setter & strippers, pipelayers, asphalt raker, jackhammer op., air tool operator, vibratory operator, chain saw operator, barco tarp operator all power driven tool operator
GROUP D: Acetylene burner
GROUP E: Wagon drill operator

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
NOTICES

STATE: Texas
COUNTIES: Bexar, Bosque, Coryell, Falls, Hill & McLennan

DESCRIPTION OF ISSUE: Building Construction (does not include single family homes and garden type apartments up to and including 4 stories). (See current heavy & highway general wage determination for paving & utilities incidental to Building Construction in Bexar, Falls, Hill & McLennan Counties).

<table>
<thead>
<tr>
<th>BUILDING CONSTRUCTION</th>
<th>Basic Hourly Rates</th>
<th>Feige Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>ASBESTOS WORKERS</td>
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<tr>
<td>ZONE 1 - Bexar, Coryell &amp; Falls</td>
<td>$ 9.88</td>
<td>.42</td>
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<tr>
<td>ZONE 2 - Bosque, Hill &amp; McLennan Counties</td>
<td>10.03</td>
<td>.40</td>
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<tr>
<td>MILLMAKERS</td>
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<tr>
<td>ZONE 1 - Bexar, Coryell Counties</td>
<td>10.00</td>
<td>.50</td>
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<td>ZONE 2 - Bosque, Falls, Hill &amp; McLennan Counties</td>
<td>9.10</td>
<td>.50</td>
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<tr>
<td>CARPENTERS</td>
<td></td>
<td></td>
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<tr>
<td>ZONE 1 - Bexar, Coryell Counties</td>
<td>8.20</td>
<td>.40</td>
</tr>
<tr>
<td>ZONE 2 - Bosque, Falls, Hill &amp; McLennan Counties</td>
<td>8.45</td>
<td>.40</td>
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<tr>
<td>ELECTRICAL MACHINES</td>
<td></td>
<td></td>
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<tr>
<td>ZONE 1 - Bexar (that part which is nearer to Houston than Austin but excluding that part of Fort Hood, the boundary which presently is located approximately 2 miles inside the Bell Co. line &amp; the City of Killeen, Bosque, Coryell (except that part of Fort Hood South of Coolhouse Creek), Falls Hill &amp; McLennan Counties)</td>
<td>8.89</td>
<td>.40</td>
</tr>
<tr>
<td>ZONE 2 - Bexar (that part which is nearer to Austin than Houston and not to extend more than 2 miles into Bell Co. from the southeast boundary line of Coryell Co., Gray Field &amp; the City of Killeen) &amp; Coryell (that part south of Coolhouse Creek)</td>
<td>9.85</td>
<td>.40</td>
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<tr>
<td>BRICKLAYERS</td>
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<tr>
<td>ZONE 1 - Bexar, Coryell Counties</td>
<td>10.60</td>
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<tr>
<td>ZONE 2 - Bosque, Falls, Hill &amp; McLennan Counties</td>
<td>9.95</td>
<td>.45</td>
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<td>MILLWRIGHTS</td>
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<td>ZONE 1 - Bexar, Coryell Counties</td>
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<td>.40</td>
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<td>ZONE 2 - Bosque, Falls, Hill &amp; McLennan Counties</td>
<td>9.00</td>
<td>.40</td>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### DECISION NO. TX77-4151

### BUILDING CONSTRUCTION

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<tr>
<th>SHEET METAL WORKERS:</th>
<th>Fringe Benefits Payments</th>
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<tr>
<td>ZONE 1 - Within a radius of 20 miles from the Hallman County Court House, Waco</td>
<td>Basic Hourly Rates</td>
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| &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &nbsp; &n
### Fringe Benefits Payments

<table>
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<th>Incidental Paving &amp; Utilities (Bella &amp; Coryell Counties)</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Penions</th>
<th>Vacation</th>
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### Fringe Benefits Payments

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<th>Incidental Paving &amp; Utilities (Hart &amp; Coryell Counties)</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Penions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tr>
<td>Pile Driver</td>
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<td>Pipelayer Helper (Concrete &amp; Clay)</td>
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<td>Zone 1 - 35 miles from base, Texas including town of Teramo</td>
<td>0.70</td>
<td>0.30</td>
<td>0.33</td>
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<td>0.03</td>
</tr>
<tr>
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<td>0.30</td>
<td>0.33</td>
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<td>Pile Driver</td>
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<td>Plumber</td>
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<tr>
<td>Zone 1 - 35 miles from base, Texas including town of Teramo</td>
<td>0.70</td>
<td>0.30</td>
<td>0.33</td>
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<tr>
<td>Zone 2 - all area not included in Zone 1</td>
<td>9.10</td>
<td>0.30</td>
<td>0.33</td>
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## INCIDENTAL PAYING & UTILITIES
(BELL & CORYELL COUNTIES)

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<th>Vocation</th>
<th>Education and/or Appr Tr</th>
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<td>Truck Drivers:</td>
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<td>Single Axle, Light</td>
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<tr>
<td>Tandem Axle or Semitrailer</td>
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<td>Lowboy-Float</td>
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<td>Loader</td>
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FEDERAL REGISTER, VOL 42, NO 131—FRIDAY, JULY 8, 1977
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<th>Appr Tr</th>
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<td>Pensions</td>
<td>Vacation</td>
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<td>.07</td>
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<td><strong>BOILERSMAKERS</strong></td>
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<td>10.00</td>
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<td>1.00</td>
<td>.02</td>
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<td><strong>BRICKLAYERS &amp; STONEMASON</strong></td>
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<td></td>
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<tr>
<td></td>
<td>9.70</td>
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<tr>
<td><strong>Carpenters:</strong></td>
<td></td>
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<tr>
<td></td>
<td>9.39</td>
<td>.20</td>
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<td><strong>Ch�s. County:</strong></td>
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<td><strong>Carpenters:</strong></td>
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<td>9.07</td>
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<td><strong>CIVIL PROJECTS:</strong></td>
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<td>8.30</td>
<td>.50</td>
<td>.07</td>
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<tr>
<td><strong>Cone ramos:</strong></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Machine operators:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>8.55</td>
<td>.50</td>
<td></td>
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<td><strong>DREDGERS:</strong></td>
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<td><strong>Zone 1 - Armstrong, Carson, Castro, Collingsworth, Daller, Deer Creek, Donley, Gray, Hunsford, Hartley, Horrell, Hutchinson, Lipcomb,霍尔, Oldham, Potter, Randall, Roberts, Sherman, Sudler &amp; Wheeler Counties:</strong></td>
<td></td>
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<tr>
<td>Electricians</td>
<td>10.13</td>
<td>.60</td>
<td>.35</td>
<td>1/2X</td>
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<tr>
<td>Cable splicers</td>
<td>11.16</td>
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<td>.35</td>
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<tr>
<td><strong>Zone 2 - Childress County:</strong></td>
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<tr>
<td>Electricians</td>
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<td>.35</td>
<td>1/16</td>
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<tr>
<td>Cable splicers</td>
<td>10.60</td>
<td>.60</td>
<td>.35</td>
<td>1/16</td>
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</table>

**GLAZIERS:**

**INDUSTRIAL GLAZIERS**

**GROUP 1 - Construction laborers, including excavation, pouring concrete, carpenter carpenters, reinforcing, shooting, digging, leading & unloading, nailing, wreathing buildings & all structures & all unskilled laborers:**

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education</th>
<th>Appr Tr</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
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<tr>
<td></td>
<td>9.00</td>
<td>.55</td>
<td>1.00</td>
<td>.10</td>
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</tbody>
</table>

**GROUP 2 - Air tool operator:**

(Asphalt, tar, brush hammer, shipping hammer, air or electricity, sand blaster, power buggy man, polishing (concrete & clay & all non-metallic pipe) & pipe wrapping; corner masons, mason tenders, plaster masons, finisher tenders, labor tenders, asphalt wheelbarrow, operators, truck drivers, drill hole man, dumper, spotter.)

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education</th>
<th>Appr Tr</th>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
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<tr>
<td></td>
<td>5.16</td>
<td>.55</td>
<td>.27</td>
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**LATHES**

**LINE CONSTRUCTION:**

**GROUP 1 - Armstrong, Carson, Castro, Collingsworth, Daller, Deer Creek, Donley, Gray, Hunsford, Hartley, Horrell, Hutchinson, Lipcomb, Hoare, Oldham, Potter, Randall, Roberts, Sherman, Sudler & Wheeler Counties:**

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education</th>
<th>Appr Tr</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
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<tr>
<td></td>
<td>10.13</td>
<td>.60</td>
<td>.35</td>
<td>1/2X</td>
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<td>11.16</td>
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<td>6.61</td>
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<tr>
<td></td>
<td>5.76</td>
<td>.60</td>
<td>.35</td>
<td>1/2X</td>
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<tr>
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<td></td>
<td>5.76</td>
<td>.60</td>
<td>.35</td>
<td>1/2X</td>
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<td>Fringe Benefits Payments</td>
<td>Education and/or Appr Tr</td>
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<td>-----------------------------</td>
<td>--------------------</td>
<td>--------------------------</td>
<td>-------------------------</td>
<td></td>
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<tr>
<td>TEXAS 2 - Childress County:</td>
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<tr>
<td>Lineman; Operator</td>
<td>$11.26</td>
<td>12</td>
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<td>Service line</td>
<td>12.39</td>
<td>12</td>
<td>1/2</td>
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<tr>
<td>Groundman, 1st 6 months</td>
<td>6.76</td>
<td>12</td>
<td>1/2</td>
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<td>Groundman, 2nd 6 months</td>
<td>7.32</td>
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<td>Groundman, 1 year &amp; over</td>
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<td>hangers; paper-tapers</td>
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<td>GROUP 2 - Structural steel</td>
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<td>painters; stacking or</td>
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<td>chair below 50 ft.</td>
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<td>GROUP 3 - Spray painters &amp; sand</td>
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<td>operator</td>
<td>8.45</td>
<td>.40</td>
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<td>PLASTERERS &amp; PIPE FITTERS:</td>
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<td>ZONE 1 - shall extend a</td>
<td>9.21</td>
<td>45</td>
<td>.60</td>
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<tr>
<td>distance of 25 road miles</td>
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<td></td>
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</tr>
<tr>
<td>from police station in either</td>
<td>9.46</td>
<td>45</td>
<td>.60</td>
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</tr>
<tr>
<td>Amarillo or Borger</td>
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<tr>
<td>ZONE 2 - shall extend a</td>
<td>9.71</td>
<td>45</td>
<td>.60</td>
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<tr>
<td>distance of 25 to 50 road</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>miles from either Amarillo or</td>
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<td>.10</td>
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<tr>
<td>Borger</td>
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</tr>
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<td>ZONE 3 - shall extend a</td>
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<tr>
<td>distance of 50 road miles</td>
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<td></td>
</tr>
<tr>
<td>&amp; over from either Amarillo</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or Borger</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>ROOFERS</td>
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<td>.55</td>
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<td>TRUCK DRIVERS:</td>
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</tr>
<tr>
<td>1/2 ton to 3 tons</td>
<td>2.00</td>
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<td>.35</td>
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<td>3 to 5 tons</td>
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<td>.35</td>
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<td>5 tons and over</td>
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<td>.25</td>
<td>.35</td>
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<td>.35</td>
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<tr>
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<td>.35</td>
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<tr>
<td>prescribed for craft</td>
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</tr>
<tr>
<td>performing operation</td>
<td></td>
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</tr>
<tr>
<td>to which welder is incidental</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

FOOTNOTE:
a - Paid holidays A thru F

PAID HOLIDAYS
A-New Year's Day; B-Memorial Day;
C-Independence Day; D-Labor Day;
E-Thanksgiving Day; F-Christmas Day
### Power Equipment Operators

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
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</tr>
<tr>
<td>Group 3</td>
<td>6.35</td>
<td>40</td>
</tr>
</tbody>
</table>

**Power Equipment Operators Classification Definitions**

**Group 1** - Blade Grader, self-propelled; Grader, Cable Way, Grader, power operated (all types); Air Compressors; Pumps; Welding Machines; Light Plants (7 to 12 machines); Broom; power operated (all types); Scraper; Elevators; Graders, self-propelled; Hoist, 2 drum or more; Jib Crane; Mixers, all types; Pile Drivers; Scraper; Bulldozers; Side Boom; Cherry Pickers - 125 tons & over; Scraper; Heavy Duty Mechanic; All Balders; All tractors with power attachments; Ditching Machines - crawler type; Farm type Tractor (Loader, 1 yd. & over) with Backhoe; All other equipment of similar nature coming within the Heavy Equipment Classification, when power operated.

**Group 2** - Air Compressors; Pumps; Welding Machines; Throttle Valves; Light Plants (2 to 6 machines); Cherry Pickers - under 125 tons; Ditch Ditch - 350 and under; Farm type Tractor (Loader under 1 yd.) with Backhoe; Crawler Diggers, 14 cu. ft. or over; Rollers over 10 tons; Air Compressors and one cylinder; Rollers, 2 or less; Winch Trucks; Front End Scoops; Loader and Pay Loaders; Blade Grader, tower; Elevators, Building; Fork Lifts; Hoist, single drum or 1 line hoisting (1 1/2 tons); Mixers less than 15 cu. ft.; Rollers; Scraping Plants; Crushing Plants; Tractors - wheel type except when hauling material; All other equipment of similar nature coming within the Light Equipment Classification, when power operated.

**Group 3** - Oiler, Fireman, Greaser.


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**NOTICES**

Date: June 2

Superseded Decision No. TX77-4153, dated March 5, 1977, in 42 FR 12671.

DESCRIPTION OF WORK: Building Construction (does not include single family homes and garden type apartments up to and including 4 stories). (See current Heavy & Highway general wage determination for Paving & Utilities Incidental to Building Construction)

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Labor Category</th>
<th>Basic Hourly Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos Workers</td>
<td>$10.00</td>
<td>.70</td>
<td>.70</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>Bricklayers</td>
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</tbody>
</table>

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**Laborers Classification Definitions**

**Group 1** - Construction labor, including excavation, concrete work, reinforcing; mason handler and wheelbarrow (stock pile), asphalt trowel and raker, water proofing trowel, pipe layer (non-metallic), pump erect pipe (handling and laying) and all building construction labor excepting that heretofore classified; window washer, carpenters trowel, canton mason trowel, vibrator operator, other mechanic trowel (except as otherwise classified); Dumper & spotter

**Group 2** - Air tool operator

**Group 3** - Well driller

**Group 4** - Cutting torch man; mason trowel; mason handler & wheelbarrow handling material from first stock pile; concrete pipe (handling and laying); Sand blaster; Tower hoist operator; plasterer trowel & bud carrier; lather trowel; well driller trowel

**Group 5** - Tool room tender; mortar mixer (loam and otherwise); Blastor, powder man; pipefitter worker

**Group 6** - Concrete nozzleman

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**Link Construction:**

Linemen & cable splicer | $11.62 | .60 | 15% | .04 |
Groundmen (1st 6 months) | 6.07 | .60 | 15% | .02 |
Groundmen (2nd 6 months) | 4.88 | .60 | 15% | .02 |
Groundmen | 6.74 | .60 | 15% | .02 |

**Materials:**

**Group 1** - All brush painting, hand roller, steam cleaning, all pneumatic tools | 9.205 | 365 | 35 | .04 |
**Group 2** - All spray painting, sandblasting, waterblasting | 9.67 | 365 | 35 | .04 |
**Group 3** - Tape, float & drywall | 9.42 | 365 | 35 | .04 |
**Group 4** - Steeple jack work, | 9.92 | 365 | 35 | .04 |
**Pipefitters** | 10.05 | .65 | .65 | .04 |
**Plasterers** | 7.50 | .77 | .30 | .02 |
**Tubers** | 10.72 | .55 | .70 | .12 |
**Sheet Metal Workers** | 10.18 | .275 | 595 | .32 |
**Soft Floor Layers** | 9.17 | .35 | 45 | .09 |
**Terra Cotta Workers** | 10.46 |
**Tile Setters** | 10.46 |

**Welders** - receives rate prescribed for craft performing operation to which welding is incidental.

**Footnotes:**

- a = 1st 6 mos. - none; 6 mos. to 5 yrs - 2%; over 5 yrs. - 4% of basic hourly rate
- b = Paid Holidays: A thru F

**Paid Holidays:**

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

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**Federal Register, Vol. 42, No. 131—Friday, July 8, 1977**
### DECISION NO. P77-6153

<table>
<thead>
<tr>
<th>Fringe Benefits Payments</th>
<th>Hourly Rates</th>
</tr>
</thead>
</table>
|                          | H & W | Pensions | Vacation | Education
| **Power Equipment Operators** |       |          |          | and/or
|                           |       |          |          | Apprentices
| **GROUP 1**              | $9.07 | .25      | .65      | .06
| **GROUP 2**              | 8.38  | .25      | .65      | .06
| **GROUP 3**              | 7.84  | .25      | .65      | .06
| **GROUP 4**              | 7.66  | .25      | .65      | .06

### Power Equipment Operators Classification Definitions

**GROUP 1** - Heavy Duty Mechanics; Blade Grader, Self-propelled; Bull Clan; Back Filler; Derrick-type operated (all types); Loin shell; Draglines; Push Cat Operator; Bull Dozer & all types Cat Tractors; Cable-Drum Backhoe; Shovel, power operated; Crane, power operated (all types); Elevating Grader, Self-propelled; Hoist, Water-Driven, 40 ft. or more; Hit Mobile; Water Well Drilling Machines, used on construction; Building Elevator, used on construction; Tug Boat Operator, assigned to construction; Inch Truck; Locomotive Crane; Concrete Mixer, 14 cubic feet or more; Paving Mixer (all types); Pile Driver; Scrapper, heavy type, over 3 cubic yards; Trenching Machine (all sizes); Gravel; High Lift; Foundation Driving Machine; Gasoline or Diesel-Driven Welding Machine, 7 or more; Pumperetone Machine Operator; Turnpulleys; UN-15 Caterpillar, 8-16 Footid and similar tractors; Asphalt Plant Mixer Operator on job; Grader Operator on job; Scrapesbphotos; Forklifts, used on construction (not including warehousing); Bell Point Pump; Concrete Batch Plant Operator; Pneumatic Rollers, self-propelled; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated.

**GROUP 2** - Air Compressors; Blade Grader, Towed; Pile Driver; 4-Foot Grade; Concrete Mixer, less than 16 cubic feet; Pumps; Pulverizers; Truck Crane Drivers; Gasoline or diesel driven welding machines (6 or more, up to 6 rachians); Hoist, Single Drum; Scraper, 3 cubic yards or less; Wagon Drill Operator; Conveyors; Generator, gasoline or diesel driven, over 150 kW; Rubber Tired Farm Tractor with attachments; A light equipment operator may run 1 or 2 195 cfm compressors; All other equipment of similar nature coming under the Light Equipment Class, when power operated.

**GROUP 3** - Fireman

**GROUP 4** - Other
<table>
<thead>
<tr>
<th>Description</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$10.05</td>
<td>H &amp; W</td>
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<tr>
<td>ASBESTOS WORKERS</td>
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<td>.40</td>
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<tr>
<td>ROOFERS</td>
<td>10.00</td>
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<td>Plasterers' tenders</td>
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<td>PLASTERERS</td>
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<td>PUMPERS &amp; PIPEFITTERS</td>
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<td>SHEET METAL WORKERS</td>
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<td>TILE SETTERS</td>
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<td>POWER EQUIPMENT OPERATORS:</td>
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<td>Backhoes</td>
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<td>Blade grinders</td>
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<td>Bulldozers</td>
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<td>Cherry pickers</td>
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<td>Drilling machine operators</td>
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<td>Scapers</td>
<td>4.28</td>
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</table>

NOTES: The wages and fringe benefits payments listed above are for a work crew of five men, with the exception of power equipment operators, who are paid on a piece-rate basis. The wage for power equipment operators is based on an hourly rate of $4.50 for a 40-hour work week.璀璨 - receive rate prescribed for craft performing operation to which welding is incidental.
### supraheas decision

**STATE:** Texas  
**COUNTY:** Lubbock  
**DECISION NO:** TX77-4155  
**DATE:** Date of Publication

Superseded Decision No TX77-4107, dated December 28, 1976, in 41 FR 56602.

**DESCRIPTION OF WORK:** Building construction (does not include single family homes and mobile type apartment units up to and including 4 stories) (see current heavy & highway general wage determination for paving & utilities incidental to building construction).

**Salary Benefits Payments**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

| ASBESTOS WORKERS | 9.95 | .55 | .45 | .07 |
| MASONRIGERS      | 10.00 | .50 | 1.00 | .02 |
| BRICKLAYER/STONECRAFTERS | 9.60 | .40 | .00 | .02 |
| CARPENTERS       | 9.00 | .40 | .00 | .01 |
| PLUMBERS         | 7.10 | .00 | .00 | .00 |
| ELECTRICIANS     | 9.50 | .60 | .03 | 1/100 |
| CABLE SPlicERS   | 9.50 | .60 | .03 | 1/100 |

**FRINGE BENEFITS PAYMENTS**

<table>
<thead>
<tr>
<th>Structural; Ornamental; Reinforcing</th>
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</thead>
<tbody>
<tr>
<td>All ironworkers on jobs 30 miles or more from the city of lubbock</td>
</tr>
<tr>
<td>LABORERS:</td>
</tr>
<tr>
<td>GROUP A - Construction laborers, including excavation, pouring, concrete, carpenter tenders, reinforcing, shoring, digging, loading &amp; unloading materials, wreking buildings &amp; all structures &amp; all construction laborers except those named below</td>
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<tr>
<td>8.355</td>
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</table>

**GROUP B** - Air tool operator

<table>
<thead>
<tr>
<th>GROUP 2 - Air tool operator (drillers, vibrators, tampers, brush hammers, chopping hammers, air or electric), power vance, pipefitters (concrete &amp; clay &amp; all non-steel pipe); handling, laying &amp; cleaning pipe, pipefitters pipe</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.925</td>
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</tbody>
</table>

**GROUP 3** - Tenter makers, mason tenders, plaster tenderers, cement finisher tenderers, labor tendency

| GROUP 3 - Mason tenderers | 5.125 | .275 | .20 |

**GROUP 4** - Union drill

<table>
<thead>
<tr>
<th>GROUP 4 - Union drill, mason tenders</th>
<th>5.275</th>
<th>.275</th>
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FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Fringe Benefits Payments

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<th>Vacation</th>
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<td><strong>Basic Hourly Rates</strong></td>
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<tr>
<td><strong>GROUP 3</strong></td>
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<td>.30</td>
<td>.50</td>
<td>.10</td>
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</table>

### POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

**GROUP 1** - Oiler-Visorman

**GROUP 2** - Air Compressors, Pumps, Welding Machines, Throttle Valves, Light Plants (3 to 6 machines); Conveyor; baggin’ Dill; Elevators Building; Power Graders; Hoist, Simple Drum; Fork Tractor including Blade and motor on rear; Mixers less than 14 cubic feet; Scraper Plants; Crushing Plants; Fork Lifts (short, under 25 feet); Concrete Pump (all types); Robust type equipment; Fork tractor or like with any attachments (except blade and motor on rear); All other equipment of similar nature coming under the Light Equipment Class, when power operated

**GROUP 3** - Backhoe; Drilling Machines (all types); Scoopmiddles; Hoist, two drums or more; Fork Lifts (over 25 feet); Winch Truck; Six Wheel Truck, when used continuously for 3 days; Mixers, Locomotives; Mixers, 14 cubic feet or more; Blade Graders, self-propelled; Cableways; Crown power operated (to 150 feet of boom); Derricks, powered operated (all types); Gravel, Hy-dra; Hop-Per; Paving Mixers (all types); Pile Drivers; Mobile Concrete Mixers over 14 cu ft.; Bulldozers, loaders, Tractorvacuums; Scrapers and Pulls; Holders; Trimming Machines; Rollers, ten tons or over; Air Compressors, Pumps, Welding Machines and Light Plants (7 to 12 machines); Air Compressor & Air Tugger; Rollers, two or more, fired by one man; Heavy Duty Mechanic; All other equipment of similar nature coming under the Heavy Equipment Class, when power operated
### Notices

**STATE:** Texas

**STATE:** Texas

**COUNTY:** Collin

**COUNTY:** Taylor

**DECISION NO.:** T-277-4155

**DECISION NO.:** T-287-4157

**DATE:** March 4, 1977, in 42 FR 12673.

**DATE:** October 5, 1976, in 41 FR 46664.

**DESCRIPTION OF WORK:** Building Construction (does not include single family homes and garden type apartments up to and including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

**DESCRIPTION OF WORK:** Building Construction (does not include single family homes and garden type apartments up to and including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

<table>
<thead>
<tr>
<th>AIR CONDITIONING MECHANICS</th>
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<td><strong>CARPENTERS</strong></td>
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<td><strong>Electricians</strong></td>
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<tr>
<td><strong>Gains</strong></td>
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</tr>
<tr>
<td><strong>Inomenders</strong></td>
<td>8.50</td>
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</tr>
<tr>
<td><strong>Lathers</strong></td>
<td>3.00</td>
<td></td>
</tr>
<tr>
<td><strong>Masons</strong></td>
<td>4.00</td>
<td></td>
</tr>
<tr>
<td><strong>Plasterers</strong></td>
<td>4.10</td>
<td></td>
</tr>
<tr>
<td><strong>Plasterers</strong></td>
<td>4.00</td>
<td></td>
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</tr>
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<td><strong>Painters</strong></td>
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<td><strong>Plumbers</strong></td>
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<td><strong>Pipes</strong></td>
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<td><strong>Sheet Metal Workers</strong></td>
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**FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977**
<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
</tbody>
</table>

**Carpenters:**
- $9.88
- .60
- .60

**Bricklayers & Stonemasons:**
- $9.64
- 50
- 60

**Elevator Constructors:**
- Mechanics
- $9.29
- .545
- .35
- .04

**Glazers:**
- $8.31
- 20

**Ironworkers:**
- $9.45
- 55
- 80

**Painters:**
- **GROUP 1 - Brush; Taping & Floating of Sheetrock**
  - $7.95
- **GROUP 2 - Paperhangings; Chipper, Burner, Torch; Skeleton Steelwork Around**
  - $8.20
- **GROUP 3 - Spray; Steam Cleaning, Sand Blast & Other Powered Equipment**
  - $8.45

**Plasterers:**
- $9.54
- .35
- .20

**Plumbers & Steamfitters:**
- $10.05
- .35
- .35

**Roofers:**
- $5.23

**Sheets Metal Workers:**
- $9.75
- 55

**Soft Floor Layers:**
- $9.17
- .35
- .45

**Sprinkler Fitters:**
- $11.15
- .45
- .95

**Tubalen Workers:**
- $7.96
- .45

**Terrazzo Workers' Finishes:**
- Terrazo Finishes
- $5.37
- Floor machine operators
- $5.77
- Base machine operators
- $5.72
- Title Stickers
- $7.96
- .45
- .45

**Welders:**
- Receive rate prescribed for craft performing operation to which welding is incidental

**Photographs:**
- a - 1st 6 mos. - none; 6 mos to 5 yrs - 25; over 5 yrs - 60% of basic hourly rate
- b - Paid Holidays A thru P

**Paid Holidays:**
- A-New Year's Day; B-Normal Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day
### DECISION NO. FC77-4558

<table>
<thead>
<tr>
<th>Power Equipment Operators Classification Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GROUP 1</strong> - Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Dozer; Back Filler; Barrels, power operated (all types); Dragline; Push Cat Operator; Front End Loader; Hauler and all types of Cat Tractors; Cable-Dray; Back Hoe; Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Mover Driven, two drawn or more; Mix Mobile; High Lift &amp; Loaders, over 11/2 cu. yds. capacity; Misch Truck; Locomotive; Mixer, 12 cu. ft. or over; Paving Mixer (all sizes); Scraper; Trenching Machine (all sizes); Grader; Foundation Boring Machine; Reciprocating; Shovels, Power Operated; Pumpcrete Machine; Gland Shell Operator; Rock Crusher, Operated on Job; Welding Machine, 6 to 12, two 125 cu. ft. Compressors; Ball Points, including Installations</td>
</tr>
<tr>
<td><strong>GROUP 2</strong> - Blade Grader, Tow; Flex Planer; Form Grader; Mixer, less than 12 cu. ft.; Pulsator; Truck Crane Driver &amp; Loader, Combination 35-ton; Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum; Pump, 24 cu. ft. or Larger; Pneumatic Rollers; High Lift &amp; Loaders, 11/2 cu. yds. or less; Forklift, 1,500 lbs. capacity or less; Air Compressors, anytime there are two or more attachments operating on a 125 cu. ft. compressor, a light equipment operator shall be employed. One 125 cu. ft. air compressor and one welding machine requires no operator. One 125 cu. ft. compressor and two welding machines or any 2 air compressors equivalent to a 125 cu. ft. air compressor requires a light equipment operator</td>
</tr>
<tr>
<td><strong>GROUP 3</strong> - Pile driver</td>
</tr>
</tbody>
</table>

### Pensions Benefits Payments

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GROUP 1</strong></td>
<td>$ 8.63</td>
<td>0.60</td>
<td>0.60</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>GROUP 2</strong></td>
<td>7.55</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
</tr>
<tr>
<td><strong>GROUP 3</strong></td>
<td>6.23</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
</tr>
<tr>
<td><strong>GROUP 4</strong></td>
<td>6.23</td>
<td>0.40</td>
<td>0.40</td>
<td>0.40</td>
</tr>
</tbody>
</table>
**SUPERSSEED DECISION**

**STATE:** Texas  
**COUNTY:** Wichita  
**DECISION NO.: TX77-4159**  
**DATE:** Date of Publication

Superseded Decision No. TX77-4007, dated January 21, 1977, in 42 FR 4107.

**DESCRIPTION OF ISSUE:** Building Construction (does not include single family homes and garden type apartments up to and including 4 stories). (See current heavy & highway general wage determination for paving & Utilities Incidental to Building Construction).

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr. Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

| ASBESTOS INSULATORS | $10.00 | .60 | .75 | .025 |
| BORCLAYERS & BORCMANDOS | 10.00 | .50 | 1.00 | .02 |
| CEMENT MASONERS | 9.64 | .30 | .30 | .05 |
| CARPENTERS | 9.07 | .43 | .40 | .07 |
| MILLWRIGHTS | 9.57 | .43 | .40 | .07 |
| CEMENT MASONERS | 8.55 | .43 | .40 | .07 |
| ELECTRICIANS: |
| ZONE 1 - Work performed within a road mile radius from the Local Union 681 business office up to 30 miles: |
| Electricians | 10.00 | .40 | .30 | 1/10% |
| Cable splicers | 10.35 | .40 | .30 | 1/10% |
| ZONE 2 - All work performed beyond Zone 1: |
| Electricians | 10.35 | .40 | .30 | 1/10% |
| Cable splicers | 10.60 | .40 | .30 | 1/10% |
| ELEVATOR CONSTRUCTORS: |
| Mechanics | 9.33 | .545 | .35 | .02 |
| Helpers (Probationary) | .535 | .35 | 40% | .02 |
| GLAZIERS | 4.97 | .405 | .30 | |
| TRENCHMEN: |
| Structural; Ornamental; Reinforcing | 8.23 | .55 | 1.00 | .10 |
| Tramliners on jobs 30 miles or more from the city of Wichita Falls | 8.23 | .55 | 1.00 | .10 |
| LABORERS: |
| GROUP 1 - General laborers | 5.025 | .275 | .27 |
| GROUP 2 - Pipelayer (concrete & clay); Power buggy operator; Gunite mixer; Cement mixers; Power tool operators; Bell hole man (pits) | 5.15 | .275 | .27 |
| GROUP 3 - Mason tender; Mason mixer mixer; Plasterer tender; Mud mixer; Plantcater mixer mixer; Concrete mixer mixer; | 5.275 | .275 | .27 |
| GROUP 4 - Powermen, blaster | 5.525 | .275 | .27 |

| LAYERS |
| LINE CONSTRUCTION: |
| Line man | 11.35 | 1.50 | 1/2% |
| Cable splicer | 12.39 | 1.50 | 1/2% |
| Groundman, 1st 6 months | 7.32 | 1.50 | 1/2% |
| Groundman, 2nd 6 months | 7.32 | 1.50 | 1/2% |
| Groundman, 1 year & over | 7.32 | 1.50 | 1/2% |
| MASON RIVERS |
| Brick | 7.50 |
| Mason | 8.20 |
| PLASTERERS |
| 9.07 |
| PIPERS & PIPE FITTERS: |
| ZONE 1 - Within 25 miles of Wichita Falls City limits | 9.55 | .35 | .55 | .02 |
| ZONE 2 - Beyond 25 & 60 miles of Wichita Falls City limits | 10.05 | .35 | .55 | .02 |
| ZONE 3 - Between 40 & 70 miles of Wichita Falls City limits | 10.35 | .35 | .55 | .02 |
| ZONE 4 - Beyond 70 & 100 miles of Wichita Falls City limits | 10.65 | .35 | .55 | .02 |
| ZONE 5 - Over 100 miles of Wichita Falls City limits | 10.95 | .35 | .55 | .02 |
| ROOFERS |
| SHEET METAL WORKERS | 9.27 |
| SOFT FLOOR LAYERS | 5.50 |
| TITRAGU MASONERS | 7.50 |
| TILE SETTERS | 6.30 |
| TRUCK DRIVERS | 2.30 |
| WELDERS | 5.42 |

FEDERAL REGISTER, VOL. 42, NO. 131—FRIDAY, JULY 8, 1977
### Notices

#### Decision No. TX77-4159

<table>
<thead>
<tr>
<th>Power Equipment Operators</th>
<th>Hourly Rates</th>
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<th>Pensions</th>
<th>Vocational</th>
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<td>.50</td>
<td>.10</td>
<td></td>
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<td>.50</td>
<td>.10</td>
<td></td>
</tr>
</tbody>
</table>

**POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS**

**GROUP 1 - Eller-Pilots**

**GROUP 2 - Air Compressors, Pumps, Welding Machines, Throttle Valves, Light**

Planes (3 to 6 machines); Conveyor; Wagon Drill; Elevators; Building; Fork

Graders; Hoist, Single Drum; Forestry and Logging on road;

Mixers less than 16 cubic feet; Scouring Plants; Graveling Plants; Fork

Lifts (above, under 25 tons); Concrete Pump (all types); Scaffold type equipment;

Final feature or lift with any attachments (except blade and room on roof); All

other equipment of similar nature coming under the Heavy Equipment Class, when

power operated.

**GROUP 3 - Backhoes; Drilling Machines (all types); Scrapers; Dredges, two

drams or more; Fork Lifts (over 25 tons); Wall Hoist; Air Dredge, when

used continuously for 5 days; Air Scraper; Locomotive; Rollers, 14 cubic feet

or over; Blade Grinders, self-propelled; Cableway; Cranes—pump operated (to

100 feet of boom); Baler, power operated (all types); Grindall; Hy-Ho; Pump

Truck; Paving Mixer (all types); Mill Drives; Mobile Concrete Mixers over 14 cu.

ft.; Pile Drivers, Loaders, Tractortowers; Scrapers and Pullers; Trenching

Tubes; Tiller, ten tons or over; Air Compressors, Pumps, Welding Machines

and Light Plants (7 to 12 machines); Air Compressor & Air Tugger; Rollers, two

or more, fired by one man; Heavy Duty Machines; All other equipment of similar

nature coming under the Heavy Equipment Class, when power operated.

[FED Doc.77-10398 Filed 7-7-77;9:46 am]